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Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study in primary care

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Manuscripts

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3 **Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study**
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5 **in primary care**
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Abstract

Objective Accurate cardiovascular risk estimations by patients and doctors are important as these affect health behaviour and medical decision-making. We aimed to determine if doctors and patients were accurately estimating the absolute cardiovascular risk of patients in primary care.

Methods A cross-sectional study was carried out in primary care clinics in Malaysia in 2014. Patients aged 35 years and above without known cardiovascular diseases were included. Face-to-face interviews with a structured questionnaire were used to collect socio-demographic and clinical data as well as patients' perception and doctors' estimate of the patients' CVD risk. Associations were tested using chi-square, correlation and independent T tests.

Results We recruited 1094 patients and 57 doctors. Using the FRS score alone, 508 patients (46.4%) were in the high-risk group. When diabetes was included as high-risk, the number increased to 776 (70.9%). Only 34.4% of patients and 55.7% of doctors correctly estimated the patient's CVD risk.

Of the high-risk patients, 664 (85.6%) underestimated their CV risk. Factors associated with underestimation by patients included not having family history of CVD [AOR: 2.705, CI:(1.538, 4.757)], higher waist circumference [AOR:0.980;(0.960, 0.999)] and ethnicity. Doctors underestimated risk in 59.8% of the high-risk group. Factors associated with underestimation by doctors were patients factors such as being female, [AOR:0.403;CI:0.302,0.711], younger age [AOR:1.099;CI:1.072,1.127, non-hypertensive [AOR:0.576;CI:0.354, 0.936], non-diabetic [AOR:0.491;CI: 0.282, 0.854], higher HDL levels [AOR:0.281;CI:0.160,0.494, lower LDL level [AOR:1.387;CI:1.009, 1.907, lower systolic BP [AOR:1.032;CI:1.019, 1.045, non-smoker [AOR:0.469;CI:0.282, 0.780] and ethnicity.

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3 **Conclusions** Consultations are being informed by inaccurate cardiovascular risk estimation
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5 mainly due to underestimation of patients' CVD risks.
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8 9 **Article summary**

10 **Strengths and limitations of this study**

- 11 • This was a large prospective study that took place in 9 different clinics and covered
12 over a thousand patient consultations.
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- 14 • It captured the perceptions and practice occurring in actual consultations in primary
15 care settings where medical decisions were being made.
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- 17 • Participants' behaviour may have been affected due to awareness of the research
18 being undertaken
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28 **Background**

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30 Despite international efforts, cardiovascular disease (CVD) remains the leading cause of
31 death worldwide, killing more than 17 million people a year.¹ Affordable, feasible and
32 effective global actions capable of averting millions of deaths from non-communicable
33 diseases have been identified to tackle this continuing crisis.² Yet, the rate of non-
34 communicable diseases, of which CVD is a major contributor, is increasing and this increase
35 is disproportionately greater in developing countries.³ Out of five interventions identified as
36 priority actions for the non-communicable disease crisis,² only one addressed individual
37 clinical services that is, access of essential drugs and technologies. This was deemed essential
38 especially for those identified to be at high risk of CVD.
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54 People at high risk of CVD can be identified using tools such as cardiovascular risk scores.
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56 These were designed to calculate an individual's risk of developing a cardiovascular (CV)
57 event from risk factors obtained from history, physical examination or investigations. Most
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3 guidelines recommend the use of risk scores to predict global risk rather than focusing on
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5 single risk modification. The majority advocates the use of Framingham risk scores or scores
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7 that have been calibrated from the Framingham study data.⁴⁻⁶ A systematic review identified
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9 21 risk scores for use in adults with no history of previous cardiovascular disease.⁷ However,
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11 the use of the risk score is surprisingly limited. Studies have reported rates of use ranging
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13 from 17-65%.⁸⁻¹⁰ Patients have also been found to be inaccurate in estimating their own CV
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15 risk.⁸ About 40% of the general population underestimates their CV risk and 20%
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17 overestimated it.¹¹⁻¹³ In studies on those at established high CV risk, only about 40% were
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19 aware of their increased risk.¹⁴ Higher CV risk perception has been shown to be associated
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21 with better acceptance towards medical management regardless of whether the perception
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23 accurately reflected actual CV risk or not.¹⁵
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30 Accurate estimations of CV risk by both patients and doctors are important as these affect
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32 health behaviour and medical decision-making. The proliferations of mobile health
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34 technology including online risk calculators and guidelines have shown potential in
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36 increasing awareness and use of CV risk scores in clinical consultations.¹⁶ But has this led to
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38 a corresponding improvement in the use of CV risk scores in practice? Our study aimed to
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40 determine if doctors and patients were able to accurately estimate the absolute cardiovascular
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42 risk of patients in a primary care health setting.
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Methodology

