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Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.

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Manuscripts

Title: Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.

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Abstract:

Objectives: To develop an evidence-based community pharmacist-delivered screening model for diabetes and cardiovascular disease (CVD), and assess its feasibility to identify and refer patients with elevated risk.

Design: A feasibility study.

Setting: A purposive sample of 12 community pharmacies in three UAE cities.

Participants: Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.

Intervention: Pharmacist screening of adults visiting pharmacies involved history, demographics, anthropometric measurements, blood pressure, and point-of-care testing including HbA1c levels and lipid panel. Participants with a 10-year CVD risk $\geq 7.5\%$, HbA1c level $\geq 5.7\%$ or American Diabetes Association risk score ≥ 5 points, were advised to visit their physician.

Primary and secondary outcome measures: (1) Development of UAE pharmacist-delivered screening model, (2) the proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk defined as $\geq 7.5\%$), (3) the proportion of participants identified as having elevated blood glucose (high HbA1c level $\geq 5.7\%$ (38.8mmol/mol)) or high self-reported diabetes risk (ADA risk score ≥ 5 points). Secondary outcomes: participants' satisfaction with the screening.

Results: The first UAE pharmacist-delivered screening model was developed and implemented. A total of 115 participants were screened, 17% had an elevated 10-year CVD risk, 21% and 11% had HbA1c levels consistent with prediabetes and diabetes respectively. Additionally, 41.8% and 67.5% of participants had elevated low-density lipoprotein and triglyceride levels respectively. Systolic blood pressure was elevated in 47% of participants, while 36.5% were overweight, and 44.3% were obese. At-risk individuals (61.7%) were referred to their physicians. 94.5% of participants were at least satisfied with their screening experience.

Conclusions: The community pharmacist-delivered screening of diabetes and CVD risk is feasible in the UAE. The model offers a platform to increase screening capacity within primary care and provides an opportunity for early detection and treatment of CVD and diabetes.

Keyword: Diabetes, Cardiovascular Diseases, Screening, Pharmacy, Point-of-Care Testing, Primary Health Care

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Strengths and limitations of this study

- Use of a UAE expert panel to develop a culturally suitable model for pharmacist-delivered screening for diabetes and cardiovascular diseases risk.
- A majority of screened participants were found to be at high risk for diabetes or CVD strongly supporting an unmet need in the UAE.
- Pharmacist-delivered screening results were acted upon by physicians.
- Follow-up with physicians on referral outcomes of participants at-risk could not be determined due to the fragmented healthcare system. We relied on patient self-report data for this study.
- The purposive sampling of community pharmacies may limit the model's generalizability such that it may not be suitable for implementation in all community pharmacies in the UAE.

Introduction

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2
3 Type 2 diabetes (T2DM) and cardiovascular disease (CVD) are leading contributors to the global burden of
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5 disease, albeit with distinct long-term trends.(1) Diabetes, a rapidly growing global epidemic, affects all
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7 countries, and is substantially caused by rapidly increasing rates of obesity over recent decades. (2) By 2040
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9 T2DM will affect an estimated 642m people; 10.4% of the adult population, compared with 8.8% in 2015.(2-4)
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11 Age-standardized CVD trends are more geographically nuanced – generally, the incidence has declined
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13 markedly in highly developed countries over several decades, but this decline has now plateaued.(5) Likewise,
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15 some middle-income regions have experienced declines in CVD mortality, but in most regions of the
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17 developing world, a rapid increased incidence has recently prevailed.(5) Globally in 2015, an estimated 422.7
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19 million prevalent cases of CVD, ischemic heart disease and stroke remained the leading causes of death.(6) A
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21 combination of an aging western society, and increasing CVD mortality rates in many developing regions, has
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23 resulted in increasing CVD-related deaths from 12.6 million in 1990 to 17.9 million in 2015.(6) Both CVD and
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25 diabetes represent major public health challenges in all countries. Globally, CVD affects 32.2% of all persons
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27 with T2DM.(7)

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29 An estimated 45.8% (174.8 million) of adult diabetes cases worldwide are undiagnosed, ranging from 24.1% to
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31 75.1% in different countries.(8) Overall, the prevention and delay of diabetes complications are facilitated by
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33 combining early detection of undiagnosed diabetes using population or opportunistic screening approaches
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35 with effective prevention interventions.(9-11)

36
37 In Arabic-speaking countries, prevalence of T2DM is at alarming levels with high morbidity and mortality
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39 rates.(12) Six Arabic-speaking countries (Kuwait, Lebanon, Qatar, the United Arab Emirates (UAE), Saudi
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41 Arabia, and Bahrain) lead the world in the prevalence of T2DM, affecting approximately one in five people.(13)
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43 There is an urgent need to increase capacity for the detection of diabetes and to reduce its burden in these
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45 Arabic-speaking countries. Previous research has identified negative health beliefs, poor health-seeking
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1 behaviors, and intentional delay in accessing available medical services are commonplace in Arabic-speaking
2 communities, hence the need for proactive and opportunistic population screenings.(14-16)
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5 The feasibility of pharmacist-delivered screening, for a variety of conditions including diabetes and CVD, is well
6 supported by evidence.(17, 18) Such screening interventions identified at-risk individuals and increased rates
7 of disease diagnosis, reduced disease risk factors, improved health behaviors, enhanced quality of care, and
8 increased patient knowledge and awareness.(19) Community pharmacists have face-to-face contact with
9 around 90% of the population annually and appear to interact regularly with those who have elevated risk of
10 diabetes and CVD, or undiagnosed diabetes.(20) The potential, therefore, exists for pharmacists to improve
11 access to health screening services and promote public health awareness.
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22 In the UAE a substantial number of people with diabetes and a high prevalence of overweight and obesity are
23 currently thought to remain undiagnosed.(21) There are around 2,500 licensed community pharmacies in UAE
24 that are generally open seven days per week, easily accessible, and have an average working day of 13 hours
25 (22, 23); this potentially makes pharmacies an effective setting to offer screening for diabetes and CVD within
26 the primary care system. To our knowledge, no systematic diabetes and CVD screening programs exist in the
27 primary care setting in the UAE, meaning these diseases continue to be undiagnosed precluding the
28 opportunity to initiate early prevention and treatment.
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39 The aim of this study was to test the feasibility of pharmacist-delivered diabetes and CVD risk screening model
40 in the UAE. The specific objectives were to:
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- 44 1. Develop locally-appropriate pharmacist-delivered diabetes and CVD risk screening model for the
45 community pharmacies in UAE.
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- 49 2. Evaluate the feasibility of implementing diabetes and CVD risk screening model in the selected
50 community pharmacies in the UAE.
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Methods

Ethical approvals

This study was approved by the Research Ethics Committee of the University of Sharjah, the Ministry of Health and Prevention in the UAE, and deemed Exempt by the Harvard T.H. Chan School of Public Health Institutional Review Board.

Study design

The study was conducted in three phases: Phase 1 (formative phase) explored development of a suitable model for diabetes screening and CVD risk assessment in community pharmacies in the UAE, Phase 2 (implementation phase) assessed the feasibility of the screening model, and Phase 3 (evaluation phase) tested the impact of the screening model.

Phase 1: Formative Phase

A systematic approach was used to develop the intervention of diabetes and CVD screening.⁽²⁴⁾ The formative phase commenced with identifying needs for diabetes and CVD risk screening program. After identifying the suitability of community pharmacies for providing screening services, a literature review of pharmacist-delivered screening models was conducted to identify useful and effective approaches to screening. The Australian Cardiovascular Absolute Risk Screening Study (CARS) was considered an appropriate template model to inform the development of the first UAE pharmacy-based screening program.⁽²⁵⁾ Two local health professionals were consulted to determine the adaptation of CARS into the local context and acceptability of the proposed protocol prior to presenting the model to an expert panel. In absence of national guidelines and frameworks regarding risk assessment and management for diabetes and CVD in the UAE, an expert panel forum was tasked to develop a consensus on the proposed screening program. Prospective panelists were identified through extensive online search; evaluating experts' specialty, experience, and research involvement. Shortlisted experts, including two cardiologists, two endocrinologists, two senior clinical

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1 pharmacists, were invited to participate in the forum. The Delphi technique was used to help arrive at a
2 consensus on a specific question in one or more rounds - supportive documents were created to aid in voting
3 and to calculate the level of agreement.⁽²⁶⁾ The Delphi discussion focused on locally-appropriate methods for
4 absolute cardiovascular and diabetes risk assessment, including: use of absolute CVD risk assessment and
5 other multi-factorial risk algorithm cut-offs; selection of screening tools; and risk factor thresholds for
6 physician referrals. The following questions were discussed during the forum:
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- 14 1. When should the participant's blood pressure measurement be taken? Moreover, what is the
15 minimum time interval needed between taking the two blood pressure readings?
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- 18 2. Which tool to use to calculate participants' absolute CVD risk?
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- 20 3. Which method would be most suitable for calculating the participants' absolute CVD risk in the
21 community pharmacy setting?
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23
- 24 4. Which self-reported tool to use to determine the participants' risk of having T2DM? What absolute
25 CVD risk threshold should be used when deciding to refer a participant to the physician?
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- 28 5. What HbA1c level should be used to refer a participant to the physician?
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- 31 6. Should at-risk participants who are referred to physicians for further testing be contacted to ask about
32 any lifestyle modifications and outcomes of a visit to a physician? And should the physicians whom the
33 referred participants visited be contacted?
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42 The screening model planning involved the development of resources in supporting pharmacists-delivered
43 screening including: training manual, data collection tools, and patient follow up documents. These were
44 developed through a process of co-production in consultation with the international co-researchers who had
45 previous experience in pharmacist-delivered screening services. To ensure local context applicability, study
46 materials were sent to three local community pharmacists for feedback and comments.
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Phase 2: Implementation Phase

Community pharmacists were trained on the study protocol, and on how to: (1) approach potential participants, (2) use point-of-care testing devices, (3) handle refusals to participate, (4) collect data, (5) communicate risk assessment results to participants, (6) engage and refer at-risk individuals to physicians, (7) counsel participants on required lifestyle changes, and (8) respond to participants' questions.

Study setting and participants

A purposive sample of 12 community pharmacies in the three emirates of Dubai, Sharjah, and Ajman in the UAE was selected. The recruited sites represented both independent and chain pharmacies. Study pharmacists were offered a small monetary incentive (AED 23 (equivalent to USD 6)) per screening as appreciation of their time and effort.

Recruitment of participants

Pharmacy-based advertising, including posters and flyers, were used to recruit participants. Individuals were mainly invited directly by the pharmacists to participate based on their judgment of the individual's age. Interested participants were pre-screened by the pharmacists to determine their eligibility. Eligible participants were given written patient information sheet and signed a consent form.

Inclusion criteria:

- Arabic or English speaking.
- Aged between 40 to 74 years. There is no international consensus on the age range for diabetes screening, however, 40 years is recommended in several guidelines and was therefore considered appropriate.

Exclusion criteria:

- Previous diagnosis of diabetes or CVD.
- Use of medications for treatment of diabetes, hypertension or any other CVD at the time of screening.
- Pregnancy.

- Terminal illness.
- Severe mental illness.

Data collection and risk factor assessment

To document the screening process, participating pharmacists completed brief paper-based records of each screening undertaken. This provided patient risk assessment data, documentation of patient counseling (e.g. lifestyle factors assessed, targets specified, and criteria for referral to a physician) and logistical information (e.g. time taken to conduct screening and counseling, number of visits required, reasons for deviating from suggested screening schedule).