This was a cross sectional study carried out in nine public primary care clinics in Malaysia in 2014 with the period of recruitment from the 1st to the 30th November 2014. The nine clinics were chosen conveniently from five regions of Malaysia: two clinics each from the northern (Ipoh), southern (Melaka) and western regions (Klang Valley), and one clinic from the eastern region (Kelantan) of Peninsular Malaysia and two clinics from East Malaysia (Sabah). All patients attending these clinics aged 35 years and above with cardiovascular (CV) risks assessments done within the past year were included. Patients with known cardiovascular diseases (CVD) were excluded.

Based on a study, which found that 40-52% of patients correctly estimated their CV risk, we used 50% to calculate the sample size, giving a total of 384 participants.¹² After stratifying by regions, and taking into account a 30% non-responder rate, a sample size of 998 was needed. About 200 patients were recruited from each region.

A face to face interview was conducted using a structured questionnaire to collect patients' data on socio-demography, CV risk factors including age, gender, family history of CVD, and perception of their own CV risk. The doctors then filled in patients' data on smoking status in the last one month, history of diabetes and hypertension, lipid profile within the last one year, statin and antiplatelet use, and estimated patients' CVD risk as per usual practice. Measurements were also taken for weight, height, waist circumference, and blood pressure using a validated digital blood pressure machine (OMRON HEM-7121). Doctors were also asked to fill up a questionnaire on their socio-demography, years of practice, and the methods they used to estimate patients' CV risks, if any.

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3 We used the D'Agostino 2008 Framingham General CVD Score (FRS) as the reference CVD
4 risk.¹⁷ This has been validated for use in Malaysia. (18) The 10-year CVD risk is classified
5 into low (<10%), moderate (10-20%) and high (>20%) risk. In this study, high CVD risk
6 group was defined as FRS >20% and/or presence of diabetes mellitus (DM).
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11 12 13 14 **Analysis**

15 Data were entered and analysed using Statistical Program for Social Sciences (SPSS) version
16 22.0 (SPSS Inc., 20). Complete-case analysis was used meaning those with missing values
17 were excluded. Frequencies were reported using percentages and proportions. Associations
18 between categorical data were tested using chi-square tests while continuous data were tested
19 using independent T test and correlation test. Kappa value were calculated to determine the
20 agreement between CV risks estimated by patient and actual risk, and CV risks estimated by
21 doctors and actual risk..
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34 **Ethical approval**

35 This study was registered in the National Medical Research Registry, Malaysia. (NMRR-13-
36 962-17898) and approved by the Malaysian Research Ethics Committee.
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43 **Results**

44 Out of the 1107 patients approached, 7 refused to participate and 6 did not fulfil the inclusion
45 criteria, giving a total of 1094 patients recruited. The mean age was 57.2 years (SD 9.8) with
46 a range of 35 to 86 years. There were 62.6% females, 60.8% had diabetes and 76.9% had
47 hypertension (Table 1). A total of 57 doctors participated in the study. The mean age of the
48 doctors was 32.3 years (SD 5.5) with a mean duration of work experience of 6.5 years (SD
49 3.8). Women comprise 63.4% of the doctors.
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Using the FRS score alone, 508 patients (46.4%) were in the high risk group. When diabetes was included, the number increased to 776 (70.9%). Of all the consultations, only 34.4% of patients and 55.7% of doctors correctly estimated the patient's CVD risk group.

Patients' estimation

Table 2 shows patients' estimation of their CV risks. Among patients in high CV risk group, only 112 (14.4%) correctly estimated their risks. The remaining 664 (85.6%) underestimated their CV risk. The correlation between patients' perceived CV risk and their actual risk was Kappa = -0.016. Factors associated with underestimation of high CV risk by patients included not having family history of CVD [AOR: 2.705, CI:(1.538, 4.757)], higher waist circumference [AOR:0.980;(0.960, 0.999)] and ethnicity [Malay; AOR: 7.729, (CI:4.252,14.050). Chinese; AOR: 10.320, CI: (4.612, 23.093). Indian; AOR: 9.676, CI:(4.272, 21.917)]. (Table 3)