After checking eligibility and obtaining consent, trained pharmacists screened participants with the following measurements:

- Anthropometric measurements: Weights, height and waist circumference were measured along with body mass index calculations.
- Point-of-care testing: Total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein (LDL) plasma levels, and glycated hemoglobin (HbA1c) level, were measured using a finger-prick point-of-care testing device (Roche Cobas b 101 POC dual system). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured after participants rested for 5 minutes using the Omron 1A1B® automated Blood Pressure (BP) monitor. Pharmacists advised participants to seek immediate medical attention if SBP was ≥ 180 mmHg, or DBP ≥ 110 mmHg.
- CVD risk assessment: Projected 10-year atherosclerotic CVD risk was calculated for each participant. Diabetes risk assessment: In addition to HbA1c level, the American Diabetes Association (ADA) T2DM risk questionnaire was completed.
- Patient History: Detailed socio-demographic information, brief medical history, family history of diabetes, smoking status, physical activity, and dietary behaviors. Patients referral and follow-up: Participants at high risk, defined as having any of the following: (1) 10-year ASCVD risk $\geq 7.5\%$ (2)

1 HbA1c level \geq 5.7 (3) ADA T2DM risk questionnaire \geq 5 points, were advised to visit their physician. All
2 participants identified, by pharmacists, as at high risk for either CVD or diabetes were given a referral
3 letter summarizing pharmacy screening results to the physician for further testing. A rapid phone
4 follow-up of all participants was conducted (within two weeks of screening) to determine participants'
5 satisfaction and experience with the pharmacy screening service. Participants were asked about
6 perceived depth and clarity of pharmacist explanation of diabetes and CVD risk; their satisfaction with
7 the risk assessment and the quality of testing and advice; instructions on the need for further
8 evaluation by a physician; and the perceived length of the screening. They were also asked about their
9 opinion on community pharmacies as a venue of the screening service, whether screening should be
10 routinely provided by community pharmacists, and their willingness to pay for future pharmacist-
11 delivered screening.
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13 The follow-up also included questions about self-reported health status, frequency, and pattern of
14 physician visits in the past year. Participants were asked if they had undergone an assessment of
15 lifestyle that affects diabetes and/or CVD risk by any healthcare professional in the past year or
16 whether they were advised of the need to reduce their diabetes or CVD risk.
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27 Outcomes

28 1. Development of UAE pharmacy-based screening model:

29 A consensus statement from the expert panel detailing the screening processes, cut off points/levels, and
30 referral mechanisms to physicians, all suited to the community pharmacy context in UAE.
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33 2. Feasibility assessment:

- 34 a) The proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk
35 defined as \geq 7.5% - as determined by the expert panel, see section 3.1).
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- 1 b) The proportion of participants identified as having elevated blood glucose (high A1c level >6.5%
2 (48mmol/mol)) or high self-reported diabetes risk (T2DM risk questionnaire score ≥ 5 points - as
3 determined by the expert panel, see section 3.1).
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7 c) Participants' acceptability and satisfaction with the pharmacist-delivered screening.
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11 **Patient and Public Involvement:** We did not involve patients or the public in our work
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14 **Data analysis**

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17 The data was entered into Microsoft Access and 10% of participant files were randomly selected for validation.
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19 Stata, release 14 (StataCorp, College Station, TX) was used for data analysis.(27) Normally distributed
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21 continuous variables were described using means and standard deviations (such as participants' age, visits to
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23 physicians and nutritional habits). Categorical variables were described using counts and frequencies (such as
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25 demographic data, BMI (grouped) and medical history). The Chi-squared test was used to test differences in
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27 risk factors by age and gender. A p-value of <0.05 was considered statistically significant.
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32 **Results**

33 **Consensus statement on screening intervention**

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36 The expert panel reached a consensus on the use of absolute risk assessment and other multi-factorial risk
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38 algorithm cut-offs, screening tools, and risk factor thresholds. Panel members unanimously agreed on: taking
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40 two seated measurements of BP after a five-minute rest and separated by two minutes. If the two systolic and
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42 diastolic BP readings differed by ≥ 10 mmHg or ≥ 6 mmHg respectively, a third measurement would be needed,
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44 and the two closest readings would be used to calculate mean BP. Regarding the calculation of 10-year
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46 atherosclerotic CVD risk score, the ACC/AHA pooled cohort equations CVD risk calculator should be used.
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48 Participants having a 10-year risk $\geq 7.5\%$ were classified as high risk and had to be referred to a physician for
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50 further testing. The official ASCVD Risk Estimator Plus smartphone application with off-line feature was
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52 deemed most feasible to perform the calculation. Other criteria that independently necessitated referral to a
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1 physician were an HbA1c level exceeding 5.7% (pre-diabetes) or a score above five points on the ADA
2 questionnaire to measure the risk of T2DM.
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5 Regarding the determination of uptake of referral and physician action on the results of the screening, the
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7 panelists suggested the impracticality of contacting physician's offices; instead it was agreed that uptake of
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9 referral and physician action would be best reported by participants themselves during follow-up calls. Clinical
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11 training manual and implementation resources were developed to ensure systematic approaches for the
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13 execution of pharmacist-delivered screening and to minimize variability amongst participating pharmacists.
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15 Data collection tools and consent forms were adapted from the CARS project. Figure 1 illustrates the final
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17 screening model.
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22 **Socio-demographic and health characteristics**

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24 From December 15, 2017 to May 8, 2018, 120 consenting participants were screened for CVD and T2DM from
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26 the population visiting the 12 participating community pharmacies. Five participants were excluded for not
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28 meeting study criteria. Socio-demographic and health characteristics are summarized in Table 1. Gender
29
30 representation was almost equal with most participants having been born in Syria and Egypt. When
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32 participants were asked about their present state of health, 32% reported being 'excellent'. On average,
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34 participants visited a physician three times a year. 24% of participants reported having regular physicians,
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36 while 18.6% had regular clinic but visited different physicians, and 38.6% visited different clinics. In the past 12
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38 months, only 6.4% reported undertaking a detailed examination of lifestyle factors by a health professional.
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44 **Cardiovascular disease and diabetes risk**

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46 Of the screened participants, 17.1% had elevated 10-year atherosclerotic cardiovascular disease risk (Table 2).
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48 Males were at significantly higher risk than females ($P < 0.001$), and risk increased significantly with age ($P <$
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50 0.001). Point-of-care testing showed 21.1% of participants had HbA1c levels consistent with prediabetes, and
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52 11% had levels indicative of diabetes. Older participants were significantly more likely to have HbA1c levels
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1 indicative of prediabetes or diabetes ($P = 0.034$). However, no significant differences were found between
2 male and female participants (Table 2).
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5 Approximately, 14.4% of participants had HDL levels considered protective against CVD (≥ 60 mg/dL), and
6
7 37.8% had low HDL levels (< 40 mg/dL). Female participants had significantly higher HDL levels than males
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9 (24.1% vs 3.7%) ($P < 0.001$). Additionally, 26.7%, 41.7%, and 67.5% of the participants had above optimal total
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11 cholesterol, LDL, and triglyceride levels respectively with no significant differences among gender or age.
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15 SBP was elevated in 44.1% of the participants. Males had significantly higher SBP levels than females ($P =$
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17 0.019), but age was not significantly associated with increased SBP. Around 45.1% of participants had elevated
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19 DBP. More than one third (36.5%) of the participants were overweight, and 44.3% were obese (Table 2).
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22 **Uptake of referral**

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24 A total of 71 (61.7%) at-risk individuals were referred to their physicians for further testing; 37 participants
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26 (52.1%) completed the second follow-up survey to determine uptake of referral (Table 3). Only nine of these
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28 participants (24.3%) had visited their physician following the screening, 29.7% had not visited their physician
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30 yet but intended to do so. Conversely, 43.2% did not visit their physician and made no such plans (Table 3).
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34 Five participants told their physicians about the pharmacy screening results; 4 of the 5 cases reported that
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36 physicians took the results seriously. Physicians ordered follow-up tests for 77.7% of the participants, including
37
38 total cholesterol and blood sugar levels (57.1% each), HDL levels and BP (42.8% each).
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42 When asked about lifestyle changes that participants adopted following the screening, 63.1% reported
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44 improved diet, 57.8% attempted to lose weight, and 40% started new medications since the screening (Table
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46 3).
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49 **Participants' experiences, feedback, and satisfaction with the screening service**

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51 All participants were contacted by telephone to determine their experiences and satisfaction with the
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53 pharmacy screening service (Table 4). A total of 75 participants completed the follow-up survey (65.2%). In
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68% of the cases, the pharmacist-initiated the conversation about the screening service. Other participants reported learning about the service from personal acquaintances (17.3%), and social media (10.7%).

Almost all participants reported that the pharmacists' explanation of their risk of developing diabetes or CVD were either 'very clear' or 'clear enough' and that pharmacists explained the various lifestyle causes of increased CVD or diabetes risk 'very comprehensively' or 'discussed several issues'.

At the conclusion of the screening, 94.5% of participants reported that pharmacists made sure participants understood all key points, and 89.3% indicated that pharmacists provided participants with a written screening report.

Most participants (94.5%) reported either being "satisfied" or "very satisfied" with the risk assessment undertaken by the pharmacists and the quality of the pharmacists' advice.

Eighty-six percent of participants thought pharmacies are good venues for conducting screening tests, and 86.6% thought pharmacists should routinely provide CVD and diabetes risk screening. Most participants (82.7%) indicated they would be willing to pay for pharmacist-delivered screening services should it be provided in the future (Table 3).

Discussion

This study is the first in an Arabic-speaking country (UAE) to assess the feasibility and performance of an evidence-based pharmacist-delivered screening program for T2DM and CVD. The screening model, adapted from the CARS model with the advice of local experts, was successfully implemented in community pharmacies and resulted in the identification and referral of at-risk individuals.(25)

The proportion of screened participants identified with high diabetes or CVD risk in this study was higher compared to reported rates in the international pharmacy screening literature. This could be partially explained by the higher prevalence of diabetes and CVD in the UAE.(21, 28) High referral rate (61.7%) in this study is consistent with the recent trend towards higher rates of referral.(18) Without systematic diabetes and CVD screening programs in the primary care of the UAE, lack of universal healthcare coverage, all in

1 tandem with poor health-seeking behavior and the delay in access to medical services these conditions will
2 continue to be undiagnosed. The potential, therefore, exists for community pharmacists who have regular
3 contact with the population to improve access to health screening services and promote public health
4 awareness.
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10 Several pharmacy and pharmacist-levels factors at selected pharmacies contributed to the success of
11 implementing pharmacist-delivered screening, these include: (i) the necessary infrastructure (such as
12 sufficient/appropriate space) to accommodate the screening service, (ii) motivation of pharmacist to learn
13 about and perform the screening, (iii) high volume and greater variability in clientele.
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19 The purposive sampling of community pharmacies and the exploratory implementation study design might
20 have limited the generalizability of study results. However, equally, it could be argued that the somewhat
21 driven community pharmacists in this study would have been representative of the expected pharmacists in
22 future program roll-out. The study was designed to demonstrate the feasibility of pharmacist-delivered
23 screening and to understand how implementation support and processes might have been optimized to
24 enable such health service. Follow-up with physicians on pharmacist-delivered screening was not carried out
25 as per the expert panel advice; due to: the complexity of access to physician services and different health
26 coverage/schemes, lack of integration and communication between services provided at the government and
27 private institutions, the current lack of integration of pharmacy services with other health care services, and
28 the scattered primary care structure in the country. Such lack of follow-up with physicians is not uncommon in
29 studies exploring early stages of pharmacy-based screening given the complexity of the primary care setting.
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The short follow-up period was perhaps inadequate to capture all further diagnostic and management activities as a result of pharmacist-delivered screening. Future studies should attempt establishing linkages between community pharmacy and physicians in primary care, creating structured referral pathways and emphasis on interprofessional coordination between pharmacists and physician.

Conclusions

It is feasible for community pharmacists to screen and refer individuals for diabetes and CVD risks in the UAE. The successful implementation of the screening model in community pharmacy, in terms of identifying at-risk individuals and advising them to visit their physicians for further evaluation, offers a new platform to increase screening capacity within the primary care setting, and represents a key opportunity for the early detection and intervention to tackle the increasing burden of both diseases. However, pathways for the integration of the pharmacist-delivered screening service with physicians in primary care are yet to be explored.

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Author contribution:

HA designed the study, supervised data collection process, assisted with data analysis, wrote, reviewed and edited the entire manuscript. SC and RC analyzed data, reviewed and edited manuscript. SH wrote parts of manuscript. KM and IK assisted with designing of the study, reviewed the methods and data analysis contributed to the discussion.

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Table 1: Demographic and health characteristics (N=115)

	Characteristic	n (%)
Gender	Female	60 (52.1)
Age(yrs)	Mean \pm SD	47.23 \pm 7.3
Nationality	Syria	32 (27.8)
	Egypt	23 (20.0)
	India	11 (9.5)
	Jordan	7 (6.0)
	Pakistan	7 (6.0)
	Other	35 (30.4)
Education	Not educated	2 (1.7)
	Primary/middle school	15 (13.0)
	High school	37 (36.2)
	University	50 (43.4)
Marital status	Married	103 (89.5)
	Single	8 (6.9)
	Divorced	3 (2.6)
	Widowed	1 (0.8)
Employment	Full-time	67 (63.2)
	Part-time	6 (5.6)
	Home duties	25 (23.5)
	Other	17 (14.7)
Self-reported health status*	Excellent	24 (32.0)
	Good	41 (54.6)
	Average	10 (13.3)
Number of visits to a physician in the past year*	Mean \pm SD	3.05 \pm 4.1
Patterns of physician use	Have a regular physician	18 (24.0)
	Have a regular clinic but often see different physicians	14 (18.6)
	Visit different physician clinics	29 (38.6)
	Rarely or never visit a physician	14 (18.6)
Source of advice to reduce risk of diabetes and CVD risk in the past 12 months (apart from pharmacy screening visit)*	A physician	13 (17.5)
	A dietitian	1 (1.3)
	A specialist physician	5 (6.7)
	A pharmacist	2 (2.7)
	Others practitioners	9 (12.1)
	A family member	7 (9.4)
Examination of lifestyle factors that affect diabetes and CVD risk by a health professional during the past 12 months*		7 (6.4)

*Number of participants is 75 (first follow-up phone call)

1 **Table 2: Diabetes and CVD risk factors by gender and age (N=115)**

Characteristic	n(%)	Total (N=115)		Gender		p-value	Age (Years)								
				Female (n=61)	Male (n=54)		40-49 (n=84)		50-59 (n=25)		≥60 (n=6)		p-value		
HbA1c	Normal	74	(67.8)	45	(77.5)	29	(56.8)	0.064	58	(73.4)	14	(56.0)	2	(40.0)	0.034*
	Prediabetes	23	(21.1)	8	(13.7)	15	(29.4)		15	(18.9)	5	(20.0)	3	(60.0)	
	Diabetes	12	(11.0)	5	(8.6)	7	(13.7)		6	(7.5)	6	(24.0)	0	(0.0)	
ADA score ≥5	High risk	51	(44.7)	18	(30.0)	33	(61.1)	0.001*	29	(34.9)	16	(64.0)	6	(100.0)	0.001*
10-year ASCVD risk	High risk	19	(17.1)	2	(3.5)	17	(31.4)	<0.001**	6	(7.3)	8	(34.7)	5	(83.3)	<0.001**
Total cholesterol level	Optimal	82	(73.2)	43	(74.1)	39	(72.2)	0.738	62	(74.7)	15	(65.2)	5	(83.3)	0.252
LDL level	Borderline high	18	(16.0)	8	(13.7)	10	(18.5)		15	(18.0)	3	(13.0)	0	(0.0)	
	High	12	(10.7)	7	(12.0)	5	(9.2)		6	(7.2)	5	(21.7)	1	(16.6)	
HDL level	Optimal	64	(58.1)	35	(61.4)	29	(54.7)	0.594	49	(59.7)	11	(50.0)	4	(66.6)	0.954
	Above optimal	29	(26.3)	14	(24.5)	15	(28.3)		22	(26.8)	6	(27.2)	1	(16.6)	
	Borderline high	12	(10.9)	6	(10.5)	6	(11.3)		8	(9.7)	3	(13.6)	1	(16.6)	
	High	3	(2.7)	2	(3.5)	1	(1.8)		2	(2.4)	1	(4.5)	0	(0.0)	
	Very high	2	(1.8)	0	(0.0)	2	(3.7)		1	(1.2)	1	(4.5)	0	(0.0)	
HDL level against CVD	Protective	16	(14.4)	14	(24.1)	2	(3.7)	<0.001**	10	(12.2)	5	(21.7)	1	(16.6)	0.492
	Borderline	53	(47.7)	36	(62.0)	17	(32.0)		41	(50.0)	8	(34.7)	4	(66.6)	
	Major CVD risk factor	42	(37.8)	8	(13.7)	34	(64.1)		31	(37.8)	10	(43.4)	1	(16.6)	
Triglyceride level	Optimal	36	(32.4)	25	(43.1)	11	(20.7)	0.055	28	(34.1)	6	(26.0)	2	(33.3)	0.093
	Borderline high	24	(21.6)	10	(17.2)	14	(24.1)		22	(26.8)	2	(8.7)	0	(0.0)	
	High	50	(45.0)	22	(37.9)	28	(52.8)		32	(39.0)	14	(60.8)	4	(66.6)	
	Very high	1	(0.9)	1	(1.7)	0	(0.0)		0	(0.0)	1	(4.3)	0	(0.0)	
Systolic BP level	Normal	58	(55.7)	37	(68.5)	21	(42.0)	0.019*	47	(60.2)	10	(47.6)	1	(20.0)	0.265
	Pre-hypertension	35	(33.6)	14	(25.6)	21	(42.0)		25	(32.0)	7	(33.3)	3	(60.0)	
	Hypertension	11	(10.5)	3	(5.5)	8	(16.0)		6	(7.6)	4	(19.0)	1	(20.0)	
Diastolic BP level	Normal	57	(54.8)	32	(59.2)	25	(50.0)	0.613	44	(56.4)	11	(52.3)	2	(40.0)	0.669
	Pre-hypertension	33	(31.7)	15	(27.7)	18	(36.0)		23	(29.4)	7	(33.3)	3	(60.0)	
Body mass index	Hypertension	14	(13.4)	7	(12.9)	7	(14.0)		11	(14.1)	3	(14.2)	0	(0.0)	
	Normal	22	(19.1)	13	(21.6)	9	(16.3)	0.501	17	(20.2)	4	(16.0)	1	(16.6)	0.653
	Overweight	42	(36.5)	19	(31.6)	23	(41.8)		33	(39.2)	8	(32.0)	1	(16.6)	
	Obese	51	(44.3)	28	(46.6)	23	(41.8)		34	(40.4)	13	(52.0)	4	(66.6)	

2 *Statistically significant p<0.05 **Statistically Significant p<0.0001

3 **Table 3: Outcomes of at-risk participants' referral (n=37)**

		n
Participants completed uptake of referral follow-up		
Participants visited a doctor to discuss pharmacist-delivered screening results		
	Visited doctor straight away	
	Made some changes and went to doctor later	
	Discussed results at routine visit	
Participants who did not visit a doctor		
	Haven't visited doctor yet but intend to	
	Didn't think it was necessary	
	Haven't visited doctor yet and made no plans	
Physician knew about pharmacy screening		
	Referral letter given to the doctor	
	Told doctor about pharmacy screening	
	Doctor treated the results of pharmacy screening seriously	
Follow-up tests were ordered by the physician		
	Blood pressure	
	Total cholesterol	
	HDL cholesterol	
	Blood sugar level	
	Waist	
	Weight	
	Other	
Lifestyle changes since screening		
	Increased regular exercise	
	Attempted to lose weight	
	Improved diet	
	Started new medications	

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16 **Table 4: Participants' experiences, feedback, and satisfaction with screening (n=75)**

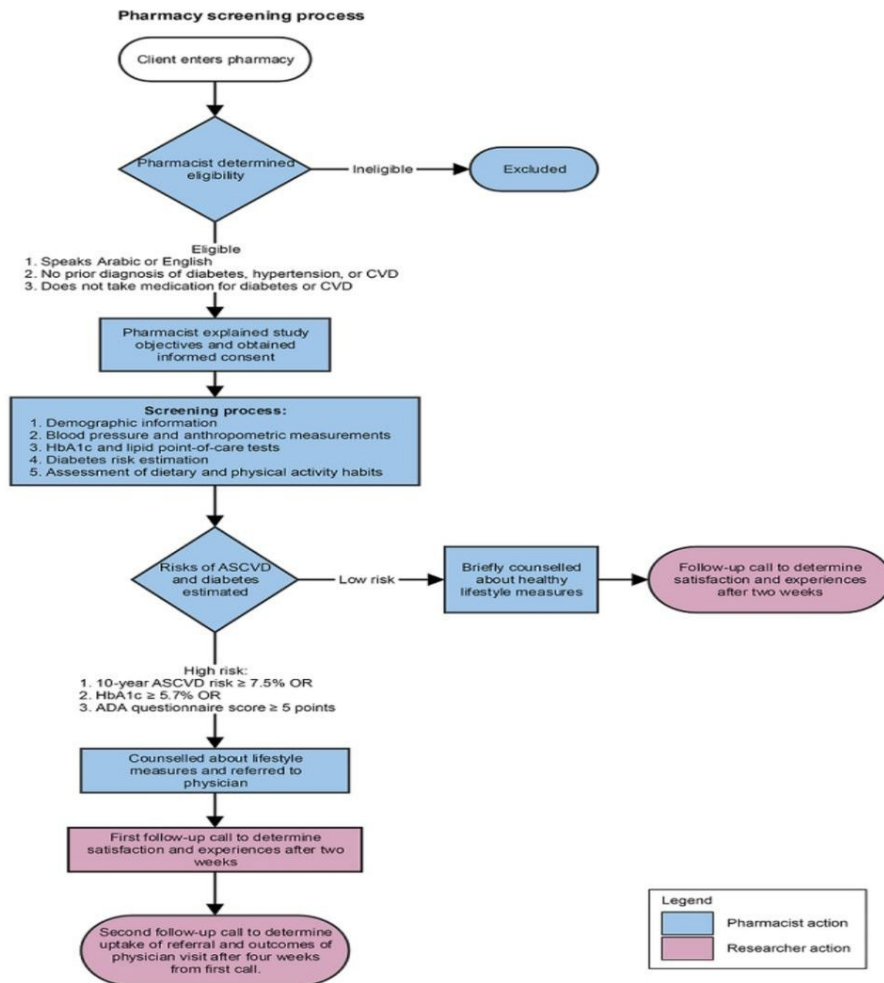
Experience and feedback on pharmacist-delivered screening		
-	Person who initiated the conversation about screening between participant and pharmacist	Another participant in the project Pharmacist Pharmacy staff Acquaintance Social media
-	Clarity of pharmacist's explanation of risk of developing diabetes and CVD	Very clear Clear enough Some parts clear Generally unclear
-	Depth of pharmacist's exploration of possible lifestyle causes of increased diabetes and CVD risks	Very comprehensive Discussed several issues Discussed only one issue
-	Steps undertaken following screening	The pharmacist provided you with a written report of your results The pharmacist made sure that you understood everything The pharmacist clearly stated when the physician follow up was required
-	Quality of the testing carried out in pharmacy	Excellent Above average Average Slightly below average
-	Perceived length of the diabetes and CVD risk screening process	Much too long A little long About right A little short
Satisfaction with the pharmacist-delivered screening		
-	Satisfaction with health risk assessment	Very satisfied Satisfied Average Dissatisfied
-	Satisfaction with the quality of advice provided in the pharmacy	Very satisfied Satisfied Average Dissatisfied
Willingness to pay for the future pharmacist-delivered screening service		
-	Yes	
-	Acceptable amount to be paid	≤50 AED (≤ USD 13.6*) 51-100 AED (USD 13.6-27.2*) 101-150 AED (USD 27.2-48.8*) >150 AED (> USD 48.8*)
-	Reasons for unwillingness to pay for future pharmacist-delivered screening service	Cannot afford it Does not think it is worth it Thinks it should be free Other

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Screening flow chart

90x90mm (300 x 300 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1 and 3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5 and 6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	11 and 12
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	13
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	13
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	15
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	15
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	16-18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.

Journal:	<i>BMJ Open</i>
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology, Cardiovascular medicine
Keywords:	Primary Health Care, Cardiovascular Diseases, Point-of-Care Testing, General diabetes < DIABETES & ENDOCRINOLOGY, Pharmacy, Screening

SCHOLARONE™
Manuscripts

1 **Title: Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing**
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32 **primary healthcare system: feasibility study.**

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For peer review only

Abstract:

Objectives: To develop an evidence-based community pharmacist-delivered screening model for diabetes and cardiovascular disease (CVD), and assess its feasibility to identify and refer patients with elevated risk.

Design: A feasibility study.

Setting: A purposive sample of 12 community pharmacies in three cities in the United Arab Emirates (UAE).

Participants: Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.

Intervention: Pharmacist screening of adults visiting pharmacies involved history, demographics, anthropometric measurements, blood pressure, and point-of-care testing including HbA1c levels and lipid panel. Participants with a 10-year CVD risk $\geq 7.5\%$, HbA1c level $\geq 5.7\%$ or American Diabetes Association risk score ≥ 5 points, were advised to visit their physician.

Primary and secondary outcome measures: (1) Development of UAE pharmacist-delivered screening model, (2) the proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk defined as $\geq 7.5\%$), (3) the proportion of participants identified as having elevated blood glucose (high HbA1c level $\geq 5.7\%$ (38.8mmol/mol)) or high self-reported diabetes risk (ADA risk score ≥ 5 points). Secondary outcomes: participants' satisfaction with the screening.

Results: The first UAE pharmacist-delivered screening model was developed and implemented. A total of 115 participants were screened, and 92.3% of the entire screening process was completed during a single visit to pharmacy. The mean duration of the complete screening process was 27 minutes. At-risk individuals (57.4%) were referred to their physicians for further testing, 94.5% of participants were at least satisfied with their screening experience.

Conclusions: The community pharmacist-delivered screening of diabetes and CVD risk is feasible in the UAE. The model offers a platform to increase screening capacity within primary care and provides an opportunity for early detection and treatment. However, pathways for the integration of the pharmacist-delivered screening service with physicians in primary care are yet to be explored.

Keyword: Diabetes, Cardiovascular Diseases, Screening, Pharmacy, Point-of-Care Testing, Primary Health Care

Strengths and limitations of this study

- An expert panel was used to adapt an international screening and develop the first contextually-tailored pharmacy screening model for diabetes and cardiovascular diseases risk in UAE.
- Lipid panel and glycated hemoglobin level were measured using a finger-prick point-of-care testing device (Roche Cobas b 101 POC dual system).
- Follow-up with physicians on referral outcomes of participants at-risk could not be determined due to the fragmented healthcare system. We relied on patient self-report data.
- Patient recruitment heavily relied on a direct invitation from pharmacists
- Follow-up times with screened participants were short and may not have encompassed all results regarding follow-up with physicians.