Doctors' estimation

Table 4 shows doctors' estimation of patients' CV risks. Among patients in high CV risk group, doctors correctly estimated 40.2% and underestimated 59.8%. The correlation between doctors' estimation of patient's CV risk versus patient's actual CV risk was Kappa = -0.084. Factors associated with underestimation of high CV risk by doctors were patients factors such as being female, [AOR:0.403;CI:0.302,0.711], younger age [AOR:1.099;CI:1.072,1.127, non-hypertensive [AOR:0.576;CI:0.354, 0.936], non-diabetic [AOR:0.491;CI: 0.282, 0.854], higher HDL levels [AOR:0.281;CI:0.160,0.494, lower LDL level [AOR:1.387;CI:1.009, 1.907, lower systolic BP [AOR:1.032;CI:1.019, 1.045, non-smoker [AOR:0.469;CI:0.282,

0.780] and ethnicity [Malay; AOR:2.562, CI:1.373,4.780, Chinese; AOR: 2.851, CI:1.397, 5.818, Indian; AOR: 6.048, CI: 2.824, 12.954]. (Table 5)

Table 6 summarises the methods used by doctors to estimate patients' CV risk. About half used online risk calculators while a quarter each used risk factor counting or manual calculation. Risk scores used included Framingham, QRISK and ACC-AHA risk scores.

Discussion

Our findings indicate that both patients and doctors were underestimating the patient's cardiovascular risk. Of those at high CV risk, only 1 in 7 patients could identify themselves as being at high risk. More worryingly, only 2 out of 5 doctors seeing these high CV risk patients could correctly identify them. This implies that medical decision-making during these consultations were poorly informed due to inaccurate CV risk estimation.

How can this occur with the easy availability of online risk calculators and guidelines recommending use of risk estimation? It is likely that risk estimation for CVD is still poorly understood. Many CVD risk scores recommended using baseline levels of risk factors for risk calculation prior to the initiation of medication. For some risk scores such as the ATP-III risk calculator and the Pooled Cohort Risk score, diabetes is automatically taken as high CV risk without the need for calculation. However, new risk calculators such as QRISK and D'Agostino now consider the effect of treatment and incorporate variables such as present use of antihypertensive or antihyperlipidemia agents into the calculation.^{17, 19} Differences in the methods used by different risk scores and over time have led to misunderstandings, confusion and uncertainty by users.

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3 A study that explored general practitioners' use of cardiovascular risk scores found that
4 doctors had great uncertainty over the use of CVD scores in treated patients.²⁰ Use of
5 patient's risk factor levels when patient is on treatment would lead to an under-estimation of
6 the true CVD risk. Prolonged exposure to previous high levels and the presence of
7 established chronic changes would mean that maximal reduction may take longer than 5
8 years and may never reach the level of a treatment naïve patient. However, doctors find it
9 difficult to obtain pre-treatment levels and over-estimation would occur if the patient's risk
10 factor had been controlled over a long period of time.
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22 Shared medical decision-making through proper risk communication ensures patients and
23 doctors are able to weigh the risk and benefits of treatment options. The underestimation of
24 risk as seen in this study population is likely to have significant impact on their management.
25 Overoptimism has also been noted in other studies which described the tendency for people
26 to be unrealistically optimistic about future life events.²¹ His research showed that subjects
27 tended to be optimistic of their chances for negative events when the event is perceived to be
28 controllable. This appears to mirror our finding where patients and doctors perceived the risk
29 for CVD as being low because of the availability of treatment and behavioural lifestyle
30 modification steps that can be taken. The mainstay of treatment of risk factors is to prevent
31 progression of disease. Yet, patients and doctors must understand that residual risk remains
32 and that treatment should be continued for most despite normalisation of risk factor levels.
33 This understanding is potentially jeopardised by optimism bias as adherence to medication
34 and preventive behaviour have been shown to be associated with higher risk perception.²²⁻²⁴
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54 The findings also suggest that patients and doctors estimated risk by risk factor profile or risk
55 factor counting as opposed to absolute risk calculation. It appears that there is good
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3 awareness of some of the risk factors for cardiovascular disease as risk perception was found
4 to be associated with these factors. However, focusing on individual risk factors or risk factor
5 counting tends to underestimate risk in those who may have slightly elevated levels of
6 multiple risk factors that synergistically increased the overall absolute CV risk.²⁵ This is why
7 most cardiovascular disease guidelines advocate the use of risk calculators to estimate
8 individual risk.^{5, 6, 26, 27}
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19 **Strengths and limitations of the study**

20 This is a prospective study that examined the risk perceptions of individual patients by both
21 the patients and the doctors seeing these patients. The study design allowed us to capture the
22 perceptions and practice occurring in actual consultations in primary care settings where
23 decisions on institution of management for cardiovascular disease prevention and treatment
24 are made. This study took place in 9 different clinics and covered over a thousand patient
25 consultations.
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36 It is possible that the doctors involved in this study may have been prompted to assess
37 patients CV risk due to awareness of the research being undertaken as informed consent was
38 obtained from all participants. However, we believe that this would only have prompted them
39 to look up cardiovascular assessment. If knowledge of this study had introduced bias to the
40 results, it would likely that the direction of the bias would be towards more accurate
41 estimation of risk. Hence the rate of inaccurate risk estimation may actually be greater than
42 was found.
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53 **Recommendations**