96 Introduction

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37 Type 2 diabetes (T2DM) and cardiovascular disease (CVD) are leading contributors to the global burden of
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98 disease, albeit with distinct long-term trends.(1) Diabetes, a rapidly growing global epidemic, affects all
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99 countries, and is substantially caused by rapidly increasing rates of obesity over recent decades. (2) By 2040
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100 T2DM will affect an estimated 642m people; 10.4% of the adult population, compared with 8.8% in 2015.(2-4)
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101 Age-standardized CVD trends are more geographically nuanced – generally, the incidence has declined
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102 markedly in highly developed countries over several decades, but this decline has now plateaued.(5) Likewise,
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103 some middle-income regions have experienced declines in CVD mortality, but in most regions of the
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104 developing world, a rapid increased incidence has recently prevailed.(5) Globally in 2015, there were an
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22 estimated 422.7 million prevalent cases of CVD, and ischemic heart disease and stroke remained the leading
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26 causes of death.(6) A combination of an aging western society, and increasing CVD mortality rates in many
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109 32.2% of all persons with T2DM.(7)
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112 An estimated 45.8% (174.8 million) of adult diabetes cases worldwide are undiagnosed, ranging from 24.1% to
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119 behaviors, and intentional delay in accessing available medical services are commonplace in Arabic-speaking
120 communities, hence the need for proactive and opportunistic population screenings.(14-16)

121 The feasibility of pharmacist-delivered screening, for a variety of conditions including diabetes and CVD, is well
122 supported by evidence.(17, 18) Such screening interventions identified at-risk individuals and increased rates
123 of disease diagnosis, reduced disease risk factors, improved health behaviors, enhanced quality of care, and
124 increased patient knowledge and awareness.(19) Community pharmacists have face-to-face contact with
125 around 90% of the population annually and appear to interact regularly with those who have elevated risk of
126 diabetes and CVD, or undiagnosed diabetes.(20) The potential, therefore, exists for pharmacists to improve
127 access to health screening services and promote public health awareness.

128 In the UAE a substantial number of people with diabetes and a high prevalence of overweight and obesity are
129 currently thought to remain undiagnosed.(21) There are around 2,500 licensed community pharmacies in UAE
130 that are generally open seven days per week, easily accessible, and have an average working day of 13 hours
131 (22, 23); this potentially makes pharmacies an effective setting to offer screening for diabetes and CVD within
132 the primary care system. To our knowledge, no systematic diabetes and CVD screening programs exist in the
133 primary care setting in the UAE, meaning these diseases continue to be undiagnosed precluding the
134 opportunity to initiate early prevention and treatment.

135 The aim of this study was to test the feasibility of pharmacist-delivered diabetes and CVD risk screening model
136 in the UAE. The specific objectives were to:

- 137 1. Develop locally-appropriate pharmacist-delivered diabetes and CVD risk screening model for the
138 community pharmacies in UAE.
- 139 2. Evaluate the feasibility of implementing diabetes and CVD risk screening model in the selected
140 community pharmacies in the UAE.

142 **Methods**

143 **Ethical approvals**

144 This study was approved by the Research Ethics Committee of the University of Sharjah, the Ministry of Health
145 and Prevention in the UAE, and deemed Exempt by the Harvard T.H. Chan School of Public Health Institutional
146 Review Board.

147 **Study design**

148 The study was conducted in three phases: Phase 1 (formative phase) explored development of a suitable
149 model for diabetes screening and CVD risk assessment in community pharmacies in the UAE, Phase 2
150 (implementation phase) assessed the feasibility of the screening model, and Phase 3 (evaluation phase) tested
151 the impact of the screening model.

152 **Phase 1: Formative Phase**

153 A systematic approach was used to develop the intervention of diabetes and CVD screening.(24) The formative
154 phase commenced with identifying needs for diabetes and CVD risk screening program. After identifying the
155 suitability of community pharmacies for providing screening services, a literature review of pharmacist-
156 delivered screening models was conducted to identify useful and effective approaches to screening. The
157 Australian Cardiovascular Absolute Risk Screening Study (CARS) was considered an appropriate template
158 model to inform the development of the first UAE pharmacy-based screening program.(25) Two local health
159 professionals were consulted to determine the adaptation of CARS into the local context and acceptability of
160 the proposed protocol prior to presenting the model to an expert panel. In the absence of national guidelines
161 and frameworks regarding risk assessment and management for diabetes and CVD in the UAE, an expert panel
162 forum was tasked to develop a consensus on the proposed screening program. Prospective panelists were
163 identified through extensive online search; evaluating experts' specialty, experience, and research
164 involvement. Shortlisted experts, including two cardiologists, two endocrinologists, two senior clinical
165 pharmacists, were invited to participate in the forum. The Delphi technique was used to help arrive at a

166 consensus on a specific question in one or more rounds - supportive documents were created to aid in voting
167 and to calculate the level of agreement.(26) The Delphi discussion focused on locally-appropriate methods for
168 absolute cardiovascular and diabetes risk assessment, including: use of absolute CVD risk assessment and
169 other multi-factorial risk algorithm cut-offs; selection of screening tools; and risk factor thresholds for
170 physician referrals. The following questions were discussed during the forum:

- 171 1. When should the participant's blood pressure measurement be taken? Moreover, what is the
172 minimum time interval needed between taking the two blood pressure readings?
- 173 2. Which tool to use to calculate participants' absolute CVD risk?
- 174 3. Which method would be most suitable for calculating the participants' absolute CVD risk in the
175 community pharmacy setting?
- 176 4. Which self-reported tool to use to determine the participants' risk of having T2DM? What absolute
177 CVD risk threshold should be used when deciding to refer a participant to a physician?
- 178 5. At what HbA1c level should a participant be referred to a physician?
- 179 6. Should at-risk participants who are referred to physicians for further testing be contacted to ask about
180 any lifestyle modifications and outcomes of a visit to a physician? And should the physicians whom the
181 referred participants visited be contacted?

182 The screening model planning involved the development of resources in supporting pharmacists-delivered
183 screening including: training manual, data collection tools, and patient follow up documents. These were
184 developed through a process of co-production in consultation with the international co-researchers who had
185 previous experience in pharmacist-delivered screening services. To ensure local context applicability, study
186 materials were sent to three local community pharmacists for feedback and comments.

187 **Phase 2: Implementation Phase**

188 Community pharmacists were trained through a face-to-face workshop that lasted for three hours on the
189 study protocol, and on how to: (1) approach potential participants, (2) use point-of-care testing devices, (3)
190 handle refusals to participate, (4) collect data, (5) communicate risk assessment results to participants, (6)

engage and refer at-risk individuals to physicians, (7) counsel participants on required lifestyle changes, and (8) respond to participants' questions.

Study setting and participants

A purposive sample of 12 community pharmacies (with necessary infrastructure) in the three emirates of Dubai, Sharjah, and Ajman in the UAE was selected. The recruited sites represented chain pharmacies. Study pharmacists were offered a small monetary incentive (AED 23 (equivalent to USD 6)) per screening in appreciation of their time and effort.

Recruitment of participants

Pharmacy-based advertising, including posters and flyers, were used to recruit participants. Individuals were mainly invited directly by the pharmacists to participate based on their judgment of the individual's age. Interested voluntary participants were pre-screened by the pharmacists to determine their eligibility. Eligible participants were given written patient information sheet and they signed a consent form.

Inclusion criteria:

- Arabic or English speaking.
- Aged between 40 to 74 years. There is no international consensus on the age range for diabetes screening, however, 40 years is recommended in several guidelines and was therefore considered appropriate.

Exclusion criteria:

- Previous diagnosis of diabetes or CVD.
- Use of medications for treatment of diabetes, hypertension or any other CVD at the time of screening.
- Pregnancy.
- Terminal illness.
- Severe mental illness.

Data collection and risk factor assessment

To document the screening process, participating pharmacists completed brief paper-based records of each screening undertaken. This provided patient risk assessment data, documentation of patient counseling (e.g. lifestyle factors assessed, targets specified, and criteria for referral to a physician) and logistical information (e.g. time taken to conduct screening and counseling, number of visits required, reasons for deviating from suggested screening schedule).

After checking eligibility and obtaining consent, trained pharmacists screened participants with the following measurements:

- Anthropometric measurements: Weight, height and waist circumference were measured along with body mass index calculations.
- Point-of-care testing: Total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein (LDL) plasma levels, and glycated hemoglobin (HbA1c) level, were measured using a finger-prick point-of-care testing device (Roche Cobas b 101 POC dual system). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured after participants rested for 5 minutes using the Omron 1A1B® automated Blood Pressure (BP) monitor. Pharmacists advised participants to seek immediate medical attention if SBP was ≥ 180 mmHg, or DBP ≥ 110 mmHg. Pharmacists also reminded 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.
- CVD risk assessment: Projected 10-year atherosclerotic CVD risk was calculated for each participant. Diabetes risk assessment: In addition to HbA1c level, the American Diabetes Association (ADA) T2DM risk questionnaire was completed.
- Patient History: Detailed socio-demographic information, brief medical history, family history of diabetes, smoking status, physical activity, and dietary behaviors. Patients referral and follow-up: Participants at high risk, defined as having any of the following: (1) 10-year ASCVD risk $\geq 7.5\%$ (2)

HbA1c level \geq 5.7 (3) ADA T2DM risk questionnaire \geq 5 points, were advised to visit their physician. All participants identified, by pharmacists, as at high risk for either CVD or diabetes were given a referral letter summarizing pharmacy screening results to the physician for further testing. A rapid phone follow-up of all participants was conducted (within two weeks of screening) by a member of the research team to determine participants' satisfaction and experience with the pharmacy screening service. Participants were asked about perceived depth and clarity of pharmacist explanation of diabetes and CVD risk; their satisfaction with the risk assessment and the quality of testing and advice; instructions on the need for further evaluation by a physician; and the perceived length of the screening. They were also asked about their opinion on community pharmacies as a venue of the screening service, whether screening should be routinely provided by community pharmacists, and their willingness to pay for future pharmacist-delivered screening.

The follow-up also included questions about self-reported health status, frequency, and pattern of physician visits in the past year. Participants were asked if they had undergone an assessment of lifestyle that affects diabetes and/or CVD risk by any healthcare professional in the past year or whether they were advised of the need to reduce their diabetes or CVD risk. The research team members identified themselves as such to the participants and informed them that their responses will not be communicated to the pharmacists who performed the screening.

Outcomes

1. Development of UAE pharmacy-based screening model:

A consensus statement from the expert panel detailing the screening processes, cut off points/levels, and referral mechanisms to physicians, all suited to the community pharmacy context in UAE.

2. Feasibility assessment:

- a) The proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk defined as \geq 7.5% - as determined by the expert panel, see section 3.1).

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1 b) The proportion of participants identified as having elevated blood glucose (high A1c level >6.5%
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3 (48mmol/mol)) or high self-reported diabetes risk (T2DM risk questionnaire score \geq 5 points - as
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5 determined by the expert panel, see section 3.1).
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8 c) Participants' acceptability and satisfaction with the pharmacist-delivered screening.
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268 **Patient and Public Involvement:** We did not involve patients or the public in our work
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269 **Data analysis**

270 The data was entered into Microsoft Access and 10% of participant files were randomly selected for validation.
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19 Stata, release 14 (StataCorp, College Station, TX) was used for data analysis.(27) Normally distributed
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21 continuous variables were described using means and standard deviations (such as participants' age, visits to
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23 physicians and nutritional habits). Categorical variables were described using counts and frequencies (such as
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25 demographic data, BMI (grouped) and medical history). The Chi-squared test was used to test differences in
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27 risk factors by age and gender. A p-value of <0.05 was considered statistically significant.
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32 **Results**

33 **Consensus statement on screening intervention**

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36 The expert panel reached a consensus on the use of absolute risk assessment and other multi-factorial risk
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38 algorithm cut-offs, screening tools, and risk factor thresholds. Panel members unanimously agreed on: taking
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40 two seated measurements of BP after a five-minute rest and separated by two minutes. If the two systolic and
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42 diastolic BP readings differed by \geq 10 mmHg or \geq 6 mmHg respectively, a third measurement would be needed,
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44 and the two closest readings would be used to calculate mean BP. Regarding the calculation of 10-year
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46 atherosclerotic CVD risk score, the ACC/AHA pooled cohort equations CVD risk calculator should be used.
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49 Participants having a 10-year risk \geq 7.5% were classified as high risk and had to be referred to a physician for
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51 further testing. The official ASCVD Risk Estimator Plus smartphone application with off-line feature was
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53 deemed most feasible to perform the calculation. Other criteria that independently necessitated referral to a
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287 physician were an HbA1c level exceeding 5.7% (pre-diabetes) or a score above five points on the ADA
288 questionnaire to measure the risk of T2DM.

289 Regarding the determination of uptake of referral and physician action on the results of the screening, the
290 panelists identified the impracticality of contacting physician's offices; instead it was agreed that uptake of
291 referral and physician action would be best reported by participants themselves during follow-up calls. Clinical
292 training manual and implementation resources were developed to ensure systematic approaches for the
293 execution of pharmacist-delivered screening and to minimize variability amongst participating pharmacists.
294 Data collection tools and consent forms were adapted from the CARS project. Figure 1 illustrates the final
295 screening model.

296 **Socio-demographic and health characteristics**

297 From December 15, 2017 to May 8, 2018, 120 consenting participants were screened for CVD and T2DM from
298 the population visiting the 12 participating community pharmacies (which had sufficient/appropriate space to
299 accommodate the screening service, and had high volume and greater variability in clientele). Five participants
300 were excluded for not meeting study criteria. Socio-demographic and health characteristics of the 115
301 screened participants are summarized in Table 1. Gender representation was almost equal with most
302 participants having been born in Syria and Egypt. When participants were asked about their present state of
303 health, 32% reported being 'excellent'. On average, participants visited a physician three times a year. 24% of
304 participants reported having regular physicians, while 18.6% had regular clinic but visited different physicians,
305 and 38.6% visited different clinics. In the past 12 months, only 6.4% reported undertaking a detailed
306 examination of lifestyle factors by a health professional.

307 **Implementation fidelity**

308 Of the screened participants, 57.4% were identified as high-risk for diabetes and/or CVD. After each screening
309 encounter, pharmacists completed a checklist that documented the screening process (Table 2). Most
310 participants (91.7%) were screened immediately following their recruitment and the signing of informed
311 consent, and the remainder were given appointments for a later time on the day of recruitment or a later

312 date. In the majority of cases (92.3%), the entire screening process was completed during a single visit to the
313 pharmacy.

314 A total of 12 participants did not undergo a complete assessment as per the screening protocol. A full lipid
315 profile was not obtained in four cases, and four other participants did not obtain an HbA1c measurement.
316 Furthermore, pharmacists did not perform a waist circumference measurement for three participants and
317 blood pressure measurement for one participant. Pharmacists documented the reasons for incomplete
318 assessments for these 10 participants: a technical error in the POC device prevented the measurement in nine
319 cases, and the participant objected to the measurement in one case. Assessments of diabetes risk as per the
320 ADA questionnaire, dietary habits, and physical activity habits were completed for all participants. One
321 average, assessment and testing took 27 ± 9.4 minutes.

322 In all cases where pharmacists documented post-assessment counseling, pharmacists explained the meaning
323 of participants' ASCVD and ADA questionnaire risk scores and the targets for suboptimal blood test results.
324 HbA1c test results were explained to 96.3% of participants. Regarding lifestyle behaviors, the pharmacists
325 documented counseling 85.8% and 81.1% of participants about healthy diet and physical activity, respectively.
326 Finally, pharmacists reported informing 87.9% of participants of the need for confirmatory testing at the
327 physician's office. Pharmacists reported that post-assessment counseling lasted 11.6 ± 6.5 minutes on average.

328 **Uptake of referral**

329 A total of 71 (61.7%) at-risk individuals were referred to their physicians for further testing; 37 participants
330 (52.1%) completed the second follow-up survey to determine uptake of referral (Table 3). Only nine of these
331 participants (24.3%) had visited their physician following the screening, 29.7% had not visited their physician
332 yet but intended to do so. Conversely, 43.2% did not visit their physician and made no such plans (Table 3).
333 Five participants told their physicians about the pharmacy screening results; 4 of the 5 cases reported that
334 physicians took the results seriously. Physicians ordered follow-up tests for 77.7% of the participants, including
335 total cholesterol and blood sugar levels (57.1% each), HDL levels and BP (42.8% each).

When asked about lifestyle changes that participants adopted following the screening, 63.1% reported improved diet, 57.8% attempted to lose weight, and 40% started new medications since the screening (Table 3).

Participants' experiences, feedback, and satisfaction with the screening service

All participants were contacted by telephone to determine their experiences and satisfaction with the pharmacy screening service (Table 4). A total of 75 participants completed the follow-up survey (65.2%). In 68% of the cases, the pharmacist-initiated the conversation about the screening service. Other participants reported learning about the service from personal acquaintances (17.3%), and social media (10.7%).

Almost all participants reported that the pharmacists' explanation of their risk of developing diabetes or CVD were either 'very clear' or 'clear enough' and that pharmacists explained the various lifestyle causes of increased CVD or diabetes risk 'very comprehensively' or 'discussed several issues'.

At the conclusion of the screening, 94.5% of participants reported that pharmacists made sure participants understood all key points, and 89.3% indicated that pharmacists provided participants with a written screening report.

Most participants (94.5%) reported either being "satisfied" or "very satisfied" with the risk assessment undertaken by the pharmacists and the quality of the pharmacists' advice.

Eighty-six percent of participants thought pharmacies are good venues for conducting screening tests, and 86.6% thought pharmacists should routinely provide CVD and diabetes risk screening. Most participants (82.7%) indicated they would be willing to pay for pharmacist-delivered screening services should it be provided in the future (Table 3).

Discussion

This study is the first in an Arabic-speaking country (UAE) to assess the feasibility and performance of an evidence-based pharmacist-delivered screening program for T2DM and CVD. The screening model, adapted

359 from the CARS model with the advice of local experts, was successfully implemented in community
1 pharmacies and resulted in the identification and referral of at-risk individuals.(25)
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361 The proportion of screened participants identified with high diabetes or CVD risk in this study was higher
6 compared to reported rates in the international pharmacy screening literature. This could be partially
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362 explained by the higher prevalence of diabetes and CVD in the UAE.(21, 28) High referral rate (61.7%) in this
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363 study is consistent with the recent trend towards higher rates of referral.(18) Without systematic diabetes
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364 and CVD screening programs in the primary care of the UAE, lack of universal healthcare coverage, all in
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365 tandem with poor health-seeking behavior and the delay in access to medical services these conditions will
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366 continue to be undiagnosed. The potential, therefore, exists for community pharmacists who have regular
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367 contact with the population to improve access to health screening services and promote public health
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368 awareness.
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370 Several pharmacy and pharmacist-levels factors at selected pharmacies contributed to the success of
28 implementing pharmacist-delivered screening, these include: (i) the necessary infrastructure (such as
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371 sufficient/appropriate space) to accommodate the screening service, (ii) motivation of pharmacist to learn
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372 about and perform the screening, (iii) high volume and greater variability in clientele.
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374 The purposive sampling of community pharmacies and the exploratory implementation study design might
38 have limited the generalizability of study results. However, equally, it could be argued that the somewhat
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375 driven community pharmacists in this study would have been representative of the expected pharmacists in
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376 future program roll-out. The study was designed to demonstrate the feasibility of pharmacist-delivered
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377 screening and to understand how implementation support and processes might have been optimized to
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378 enable such a health service. Follow-up with physicians on pharmacist-delivered screening was not carried out
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379 as per the expert panel advice; due to: the complexity of access to physician services and different health
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380 coverage/schemes, lack of integration and communication between services provided at the government and
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381 private institutions, the current lack of integration of pharmacy services with other health care services, and
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382 the scattered primary care structure in the country. Such lack of follow-up with physicians is not uncommon in
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384 studies exploring early stages of pharmacy-based screening given the complexity of the primary care setting.
385 To optimize the health impacts of a screening service a more effective referral pathway will need to be
386 established in further discussions between pharmacists and physicians. Better uptake of screening may have
387 been achieved with training of other staff of the pharmacy to aid in recruitment. A focused advertising
388 campaign, including advertorials in local media may also have boosted uptake. A better follow-up rate may
389 have been achieved if the pharmacist him/herself followed up screened participants several weeks after the
390 referral was given. In this follow-up, the pharmacist could check if at-risk screened individuals had taken up
391 the referral or prompt them to act upon it if they had yet done so. It may also have been helpful to send a
392 copy of the referral directly to the referred individual's nominated physician.

393 Participant selection was heavily based on pharmacist perception of their age. Until screening becomes known
394 and accepted as a community pharmacy service in UAE, the most likely pathway to uptake of screening in
395 community pharmacy in the UAE is by direct invitation from a pharmacist. It is also likely to yield more
396 individuals at high risk and in need of further testing and diagnosis. This has also been the case in other
397 screening trials (Krass et al 2007, CARS trial). Once such service becomes established it is likely that consumers
398 may request it themselves in response to advertising, posters in the pharmacy etc. The research team, at
399 planning phase, wanted to document proportion of patients approached, proportion consented and record
400 reason(s) for people refusal to screen, however, pharmacists reported that this would be an added work and
401 preferred not to collect such data. The short follow-up period with the patients was perhaps inadequate to
402 capture all further diagnostic and management activities as a result of pharmacist-delivered screening. This
403 feasibility study was continued into a larger scale sensitivity phase to evaluate the effectiveness of pharmacist-
404 delivered screening in identifying the proportion of screened participants identified as having high diabetes
405 and/or CVD risk in the UAE. Additional future studies should evaluate strategies to establish closer links
406 between community pharmacy and physicians in primary care, creating structured referral pathways and
407 emphasis on interprofessional coordination between pharmacists and physician.

Conclusions

It is feasible for community pharmacists to screen and refer individuals for diabetes and CVD risks in the UAE. The successful implementation of the screening model in community pharmacy, in terms of identifying at-risk individuals and advising them to visit their physicians for further evaluation, offers a new platform to increase screening capacity within the primary care setting, and represents a key opportunity for the early detection and intervention to tackle the increasing burden of both diseases. However, pathways for the integration of the pharmacist-delivered screening service with physicians in primary care are yet to be explored.

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Author contribution: HA designed the study, supervised data collection process, assisted with data analysis, wrote, reviewed and edited the entire manuscript. SC and RC analyzed data, reviewed and edited manuscript. SH wrote parts of manuscript. KM and IK assisted with designing of the study, reviewed the methods and data analysis contributed to the discussion, and reviewed all drafts.

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Table 1: Demographic and health characteristics (N=115)

	Characteristic	n (%)
Gender	Female	60 (52.1)
Age(yrs)	Mean \pm SD	47.23 \pm 7.3
Nationality	Syria	32 (27.8)
	Egypt	23 (20.0)
	India	11 (9.5)
	Jordan	7 (6.0)
	Pakistan	7 (6.0)
	Other	35 (30.4)
Education	Not educated	2 (1.7)
	Primary/middle school	15 (13.0)
	High school	37 (36.2)
	University	50 (43.4)
Marital status	Married	103 (89.5)
	Single	8 (6.9)
	Divorced	3 (2.6)
	Widowed	1 (0.8)
Employment	Full-time	67 (63.2)
	Part-time	6 (5.6)
	Home duties	25 (23.5)
	Other	17 (14.7)
Self-reported health status*	Excellent	24 (32.0)
	Good	41 (54.6)
	Average	10 (13.3)
Number of visits to a physician in the past year*	Mean \pm SD	3.05 \pm 4.1
Patterns of physician use	Have a regular physician	18 (24.0)
	Have a regular clinic but often see different physicians	14 (18.6)
	Visit different physician clinics	29 (38.6)
	Rarely or never visit a physician	14 (18.6)
Source of advice to reduce risk of diabetes and CVD risk in the past 12 months (apart from pharmacy screening visit)*	A physician	13 (17.5)
	A dietitian	1 (1.3)
	A specialist physician	5 (6.7)
	A pharmacist	2 (2.7)
	Others practitioners	9 (12.1)
	A family member	7 (9.4)
Examination of lifestyle factors that affect diabetes and CVD risk by a health professional during the past 12 months*		7 (6.4)

*Number of participants is 75 (first follow-up phone call)

Table 2: Pharmacist-documented components of screening model completed (N=112)

Component of screening model	
Timing of screening	Immediately following recruitment By appointment on same day By appointment on another day
Number of visits needed to complete screening	One visit Two visits
Assessments and measurements completed	Anthropometric measurements Diabetes risk assessment ASCVD risk score calculation Dietary habits assessment Physical activity habits assessment
Tests and measurements not completed	Lipid profile HbA1c Waist circumference Blood pressure
Reason for not completing test/measurement	Technical error in device Participant objection*
Assessment, testing, and measurement duration	Mean duration \pm SD (minutes) 10 – 20 minutes 21 – 30 minutes 31 – 40 minutes Over 40 minutes
Post-assessment counseling	ASCVD risk score interpretation ADA questionnaire score interpretation HbA1c result interpretation** Guideline targets for suboptimal blood test results Lifestyle behaviors (top two covered aspects) - Dietary behaviors - Physical activity Need for further/confirmatory testing at physician's office
Post-assessment counseling duration	Mean duration \pm SD (minutes) 1 – 10 minutes 11 – 20 minutes 21- 30 minutes Not reported

* One participant objected to waist circumference measurement. ** Documentation was missing for 30 participants.