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3 In view of these findings, future studies should look at developing interventional strategies to
4 implement formal CVD risk calculation into consultation and testing the strategies in actual
5 consultations. Examples are system processes that incorporate risk calculators into electronic
6 medical records or simple displays of risk charts on clinic desks.²⁵ Accurate risk estimations
7 should then be conveyed to patients to allow them to be fully informed when making
8 decisions regarding their management in clinical practice.
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19 **Conclusion**

20 The majority of consultations occurring between doctors and patients are being informed by
21 inaccurate cardiovascular risk estimation. Inaccuracy is mainly due to underestimation of
22 patients' CVD risks. Interventions are required to improve CVD risk estimation in order to
23 inform shared decision-making in primary care consultations.
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48 **Contributorship statement**

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51 NZ- Nurfarhana Zaidi, HY- Harny Yussof
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3 The study was conceived by SML, WKL, EMK, IZ and HY. SML, WKL, EMK, IZ, SA, MO,
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5 SZ, JS and HY contributed to the planning and data analysis of the study. WKL, IZ, SA, MO,
6
7 SZ, and JS assisted with data collection. NZ assisted with data analysis of the study. SML
8
9 drafted the manuscript and the final version was revised and approved by SML, WKL, EMK,
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11 IZ, SA, MO, SZ, JS, NZ and HY.
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Table 1: Socio-demography and profile of the respondents

Demographic data and profile		Frequency (%)
Mean Age ± SD (years)		57.23 ± 9.81
Mean income ± SD (RM)		1824.34 ± 2112.09
Mean body mass index ± SD (kg/m²)		28.02 ± 13.17
Gender	Female	685 (62.6)
Ethnicity	Malay	559 (51.1)
	Chinese	234 (21.4)
	Indian	161 (14.7)
	Bumiputera	112 (10.2)
	Other	28 (2.6)
Smoker		185 (16.9)
Diabetes		665 (60.8)
Hypertension		840 (76.8)
Family history of Stroke		165 (15.1)
Family history of Cardiovascular Disease		158 (14.4)

Table 2: Accurate estimation of high CV risk by patient, n= 1094

Actual CV risk		
Patient's estimation	High (%)	Low/ moderate
High	112 (14.4)	54 (17.0)
Low/ Moderate	664 (85.6)	264(83.0)

Table 3: Characteristics of patients who has high CVD risk but self-perceived as low and moderate risk

	Significance value	Adjusted odds ratio	95% Confidence Interval	
			Lower	Upper
Age	0.550	1.009	0.981	1.037
Income	0.280	1.000	1.000	1.000
Systolic BP	0.482	1.006	0.989	1.023
Diastolic BP	0.194	0.982	0.955	1.009
Waist Circumference	0.043	0.980	0.960	0.999
Body Mass Index	0.230	0.981	0.952	1.012
Total Cholesterol	0.211	0.770	0.512	1.160
LDL Cholesterol	0.154	1.364	0.890	2.090
HDL Cholesterol	0.252	1.484	0.755	2.917
Ethnicity				
Bumiputera/Others	-			
Malay	0.000	7.729	4.252	14.050

Chinese	0.000	10.320	4.612	23.093
Indian	0.000	9.676	4.272	21.917
Hypertension				
Yes	-			
No	0.370	1.335	0.709	2.514
Diabetes				
Yes	-			
No	0.596	1.230	0.572	2.644
Anti-platelet use				
Yes	-			
No	0.523	1.186	0.703	2.000
Statin use				
Yes	-			
No	0.739	0.905	0.504	1.626
Family History with Stroke				
Yes	-			
No	0.198	1.494	0.811	2.753
Family History with CVD				
Yes	-			
No	0.001	2.705	1.538	4.757

Table 4: Doctor's estimation of patient's CV risk vs patient's actual risk, n=1089

Patient's Actual risk		
Doctors estimation	High (%)	Low/ moderate
High	310 (40.2)	20 (6.3)
Low/ Moderate	462 (59.8)	297 (93.7)

Table 5: Factors associated with doctor's underestimation of patients' actual risk

	Significance value	Adjusted odds ratio	95% Confidence Interval	
			Lower	Upper
DOCTORS' FACTORS				
Age	0.819	1.010	0.931	1.095
Experience	0.065	0.896	0.798	1.007
Gender				
Male	-			
Female	0.094	0.702	0.465	1.061
PATIENTS' FACTORS				
Age	0.000	1.099	1.072	1.127
Income	0.056	1.000	1.000	1.000
Waist Circumference	0.552	1.006	0.986	1.027
Body Mass Index	0.418	0.979	0.929	1.031
Systolic BP	0.000	1.032	1.019	1.045
Diastolic BP	0.109	0.983	0.962	1.004

Total Cholesterol	0.610	1.081	0.800	1.462
HDL Cholesterol	0.000	0.281	0.160	0.494
LDL Cholesterol	0.044	1.387	1.009	1.907
Gender	-			
Male	0.000	0.463	0.302	0.711
Female				
Ethnic	-			
Bumiputera/ Others				
Malay	0.003	2.562	1.373	4.780
Chinese	0.004	2.851	1.397	5.818
Indian	0.000	6.048	2.824	12.954
Smoker	-			
Yes				
No	0.004	0.469	0.282	0.780
Hypertension	-			
Yes				
No	0.026	0.576	0.354	0.936
Diabetes	-			
Yes				
No	0.012	0.491	0.282	0.854
Family History with CVD	-			
Yes				
No	0.518	1.188	0.706	1.999

Family History with				
Stroke				
Yes	-			
No	0.768	0.925	0.552	1.551
Anti-platelet use				
Yes	-			
No	0.330	0.821	0.552	1.221
Statin use				
Yes	-			
No	0.730	1.084	0.686	1.712

Table 6: Methods used by the doctors to estimate CV risk

Methods of CV calculation	n	%
Risk factor counting	244	22.3
Paper/ chart based	250	22.9
Online risk calculator	544	50.1
None	51	4.7

	Item no.	Recommendation	Page numbers	Checklist
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title of abstract	1	✓
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3	✓
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4	✓
Objectives	3	State specific objectives, including any prespecified hypotheses	4	✓
Methods				
Study design	4	Present key elements of study design early in the paper	5	✓
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5	✓
Participants	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	5	✓
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6	✓
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	5-6	✓
Bias	9	Describe any efforts to address potential sources of bias	5-6	✓
Study size	10	Explain how the study size was arrived at	5	✓
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6	✓
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6	✓
		(b) Describe any methods used to examine subgroups and interactions	6	✓
		(c) Explain how missing data were addressed	6	✓
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	6	✓
		(e) Describe any sensitivity analyses	NA	
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,	6	✓

		completing follow-up, and analysed		
		(b) Give reasons for non-participation at each stage	6	✓
		(c) Consider use of a flow diagram	NA	
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6	✓
Outcome data	15	Report numbers of outcome events or summary measures	7	✓
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	7	✓
		(b) Report category boundaries when continuous variables were categorized	7	✓
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7	✓
Discussion				
Key results	18	Summarise key results with reference to study objectives	8	✓
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	10	✓
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9	✓
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9	✓
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	11	✓

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Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study in primary care

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3 **Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study**
4
5 **in primary care**
6

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50 family medicine
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Abstract

Objective Accurate cardiovascular risk estimations by patients and doctors are important as these affect health behaviour and medical decision-making. We aimed to determine if doctors and patients were accurately estimating the absolute cardiovascular risk of patients in primary care.

Methods A cross-sectional study was carried out in primary care clinics in Malaysia in 2014. Patients aged 35 years and above without known cardiovascular diseases were included. Face-to-face interviews with a structured questionnaire were used to collect socio-demographic and clinical data as well as patients' perception and doctors' estimate of the patients' cardiovascular disease (CVD) risk. Associations were tested using chi-square, correlation and independent T tests.

Results We recruited 1094 patients and 57 doctors. Using the Framingham Risk Score (FRS) score alone, 508 patients (46.4%) were in the high-risk group. When diabetes was included as high-risk, the number increased to 776 (70.9%). Only 34.4% of patients and 55.7% of doctors correctly estimated the patient's CVD risk in comparison to the reference FRS score.

Of the high-risk patients, 664 (85.6%) underestimated their CV risk. Factors associated with underestimation by patients included not having family history of CVD [AOR: 2.705, CI:(1.538, 4.757)], smaller waist circumference [AOR:0.979,(0.960, 0.999)] and ethnicity in comparison to the Malay as reference group [Indigenous/Others; AOR:0.129 CI: (0.071, 0.235)] Doctors underestimated risk in 59.8% of the high-risk group. Factors associated with underestimation by doctors were patients factors such as being female, [AOR:2.232;CI:1.460,3.410], younger age [AOR:0.908;CI:0.886,0.930], non-hypertensive [AOR:1.731;CI:1.067, 2.808], non-diabetic [AOR:1.931;CI: 1.114, 3.348], higher HDL levels [AOR:3.546;CI:2.025,6.209], , lower systolic BP [AOR:0.970;CI:0.957, 0.982], non-smoker [AOR:2.246;CI:1.354, 3.726] and ethnicity in comparison to the Malay as reference

group [Indian; AOR: 0.430, CI: 0.257, 0.720. Indigenous/Others; AOR: 2.498, CI: (1.346, 4.636).