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3 **515 Table 3: Outcomes of at-risk participants' referral (n=37)**
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5	Participants completed uptake of referral follow-up	
6	Participants visited a doctor to discuss pharmacist-delivered screening results	
7	Visited doctor straight away	
8	Made some changes and went to doctor later	
9	Discussed results at routine visit	
10	Participants who did not visit a doctor	
11	Haven't visited doctor yet but intend to	
12	Didn't think it was necessary	
13	Haven't visited doctor yet and made no plans	
14	Physician knew about pharmacy screening	
15	Referral letter given to the doctor	
16	Told doctor about pharmacy screening	
17	Doctor treated the results of pharmacy screening seriously	
18	Follow-up tests were undertaken by the physician	
19	Blood pressure	
20	Total cholesterol	
21	HDL cholesterol	
22	Blood sugar level	
23	Waist	
24	Weight	
25	Other	
26	Lifestyle changes since screening	
27	Increased regular exercise	
28	Attempted to lose weight	
29	Improved diet	
30	Started new medications	

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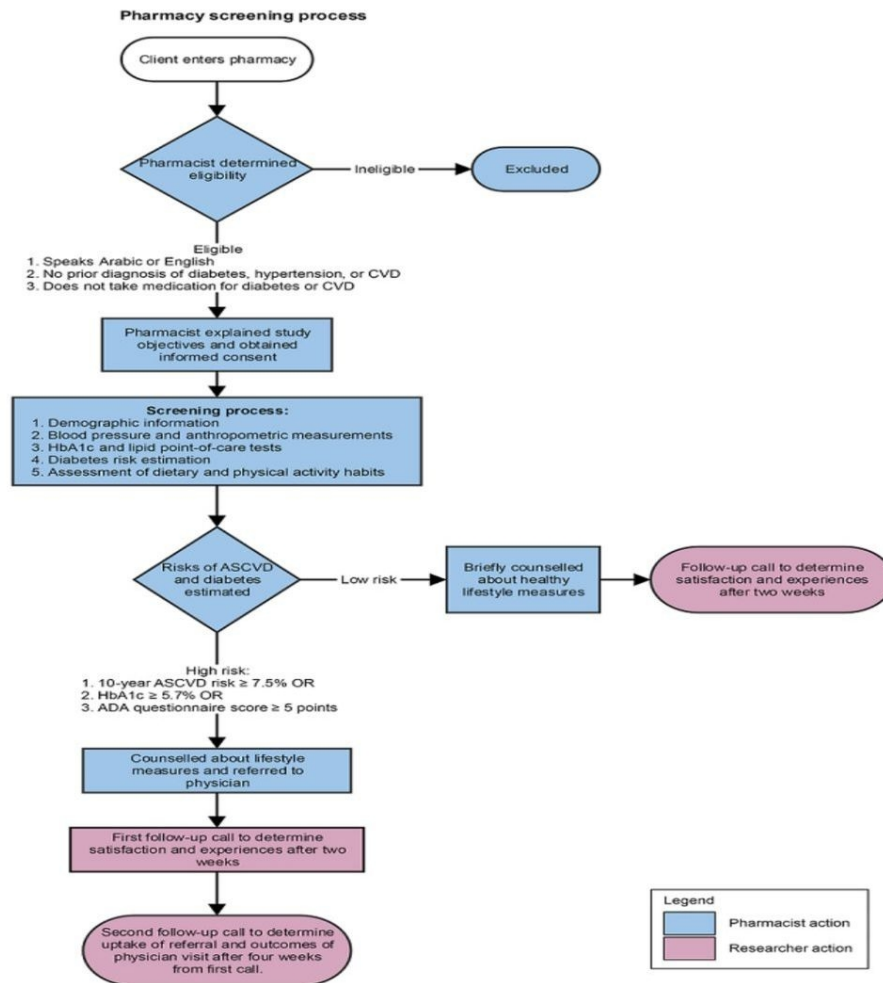
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529 **Table 4: Participants' experiences, feedback, and satisfaction with screening (n=75)**

Experience and feedback on pharmacist-delivered screening		
-	Person who initiated the conversation about screening between participant and pharmacist	Another participant in the project Pharmacist Pharmacy staff Acquaintance Social media
-	Clarity of pharmacist's explanation of risk of developing diabetes and CVD	Very clear Clear enough Some parts clear Generally unclear
-	Depth of pharmacist's exploration of possible lifestyle causes of increased diabetes and CVD risks	Very comprehensive Discussed several issues Discussed only one issue
-	Steps undertaken following screening	The pharmacist provided you with a written report of your results The pharmacist made sure that you understood everything The pharmacist clearly stated when the physician follow up was required
-	Quality of the testing carried out in pharmacy	Excellent Above average Average Slightly below average
-	Perceived length of the diabetes and CVD risk screening process	Much too long A little long About right A little short
Satisfaction with the pharmacist-delivered screening		
-	Satisfaction with health risk assessment	Very satisfied Satisfied Average Dissatisfied
-	Satisfaction with the quality of advice provided in the pharmacy	Very satisfied Satisfied Average Dissatisfied
Willingness to pay for the future pharmacist-delivered screening service		
-	Yes	
-	Acceptable amount to be paid	≤50 AED (≤ USD 13.6*) 51-100 AED (USD 13.6-27.2*) 101-150 AED (USD 27.2-48.8*) >150 AED (> USD 48.8*)
-	Reasons for unwillingness to pay for future pharmacist-delivered screening service	Cannot afford it Does not think it is worth it Thinks it should be free Other

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531 **Figure 1: Pharmacy Screening Model in the UAE**



Screening flow chart

90x90mm (300 x 300 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1 and 3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5 and 6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	11 and 12
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	13
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	13
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	15
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	15
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	16-18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.

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Keywords:	Primary Health Care, Cardiovascular Diseases, Point-of-Care Testing, General diabetes < DIABETES & ENDOCRINOLOGY, Pharmacy, Screening

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Manuscripts

Title: Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.

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For peer review only

Abstract:

Objectives: To develop an evidence-based community pharmacist-delivered screening model for diabetes and cardiovascular disease (CVD), and assess its feasibility to identify and refer patients with elevated risk.

Design: A feasibility study.

Setting: A purposive sample of 12 community pharmacies in three cities in the United Arab Emirates (UAE).

Participants: Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.

Intervention: Pharmacist screening of adults visiting pharmacies involved history, demographics, anthropometric measurements, blood pressure, and point-of-care testing including HbA1c levels and lipid panel. Participants with a 10-year CVD risk $\geq 7.5\%$, HbA1c level $\geq 5.7\%$ or American Diabetes Association risk score ≥ 5 points, were advised to visit their physician.

Primary and secondary outcome measures: (1) Development of UAE pharmacist-delivered screening model, (2) the proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk defined as $\geq 7.5\%$), (3) the proportion of participants identified as having elevated blood glucose (high HbA1c level $\geq 5.7\%$ (38.8mmol/mol)) or high self-reported diabetes risk (ADA risk score ≥ 5 points). Secondary outcomes: participants' satisfaction with the screening.

Results: The first UAE pharmacist-delivered screening model was developed and implemented. A total of 115 participants were screened, and 92.3% of the entire screening process was completed during a single visit to pharmacy. The mean duration of the complete screening process was 27 minutes. At-risk individuals (57.4%) were referred to their physicians for further testing, 94.5% of participants were at least satisfied with their screening experience.

Conclusions: The community pharmacist-delivered screening of diabetes and CVD risk is feasible in the UAE. The model offers a platform to increase screening capacity within primary care and provides an opportunity for early detection and treatment. However, pathways for the integration of the pharmacist-delivered screening service with physicians in primary care are yet to be explored.

Keyword: Diabetes, Cardiovascular Diseases, Screening, Pharmacy, Point-of-Care Testing, Primary Health Care

Strengths and limitations of this study

- An expert panel was used to adapt an international screening and develop the first contextually-tailored pharmacy screening model for diabetes and cardiovascular diseases risk in UAE.
- Lipid panel and glycated hemoglobin level were measured using a finger-prick point-of-care testing device (Roche Cobas b 101 POC dual system).
- Follow-up with physicians on referral outcomes of participants at-risk could not be determined due to the fragmented healthcare system. We relied on patient self-report data.
- Patient recruitment heavily relied on a direct invitation from pharmacists
- Follow-up times with screened participants were short and may not have encompassed all results regarding follow-up with physicians.

96 Introduction

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37 Type 2 diabetes (T2DM) and cardiovascular disease (CVD) are leading contributors to the global burden of
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98 disease, albeit with distinct long-term trends.(1) Diabetes, a rapidly growing global epidemic, affects all
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99 countries, and is substantially caused by rapidly increasing rates of obesity over recent decades. (2) By 2040
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100 T2DM will affect an estimated 642m people; 10.4% of the adult population, compared with 8.8% in 2015.(2-4)
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101 Age-standardized CVD trends are more geographically nuanced – generally, the incidence has declined
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102 markedly in highly developed countries over several decades, but this decline has now plateaued.(5) Likewise,
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103 some middle-income regions have experienced declines in CVD mortality, but in most regions of the
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104 developing world, a rapid increased incidence has recently prevailed.(5) Globally in 2015, there were an
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22 estimated 422.7 million prevalent cases of CVD, and ischemic heart disease and stroke remained the leading
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26 causes of death.(6) A combination of an aging western society, and increasing CVD mortality rates in many
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109 32.2% of all persons with T2DM.(7)
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112 An estimated 45.8% (174.8 million) of adult diabetes cases worldwide are undiagnosed, ranging from 24.1% to
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119 behaviors, and intentional delay in accessing available medical services are commonplace in Arabic-speaking
120 communities, hence the need for proactive and opportunistic population screenings.(14-16)

121 The feasibility of pharmacist-delivered screening, for a variety of conditions including diabetes and CVD, is well
122 supported by evidence.(17, 18) Such screening interventions identified at-risk individuals and increased rates
123 of disease diagnosis, reduced disease risk factors, improved health behaviors, enhanced quality of care, and
124 increased patient knowledge and awareness.(19) Community pharmacists have face-to-face contact with
125 around 90% of the population annually and appear to interact regularly with those who have elevated risk of
126 diabetes and CVD, or undiagnosed diabetes.(20) The potential, therefore, exists for pharmacists to improve
127 access to health screening services and promote public health awareness.

128 In the UAE a substantial number of people with diabetes and a high prevalence of overweight and obesity are
129 currently thought to remain undiagnosed.(21) There are around 2,500 licensed community pharmacies in UAE
130 that are generally open seven days per week, easily accessible, and have an average working day of 13 hours
131 (22, 23); this potentially makes pharmacies an effective setting to offer screening for diabetes and CVD within
132 the primary care system. To our knowledge, no systematic diabetes and CVD screening programs exist in the
133 primary care setting in the UAE, meaning these diseases continue to be undiagnosed precluding the
134 opportunity to initiate early prevention and treatment.

135 The aim of this study was to test the feasibility of pharmacist-delivered diabetes and CVD risk screening model
136 in the UAE. The specific objectives were to:

- 137 1. Develop locally-appropriate pharmacist-delivered diabetes and CVD risk screening model for the
138 community pharmacies in UAE.
- 139 2. Evaluate the feasibility of implementing diabetes and CVD risk screening model in the selected
140 community pharmacies in the UAE.

142 **Methods**

143 **Ethical approvals**

144 This study was approved by the Research Ethics Committee of the University of Sharjah, the Ministry of Health
145 and Prevention in the UAE, and deemed Exempt by the Harvard T.H. Chan School of Public Health Institutional
146 Review Board.

147 **Study design**

148 The study was conducted in three phases: Phase 1 (formative phase) explored development of a suitable
149 model for diabetes screening and CVD risk assessment in community pharmacies in the UAE, Phase 2
150 (implementation phase) assessed the feasibility of the screening model, and Phase 3 (evaluation phase) tested
151 the impact of the screening model.

152 **Phase 1: Formative Phase**

153 A systematic approach was used to develop the intervention of diabetes and CVD screening.(24) The formative
154 phase commenced with identifying needs for diabetes and CVD risk screening program. After identifying the
155 suitability of community pharmacies for providing screening services, a literature review of pharmacist-
156 delivered screening models was conducted to identify useful and effective approaches to screening. The
157 Australian Cardiovascular Absolute Risk Screening Study (CARS) was considered an appropriate template
158 model to inform the development of the first UAE pharmacy-based screening program.(25) Two local health
159 professionals were consulted to determine the adaptation of CARS into the local context and acceptability of
160 the proposed protocol prior to presenting the model to an expert panel. In the absence of national guidelines
161 and frameworks regarding risk assessment and management for diabetes and CVD in the UAE, an expert panel
162 forum was tasked to develop a consensus on the proposed screening program. Prospective panelists were
163 identified through extensive online search; evaluating experts' specialty, experience, and research
164 involvement. Shortlisted experts, including two cardiologists, two endocrinologists, two senior clinical
165 pharmacists, were invited to participate in the forum. The Delphi technique was used to help arrive at a

166 consensus on a specific question in one or more rounds - supportive documents were created to aid in voting
167 and to calculate the level of agreement.(26) The Delphi discussion focused on locally-appropriate methods for
168 absolute cardiovascular and diabetes risk assessment, including: use of absolute CVD risk assessment and
169 other multi-factorial risk algorithm cut-offs; selection of screening tools; and risk factor thresholds for
170 physician referrals. The following questions were discussed during the forum:

- 171 1. When should the participant's blood pressure measurement be taken? Moreover, what is the
172 minimum time interval needed between taking the two blood pressure readings?
- 173 2. Which tool to use to calculate participants' absolute CVD risk?
- 174 3. Which method would be most suitable for calculating the participants' absolute CVD risk in the
175 community pharmacy setting?
- 176 4. Which self-reported tool to use to determine the participants' risk of having T2DM? What absolute
177 CVD risk threshold should be used when deciding to refer a participant to a physician?
- 178 5. At what HbA1c level should a participant be referred to a physician?
- 179 6. Should at-risk participants who are referred to physicians for further testing be contacted to ask about
180 any lifestyle modifications and outcomes of a visit to a physician? And should the physicians whom the
181 referred participants visited be contacted?