Conclusions The majority of consultations occurring between doctors and patients are being informed by inaccurate cardiovascular risk estimation. Inaccuracy is mainly due to underestimation of patients' CVD risks by both patients and doctors.

Article summary

Strengths and limitations of this study

- This was a large cross-sectional study that took place in 9 different clinics and covered over a thousand patient consultations.
- It captured the perceptions and practice occurring in actual consultations in primary care settings where medical decisions were being made.
- Participants' behaviour may have been affected due to awareness of the research being undertaken

Background

Despite international efforts, cardiovascular disease (CVD) remains the leading cause of death worldwide, killing more than 17 million people a year.¹ Affordable, feasible and effective global actions capable of averting millions of deaths from non-communicable diseases have been identified to tackle this continuing crisis.² Yet, the rate of non-communicable diseases, of which CVD is a major contributor, is increasing and this increase is disproportionately greater in developing countries.³ Out of five interventions identified as priority actions for the non-communicable disease crisis,² only one addressed individual clinical services that is, access of essential drugs and technologies. This was deemed essential especially for those identified to be at high risk of CVD.

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3 People at high risk of CVD can be identified using tools such as cardiovascular risk scores.
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5 These were designed to calculate an individual's risk of developing a cardiovascular (CV)
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7 event from risk factors obtained from history, physical examination or investigations. Most
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9 guidelines recommend the use of risk scores to predict global risk rather than focusing on
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11 single risk modification. The majority advocates the use of Framingham risk scores or scores
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13 that have been calibrated from the Framingham study data.⁴⁻⁶ A systematic review identified
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15 21 risk scores for use in adults with no history of previous cardiovascular disease.⁷ However,
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17 the use of the risk score is surprisingly limited. Studies have reported rates of use ranging
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19 from 17-65%.⁸⁻¹⁰ Studies have shown that subjective estimation of cardiovascular risk by
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21 doctors is inaccurate.¹¹⁻¹⁶ They tended to underestimate risk when the study used actual
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23 patients¹¹⁻¹⁶ and overestimate risk for case reports or vignettes¹²⁻¹⁵ Patients have also been
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25 found to be inaccurate in estimating their own CV risk.⁸ About 40% of the general population
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27 underestimates their CV risk and 20% overestimated it.^{11,17,18,19} In studies on those at
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29 established high CV risk, only about 40% were aware of their increased risk.²⁰ Higher CV
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31 risk perception has been shown to be associated with better acceptance towards medical
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33 management regardless of whether the perception accurately reflected actual CV risk or not.²¹
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41 Accurate estimations of CV risk by both patients and doctors are important as these affect
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43 health behaviour and medical decision-making. The proliferations of mobile health
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45 technology including online risk calculators and guidelines have shown potential in
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47 increasing awareness and use of CV risk scores in clinical consultations.²² But has this led to
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49 a corresponding improvement in the use of CV risk scores in practice? Our study aimed to
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51 determine if doctors and patients were able to accurately estimate the absolute cardiovascular
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53 risk of patients in a primary care health setting.
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Methodology

This was a cross sectional study carried out in nine public primary care clinics in Malaysia in 2014 with the period of recruitment from the 1st to the 30th November 2014. The nine clinics were chosen conveniently from five regions of Malaysia: two clinics each from the northern (Ipoh), southern (Melaka) and western regions (Klang Valley), and one clinic from the eastern region (Kelantan) of Peninsular Malaysia and two clinics from East Malaysia (Sabah). All patients attending these clinics aged 35 years and above with cardiovascular (CV) risks assessments done within the past year were included. Patients with known cardiovascular diseases (CVD) for example ischaemic heart disease and strokes were excluded.

Based on a study, which found that 40-52% of patients correctly estimated their CV risk, we used 50% to calculate the sample size, giving a total of 384 participants.¹⁷ After stratifying by regions, and taking into account a 30% non-responder rate, a sample size of 998 was needed. About 200 patients were recruited from each region.

A face to face interview was conducted using a structured questionnaire to collect patients' data on socio-demography, CV risk factors including age, gender and family history of CVD,. Patients were asked to rate their risk of having a heart attack or stroke within the next 10 years as being low, moderate or high. The doctors then filled in patients' data on smoking status in the last one month, history of diabetes and hypertension, lipid profile within the last one year, antihypertensive, statin and antiplatelet use, and estimated patients' CVD risk in the next 10 years as per usual practice namely low (<10%), moderate (10-20%) and high (>20%) Measurements were also taken for weight, height, waist circumference, and blood pressure using a validated digital blood pressure machine (OMRON HEM-7121). Doctors

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3 were also asked to fill up a questionnaire on their socio-demography, years of practice, and
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5 the methods they used to estimate patients' CV risks, if any.
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10 We used the D'Agostino 2008 Framingham General CVD Score (FRS) as the reference CVD
11 risk.²² This has been validated for use in Malaysia without requiring adjustment for
12 demographic variables such as ethnicity.²³⁻²⁴ The 10-year CVD risk is classified into low
13 (<10%), moderate (10-20%) and high (>20%) risk. In this study, high CVD risk group was
14 defined as FRS >20% and/or presence of diabetes mellitus (DM). Estimations made by the
15 patients and doctors were deemed to be correct when there was agreement with the
16 Framingham score as calculated by the research team; underestimation occurred when
17 estimations were low or moderate in those scored as high risk by the research team.
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29 **Analysis**

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31 Data were entered and analysed using Statistical Program for Social Sciences (SPSS) version
32 22.0 (SPSS Inc., 20). Complete-case analysis was used meaning those with missing values
33 were excluded. Frequencies were reported using percentages and proportions. Associations
34 between categorical data were tested using chi-square tests while continuous data were tested
35 using independent T test and correlation test. Kappa value were calculated to determine the
36 agreement between CV risks estimated by patient and actual risk, and CV risks estimated by
37 doctors and actual risk. Univariate and multivariate binary logistic analyses were used, with
38 underestimation of those at high risk as the outcome of interest.
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49 **Ethical approval**

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51 This study was registered in the National Medical Research Registry, Malaysia. (NMRR-13-
52 962-17898) and approved by the Malaysian Research Ethics Committee. Potential
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3 participants were given verbal and written information regarding the study and informed
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5 consent was obtained from those who were recruited.
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9 10 **Results**

11 Out of the 1107 patients approached, 7 refused to participate and 6 did not fulfil the inclusion
12 criteria, giving a total of 1094 patients recruited. The mean age was 57.2 years (SD 9.8) with
13 a range of 35 to 86 years. There were 62.6% females, 60.8% had diabetes and 76.9% had
14 hypertension (Table 1). A total of 57 doctors participated in the study. The mean age of the
15 doctors was 32.3 years (SD 5.5) with a mean duration of work experience of 6.5 years (SD
16 3.8). Women comprise 63.4% of the doctors.
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27 Using the FRS score alone, 508 patients (46.4%) were in the high risk group. When diabetes
28 was included, the number increased to 776 (70.9%). Of all the consultations, only 34.4% of
29 patients and 55.7% of doctors correctly estimated the patient's CVD risk group.
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36 **Patients' estimation**

37 Table 2 shows patients' estimation of their CV risks. Among patients in high CV risk group,
38 only 112 (14.4%) correctly estimated their risks. The remaining 664 (85.6%) underestimated
39 their CV risk. The correlation between patients' perceived CV risk and their actual risk was
40 Kappa = -0.016. Factors associated with underestimation by patients included not having
41 family history of CVD [AOR: 2.747, CI:(1.566, 4.818)], smaller waist circumference
42 [AOR:0.980; (0.960, 0.999)] and ethnicity in comparison to the Malay as reference group.
43 [Indigenous/Others; AOR:0.129 CI: (0.071, 0.235)]. (Table 3)
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55 **Doctors' estimation**

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3 Table 4 shows doctors' estimation of patients' CV risks. Among patients in high CV risk
4 group, doctors correctly estimated 40.2% and underestimated 59.8%. The correlation between
5 doctors' estimation of patient's CV risk versus patient's actual CV risk was Kappa = -0.084.
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10 Factors associated with underestimation of high CV risk by doctors were patients factors such
11 as being female, [AOR:2.232;CI:1.460,3.410], younger age [AOR:0.908;CI:0.886,0.930],
12 non-hypertensive [AOR:1.731;CI:1.067, 2.808], non-diabetic [AOR:1.931;CI: 1.114, 3.348],
13 higher HDL levels [AOR:3.546;CI:2.025,6.209], , lower systolic BP [AOR:0.970;CI:0.957,
14 0.982], non-smoker [AOR:2.246;CI:1.354, 3.726] and ethnicity in comparison to the Malay
15 as reference group [Indian; AOR: 0.430, CI: 0.257, 0.720. Indigenous/Others; AOR: 2.498,
16 CI: (1.346, 4.636).]. (Table 5)
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25 Table 6 summarises the methods used by doctors to estimate patients' CV risk. About half
26 used online risk calculators while a quarter each used risk factor counting or manual
27 calculation. Risk scores used included Framingham, QRISK and ACC-AHA risk scores.
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34 Discussion