182 The screening model planning involved the development of resources in supporting pharmacists-delivered
183 screening including: training manual, data collection tools, and patient follow up documents. These were
184 developed through a process of co-production in consultation with the international co-researchers who had
185 previous experience in pharmacist-delivered screening services. To ensure local context applicability, study
186 materials were sent to three local community pharmacists for feedback and comments.

187 **Phase 2: Implementation Phase**

188 Community pharmacists were trained through a face-to-face workshop that lasted for three hours on the
189 study protocol, and on how to: (1) approach potential participants, (2) use point-of-care testing devices, (3)
190 handle refusals to participate, (4) collect data, (5) communicate risk assessment results to participants, (6)

engage and refer at-risk individuals to physicians, (7) counsel participants on required lifestyle changes, and (8) respond to participants' questions.

Study setting and participants

A purposive sample of 12 community pharmacies (with necessary infrastructure) in the three emirates of Dubai, Sharjah, and Ajman in the UAE was selected. The recruited sites represented chain pharmacies. Study pharmacists were offered a small monetary incentive (AED 23 (equivalent to USD 6)) per screening in appreciation of their time and effort.

Recruitment of participants

Pharmacy-based advertising, including posters and flyers, were used to recruit participants. Individuals were mainly invited directly by the pharmacists to participate based on their judgment of the individual's age. Interested voluntary participants were pre-screened by the pharmacists to determine their eligibility. Eligible participants were given written patient information sheet and they signed a consent form.

Inclusion criteria:

- Arabic or English speaking.
- Aged between 40 to 74 years. There is no international consensus on the age range for diabetes screening, however, 40 years is recommended in several guidelines and was therefore considered appropriate.

Exclusion criteria:

- Previous diagnosis of diabetes or CVD.
- Use of medications for treatment of diabetes, hypertension or any other CVD at the time of screening.
- Pregnancy.
- Terminal illness.
- Severe mental illness.

Data collection and risk factor assessment

To document the screening process, participating pharmacists completed brief paper-based records of each screening undertaken. This provided patient risk assessment data, documentation of patient counseling (e.g. lifestyle factors assessed, targets specified, and criteria for referral to a physician) and logistical information (e.g. time taken to conduct screening and counseling, number of visits required, reasons for deviating from suggested screening schedule).

After checking eligibility and obtaining consent, trained pharmacists screened participants with the following measurements:

- Anthropometric measurements: Weight, height and waist circumference were measured along with body mass index calculations.
- Point-of-care testing: Total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein (LDL) plasma levels, and glycated hemoglobin (HbA1c) level, were measured using a finger-prick point-of-care testing device (Roche Cobas b 101 POC dual system). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured after participants rested for 5 minutes using the Omron 1A1B® automated Blood Pressure (BP) monitor. Pharmacists advised participants to seek immediate medical attention if SBP was ≥ 180 mmHg, or DBP ≥ 110 mmHg. 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.
- CVD risk assessment: Projected 10-year atherosclerotic CVD risk was calculated for each participant. Diabetes risk assessment: In addition to HbA1c level, the American Diabetes Association (ADA) T2DM risk questionnaire was completed.
- Patient History: Detailed socio-demographic information, brief medical history, family history of diabetes, smoking status, physical activity, and dietary behaviors. Patients referral and follow-up: Participants at high risk, defined as having any of the following: (1) 10-year ASCVD risk $\geq 7.5\%$ (2)

HbA1c level ≥ 5.7 (3) ADA T2DM risk questionnaire ≥ 5 points, were advised to visit their physician. All participants identified, by pharmacists, as at high risk for either CVD or diabetes were given a referral letter summarizing pharmacy screening results to the physician for further testing. A rapid phone follow-up of all participants was conducted (within two weeks of screening) by a member of the research team to determine participants' satisfaction and experience with the pharmacy screening service. Participants were asked about perceived depth and clarity of pharmacist explanation of diabetes and CVD risk; their satisfaction with the risk assessment and the quality of testing and advice; instructions on the need for further evaluation by a physician; and the perceived length of the screening. They were also asked about their opinion on community pharmacies as a venue of the screening service, whether screening should be routinely provided by community pharmacists, and their willingness to pay for future pharmacist-delivered screening.

The follow-up also included questions about self-reported health status, frequency, and pattern of physician visits in the past year. Participants were asked if they had undergone an assessment of lifestyle that affects diabetes and/or CVD risk by any healthcare professional in the past year or whether they were advised of the need to reduce their diabetes or CVD risk. The research team members identified themselves as such to the participants and informed them that their responses would not be communicated to the pharmacists who performed the screening.

Outcomes

1. Development of UAE pharmacy-based screening model:

A consensus statement from the expert panel detailing the screening processes, cut off points/levels, and referral mechanisms to physicians, all suited to the community pharmacy context in UAE.

2. Feasibility assessment:

- a) The proportion of screened participants identified as having high CVD risk (ASCVD 10-year risk defined as $\geq 7.5\%$ - as determined by the expert panel, see section 3.1).

- 264
1 b) The proportion of participants identified as having elevated blood glucose (high A1c level >6.5%
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3 (48mmol/mol)) or high self-reported diabetes risk (T2DM risk questionnaire score \geq 5 points - as
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5 determined by the expert panel, see section 3.1).
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8 c) Participants' acceptability and satisfaction with the pharmacist-delivered screening.
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268 **Patient and Public Involvement:** We did not involve patients or the public in our work
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269 **Data analysis**

270 The data was entered into Microsoft Access and 10% of participant files were randomly selected for validation.
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19 Stata, release 14 (StataCorp, College Station, TX) was used for data analysis.(27) Normally distributed
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21 continuous variables were described using means and standard deviations (such as participants' age, visits to
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23 physicians and nutritional habits). Categorical variables were described using counts and frequencies (such as
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25 demographic data, BMI (grouped) and medical history). The Chi-squared test was used to test differences in
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27 risk factors by age and gender. A p-value of <0.05 was considered statistically significant.
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276 **Results**

277 **Consensus statement on screening intervention**

278 The expert panel reached a consensus on the use of absolute risk assessment and other multi-factorial risk
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40 algorithm cut-offs, screening tools, and risk factor thresholds. Panel members unanimously agreed on: taking
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42 two seated measurements of BP after a five-minute rest and separated by two minutes. If the two systolic and
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44 diastolic BP readings differed by \geq 10 mmHg or \geq 6 mmHg respectively, a third measurement would be needed,
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46 and the two closest readings would be used to calculate mean BP. Regarding the calculation of 10-year
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48 atherosclerotic CVD risk score, the ACC/AHA pooled cohort equations CVD risk calculator should be used.
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51 Participants having a 10-year risk \geq 7.5% were classified as high risk and had to be referred to a physician for
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53 further testing. The official ASCVD Risk Estimator Plus smartphone application with off-line feature was
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55 deemed most feasible to perform the calculation. Other criteria that independently necessitated referral to a
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287 physician were an HbA1c level exceeding 5.7% (pre-diabetes) or a score above five points on the ADA
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questionnaire to measure the risk of T2DM.

Regarding the determination of uptake of referral and physician action on the results of the screening, the panelists identified the impracticality of contacting physician's offices; instead it was agreed that uptake of referral and physician action would be best reported by participants themselves during follow-up calls. Clinical training manual and implementation resources were developed to ensure systematic approaches for the execution of pharmacist-delivered screening and to minimize variability amongst participating pharmacists. Data collection tools and consent forms were adapted from the CARS project. Figure 1 illustrates the final screening model.

Socio-demographic and health characteristics

From December 15, 2017 to May 8, 2018, 120 consenting participants were screened for CVD and T2DM from the population visiting the 12 participating community pharmacies (which had sufficient/appropriate space to accommodate the screening service, and had high volume and variability in clientele). Five participants were excluded for not meeting study criteria. Socio-demographic and health characteristics of the 115 screened participants are summarized in Table 1. Gender representation was almost equal with most participants having been born in Syria and Egypt. When participants were asked about their present state of health, 32% reported being 'excellent'. On average, participants visited a physician three times a year. 24% of participants reported having regular physicians, while 18.6% had regular clinic but visited different physicians, and 38.6% visited different clinics. In the past 12 months, only 6.4% reported undertaking a detailed examination of lifestyle factors by a health professional.

Implementation fidelity

Of the screened participants, 57.4% were identified as high-risk for diabetes and/or CVD. After each screening encounter, pharmacists completed a checklist that documented the screening process (Table 2). Most participants (91.7%) were screened immediately following their recruitment and the signing of informed

311 consent, and the remainder were given appointments for a later time. In the majority of cases (92.3%), the
312 entire screening process was completed during a single visit to the pharmacy.

313 A total of 12 participants did not undergo a complete assessment as per the screening protocol. A full lipid
314 profile was not obtained in four cases, and four other participants did not obtain an HbA1c measurement.
315 Furthermore, pharmacists did not perform a waist circumference measurement for three participants and
316 blood pressure measurement for one participant. Pharmacists documented the reasons for incomplete
317 assessments for these 10 participants: a technical error in the POC device prevented the measurement in nine
318 cases, and the participant objected to the measurement in one case. Assessments of diabetes risk as per the
319 ADA questionnaire, dietary habits, and physical activity habits were completed for all participants. On average,
320 assessment and testing took 27 ± 9.4 minutes.

321 In all cases where pharmacists documented post-assessment counseling, pharmacists explained the meaning
322 of participants' ASCVD and ADA questionnaire risk scores and the targets for suboptimal blood test results.
323 HbA1c test results were explained to 96.3% of participants. Regarding lifestyle behaviors, the pharmacists
324 documented counseling 85.8% and 81.1% of participants about healthy diet and physical activity, respectively.
325 Finally, pharmacists reported informing 87.9% of participants of the need for confirmatory testing at the
326 physician's office. Pharmacists reported that post-assessment counseling lasted 11.6 ± 6.5 minutes on average.

327 **Uptake of referral**

328 A total of 71 (61.7%) at-risk individuals were referred to their physicians for further testing; 37 participants
329 (52.1%) completed the second follow-up survey to determine uptake of referral (Table 3). Only nine of these
330 participants (24.3%) had visited their physician following the screening, 29.7% had not visited their physician
331 yet but intended to do so. Conversely, 43.2% did not visit their physician and made no such plans (Table 3).
332 Five participants told their physicians about the pharmacy screening results; 4 of the 5 cases reported that
333 physicians took the results seriously. Physicians ordered follow-up tests for 77.7% of the participants, including
334 total cholesterol and blood sugar levels (57.1% each), HDL levels and BP (42.8% each).

When asked about lifestyle changes that participants adopted following the screening, 63.1% reported improved diet, 57.8% attempted to lose weight, and 40% started new medications since the screening (Table 3).

Participants' experiences, feedback, and satisfaction with the screening service

All participants were contacted by telephone to determine their experiences and satisfaction with the pharmacy screening service (Table 4). A total of 75 participants completed the follow-up survey (65.2%). In 68% of the cases, the pharmacist-initiated the conversation about the screening service. Other participants reported learning about the service from personal acquaintances (17.3%), and social media (10.7%).

Almost all participants reported that the pharmacists' explanation of their risk of developing diabetes or CVD were either 'very clear' or 'clear enough' and that pharmacists explained the various lifestyle causes of increased CVD or diabetes risk 'very comprehensively' or 'discussed several issues'.

At the conclusion of the screening, 94.5% of participants reported that pharmacists made sure participants understood all key points, and 89.3% indicated that pharmacists provided participants with a written screening report.

Most participants (94.5%) reported either being "satisfied" or "very satisfied" with the risk assessment undertaken by the pharmacists and the quality of the pharmacists' advice.

Eighty-six percent of participants thought pharmacies are good venues for conducting screening tests, and 86.6% thought pharmacists should routinely provide CVD and diabetes risk screening. Most participants (82.7%) indicated they would be willing to pay for pharmacist-delivered screening services should it be provided in the future (Table 3).

Discussion

This study is the first in an Arabic-speaking country (UAE) to assess the feasibility and performance of an evidence-based pharmacist-delivered screening program for T2DM and CVD. The screening model, adapted

358 from the CARS model with the advice of local experts, was successfully implemented in community
1 pharmacies and resulted in the identification and referral of at-risk individuals.(25)
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360 The proportion of screened participants identified with high diabetes or CVD risk in this study was higher
6 compared to reported rates in the international pharmacy screening literature. This could be partially
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361 explained by the higher prevalence of diabetes and CVD in the UAE.(21, 28) The high referral rate (61.7%) in
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362 this study is consistent with the recent trend towards higher rates of referral.(18) Without systematic
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363 diabetes and CVD screening programs in the primary care setting in the UAE, lack of universal healthcare
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364 coverage, all in tandem with poor health-seeking behavior and the delay in access to medical services these
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365 conditions are likely to continue to be undiagnosed. The potential, therefore, exists for community
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366 pharmacists who have regular contact with the population to improve access to health screening services and
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367 promote public health awareness.
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369 Several pharmacy and pharmacist-levels factors at selected pharmacies contributed to the success of
28 implementing pharmacist-delivered screening, these include: (i) the necessary infrastructure (such as
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370 sufficient/appropriate space) to accommodate the screening service, (ii) motivation of the pharmacist to learn
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371 about and perform the screening, (iii) the high volume and variability in clientele.
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373 The purposive sampling of community pharmacies and the exploratory study design might have limited the
38 generalizability of study results. However, equally, it could be argued that the somewhat driven community
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374 pharmacists in this study would have been representative of the expected pharmacists in future program roll-
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375 out. The study was designed to demonstrate the feasibility of pharmacist-delivered screening and to
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376 understand how implementation support and processes might have been optimized to enable such a health
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377 service. Follow-up with physicians on pharmacist-delivered screening was not carried out as per the expert
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378 panel advice; due to: the complexity of access to physician services and different health coverage/schemes, lack
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379 of integration and communication between services provided at the government and private institutions, the
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380 current lack of integration of pharmacy services with other health care services, and the scattered primary
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381 care structure in the country. Such lack of follow-up with physicians is not uncommon in studies exploring
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early stages of pharmacy-based screening given the complexity of the primary care setting. 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. Better uptake of screening may have been achieved with training of other staff in 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 advised. 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 had they not done so. It may also have been helpful to send a copy of the referral directly to the referred individual's nominated physician. It could also have been that participants still questioned the validity of the risk screening process carried out in community pharmacies, and that they could have taken its results more seriously had it 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 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.(29-31) 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. 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 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

408 intervention reported in patient surveys. In these focus groups, there were a number of comments suggesting
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3 greater confidence and trust in Arabic pharmacists and pharmacy systems than their Australian counterparts.
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6 What this process missed was consumer guidance regarding their specific support needs in the context of this
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8 model being operated in within the UAE health system. We have relied on health professionals and experts for
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10 guidance on this because of the complexity of the health system, absence of primary care, and the novelty of
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12 the intervention, which required a significant level of insight and extensive engagement to determine a model
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14 that might work. We fully acknowledge that we need to engage UAE consumers further before scaling up this
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16 intervention.
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20 Participant selection was heavily based on pharmacist perception of their age. Until screening becomes known
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22 and accepted as a community pharmacy service in UAE, the most likely pathway to uptake of screening in
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24 community pharmacy in the UAE is by direct invitation from a pharmacist. It is also likely to yield more
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26 individuals at high risk and in need of further testing and diagnosis. This has also been the case in other
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28 screening trials (Krass et al 2007, CARS trial). Once such service becomes established it is likely that consumers
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30 may request it themselves in response to advertising, posters in the pharmacy etc. The six-dollar per
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32 participant was an incentive for the pharmacists to engage in the study, and it was not based on a calculation
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34 of what an actual service would cost. Future studies should aim to establish effectiveness of the pharmacist-
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36 delivered screening model for diabetes and CVD in the UAE, and generate evidence of its cost-effectiveness.
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38 Then pharmacists' remuneration would eventually need to be negotiated with government and private
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40 insurance. At this point, this was not within the scope of this study.
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47 The research team, at the planning phase, aimed to document the proportion of patients approached, the
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49 proportion of those who consented to be screened and the reason(s) for individual refusal to be screened.
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51 However, pharmacists reported that this would be an added work and preferred not to collect such data. The
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53 short follow-up period with patients was perhaps inadequate to capture all further diagnostic and
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55 management activities as a result of pharmacist-delivered screening. This feasibility study was continued on a
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57 larger scale to evaluate the efficacy of pharmacist-delivered screening in identifying participants with high
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diabetes and/or CVD risk in the UAE. Additional future studies should evaluate strategies to establish closer links between community pharmacy and physicians in primary care, creating structured referral pathways and emphasis on interprofessional coordination between pharmacists and physicians.

Conclusions

It is feasible for community pharmacists to screen and refer individuals for diabetes and CVD risks in the UAE. The successful implementation of the screening model in community pharmacy, in terms of identifying at-risk individuals and advising them to visit their physicians for further evaluation, offers a new platform to increase screening capacity within the primary care setting, and represents a key opportunity for the early detection and intervention to tackle the increasing burden of both diseases. However, pathways for the integration of the pharmacist-delivered screening service with physicians in primary care are yet to be explored.

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Author contribution: HA designed the study, supervised data collection process, assisted with data analysis, wrote, reviewed and edited the entire manuscript. SC and RC analyzed data, reviewed and edited manuscript. SH wrote parts of manuscript. KM and IK assisted with designing of the study, reviewed the methods and data analysis contributed to the discussion, and reviewed all drafts.

Competing interests: None declared.

Data sharing statement: All feasibility-related data were reported, additional participants' lifestyle data are available upon reasonable request.

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Table 1: Demographic and health characteristics (N=115)

Characteristic	n (%)
Gender	Female 60 (52.1)
Age(yrs)	Mean \pm SD 47.23 \pm 7.3
Nationality	Syria 32 (27.8)
	Egypt 23 (20.0)
	India 11 (9.5)
	Jordan 7 (6.0)
	Pakistan 7 (6.0)
	Other 35 (30.4)
Education	Not educated 2 (1.7)
	Primary/middle school 15 (13.0)
	High school 37 (36.2)
	University 50 (43.4)
Marital status	Married 103 (89.5)
	Single 8 (6.9)
	Divorced 3 (2.6)
	Widowed 1 (0.8)
Employment	Full-time 67 (63.2)
	Part-time 6 (5.6)
	Home duties 25 (23.5)
	Other 17 (14.7)
Self-reported health status*	Excellent 24 (32.0)
	Good 41 (54.6)
	Average 10 (13.3)
Number of visits to a physician in the past year*	Mean \pm SD 3.05 \pm 4.1
Patterns of physician use	Have a regular physician 18 (24.0)
	Have a regular clinic but often see different physicians 14 (18.6)
	Visit different physician clinics 29 (38.6)
	Rarely or never visit a physician 14 (18.6)
Source of advice to reduce risk of diabetes and CVD risk in the past 12 months (apart from pharmacy screening visit)*	13 (17.5)
	A physician
	A dietitian 1 (1.3)
	A specialist physician 5 (6.7)
	A pharmacist 2 (2.7)
	Others practitioners 9 (12.1)
	A family member 7 (9.4)
Examination of lifestyle factors that affect diabetes and CVD risk by a health professional during the past 12 months*	7 (6.4)

*Number of participants is 75 (first follow-up phone call)

Table 2: Pharmacist-documented components of screening model completed (N=112)

Component of screening model	
Timing of screening	Immediately following recruitment By appointment on same day By appointment on another day
Number of visits needed to complete screening	One visit Two visits
Assessments and measurements completed	Anthropometric measurements Diabetes risk assessment ASCVD risk score calculation Dietary habits assessment Physical activity habits assessment
Tests and measurements not completed	Lipid profile HbA1c Waist circumference Blood pressure
Reason for not completing test/measurement	Technical error in device Participant objection*
Assessment, testing, and measurement duration	Mean duration \pm SD (minutes) 10 – 20 minutes 21 – 30 minutes 31 – 40 minutes Over 40 minutes
Post-assessment counseling	ASCVD risk score interpretation ADA questionnaire score interpretation HbA1c result interpretation** Guideline targets for suboptimal blood test results Lifestyle behaviors (top two covered aspects) - Dietary behaviors - Physical activity Need for further/confirmatory testing at physician's office
Post-assessment counseling duration	Mean duration \pm SD (minutes) 1 – 10 minutes 11 – 20 minutes 21- 30 minutes Not reported

* One participant objected to waist circumference measurement. ** Documentation was missing for 30 participants.

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546 **Table 3: Outcomes of at-risk participants' referral (n=37)**

		n
Participants completed uptake of referral follow-up		
Participants visited a doctor to discuss pharmacist-delivered screening results		
	Visited doctor straight away	
	Made some changes and went to doctor later	
	Discussed results at routine visit	
Participants who did not visit a doctor		
	Haven't visited doctor yet but intend to	
	Didn't think it was necessary	
	Haven't visited doctor yet and made no plans	
Physician knew about pharmacy screening		
	Referral letter given to the doctor	
	Told doctor about pharmacy screening	
	Doctor treated the results of pharmacy screening seriously	
Follow-up tests were undertaken by the physician		
	Blood pressure	
	Total cholesterol	
	HDL cholesterol	
	Blood sugar level	
	Waist	
	Weight	
	Other	
Lifestyle changes since screening		
	Increased regular exercise	
	Attempted to lose weight	
	Improved diet	
	Started new medications	

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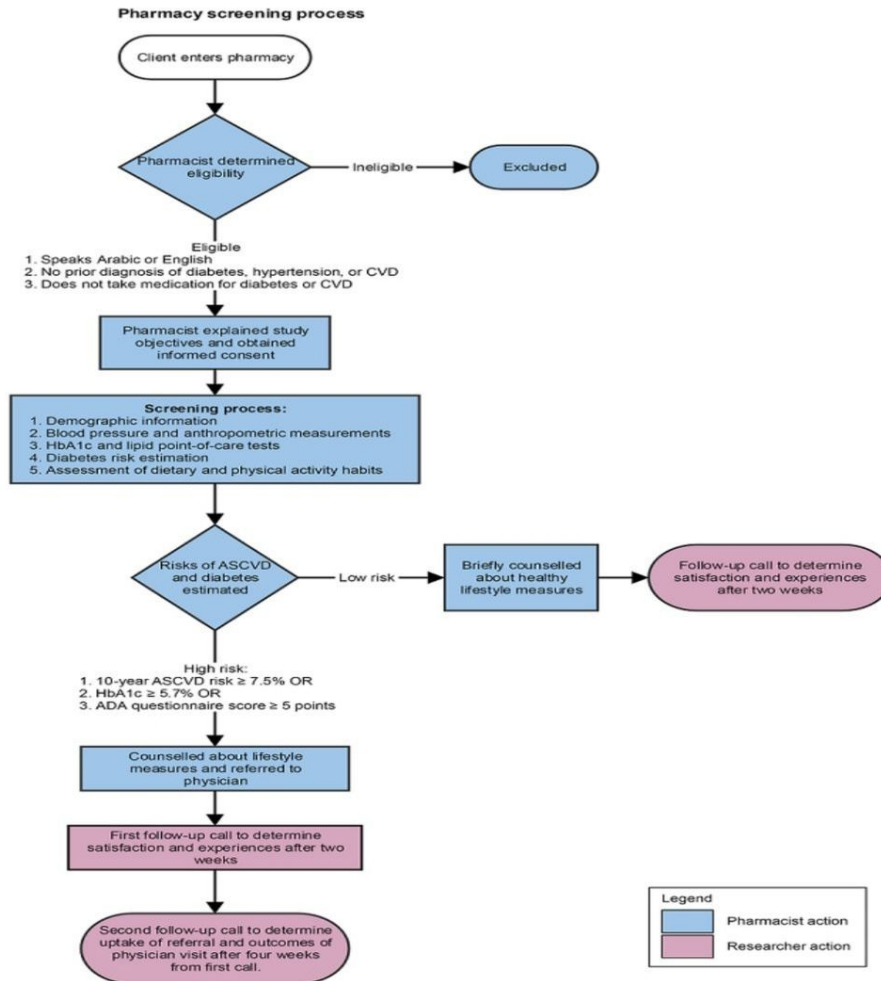
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560 **Table 4: Participants' experiences, feedback, and satisfaction with screening (n=75)**

Experience and feedback on pharmacist-delivered screening		
-	Person who initiated the conversation about screening between participant and pharmacist	Another participant in the project Pharmacist Pharmacy staff Acquaintance Social media
-	Clarity of pharmacist's explanation of risk of developing diabetes and CVD	Very clear Clear enough Some parts clear Generally unclear
-	Depth of pharmacist's exploration of possible lifestyle causes of increased diabetes and CVD risks	Very comprehensive Discussed several issues Discussed only one issue
-	Steps undertaken following screening	The pharmacist provided you with a written report of your results The pharmacist made sure that you understood everything The pharmacist clearly stated when the physician follow up was required
-	Quality of the testing carried out in pharmacy	Excellent Above average Average Slightly below average
-	Perceived length of the diabetes and CVD risk screening process	Much too long A little long About right A little short
Satisfaction with the pharmacist-delivered screening		
-	Satisfaction with health risk assessment	Very satisfied Satisfied Average Dissatisfied
-	Satisfaction with the quality of advice provided in the pharmacy	Very satisfied Satisfied Average Dissatisfied
Willingness to pay for the future pharmacist-delivered screening service		
-	Yes	
-	Acceptable amount to be paid	≤50 AED (≤ USD 13.6*) 51-100 AED (USD 13.6-27.2*) 101-150 AED (USD 27.2-48.8*) >150 AED (> USD 48.8*)
-	Reasons for unwillingness to pay for future pharmacist-delivered screening service	Cannot afford it Does not think it is worth it Thinks it should be free Other

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562 **Figure 1: Pharmacy Screening Model in the UAE**



Screening flow chart

90x90mm (300 x 300 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1 and 3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5 and 6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	11 and 12
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	13
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	13
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	15
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	15
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	16-18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.