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36 Our findings indicate that both patients and doctors were underestimating the patient's
37 cardiovascular risk. Of those at high CV risk, only 1 in 7 patients could identify themselves
38 as being at high risk. More worryingly, only 2 out of 5 doctors seeing these high CV risk
39 patients could correctly identify them. This implies that medical decision-making during
40 these consultations were poorly informed due to inaccurate CV risk estimation.
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50 How can this occur with the easy availability of online risk calculators and guidelines
51 recommending use of risk estimation? It is likely that risk estimation for CVD is still poorly
52 understood. Many CVD risk scores recommended using baseline levels of risk factors for risk
53 calculation prior to the initiation of medication. For some risk scores such as the ATP-III risk
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3 calculator and the Pooled Cohort Risk score, diabetes is automatically taken as high CV risk
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5 without the need for calculation. However, new risk calculators such as QRISK and
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7 D'Agostino now consider the effect of treatment and incorporate variables such as present
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9 use of antihypertensive or lipid lowering agents into the calculation.^{25,26} Differences in the
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11 methods used by different risk scores and over time have led to misunderstandings, confusion
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13 and uncertainty by users.
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18 A study that explored general practitioners' use of cardiovascular risk scores found that
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20 doctors had great uncertainty over the use of CVD scores in treated patients.²⁷ Use of
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22 patient's risk factor levels when patient is on treatment would lead to an under-estimation of
23
24 the true CVD risk. Prolonged exposure to previous high levels and the presence of
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26 established chronic changes would mean that maximal reduction may take longer than 5
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28 years and may never reach the level of a treatment naïve patient. However, doctors find it
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30 difficult to obtain pre-treatment levels and over-estimation would occur if the patient's risk
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32 factor had been controlled over a long period of time.
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38 Shared medical decision-making through proper risk communication ensures patients and
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40 doctors are able to weigh the risk and benefits of treatment options. The underestimation of
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42 risk as seen in this study population is likely to have significant impact on their management.
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44 Overoptimism has also been noted in other studies which described the tendency for people
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46 to be unrealistically optimistic about future life events.²⁸ The research showed that subjects
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48 tended to be optimistic of their chances for negative events when the event is perceived to be
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50 controllable. This appears to mirror our finding where patients and doctors perceived the risk
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52 for CVD as being low because of the availability of treatment and behavioural lifestyle
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54 modification steps that can be taken. The mainstay of treatment of risk factors is to prevent
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3 progression of disease. Yet, patients and doctors must understand that residual risk remains
4 and that treatment should be continued for most despite normalisation of risk factor levels.
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7 This understanding is potentially jeopardised by optimism bias as adherence to medication
8 and preventive behaviour have been shown to be associated with higher risk perception.²⁹⁻³¹
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14 The findings also suggest that patients and doctors estimated risk by risk factor profile or risk
15 factor counting as opposed to absolute risk calculation. It appears that there is good
16 awareness of some of the risk factors for cardiovascular disease as risk perception was found
17 to be associated with these factors namely age, gender, co-morbidities and smoking.
18
19 However, focusing on individual risk factors or risk factor counting tends to underestimate
20 risk in those who may have slightly elevated levels of multiple risk factors that synergistically
21 increased the overall absolute CV risk.³² This is why most cardiovascular disease guidelines
22 advocate the use of risk calculators to estimate individual risk.^{5, 6, 33-34} Patients appeared to be
23 more aware of family history and having a higher waist circumference as conferring risk
24 compared to other risk factors. Family history and obesity have been shown to be associated
25 with increased self-perception of risk.¹² It is useful to identify factors that have greater
26 meaning to patients. Otherwise, a mismatch between doctors' and patients' perception on the
27 importance of particular risk factors can affect the communication of risk. The very low
28 correlation between provider and patient estimates that we found in this study indicates that
29 this mismatch is occurring.
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47 Ethnicity also was found to be significantly associated with underestimation of risk. It is
48 unclear as to why this should occur. This finding can be used to target those at greater risk of
49 inaccurate estimations for intervention.
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56 **Strengths and limitations of the study**

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3 This is a cross-sectional study that examined the risk perceptions of individual patients by
4 both the patients and the doctors seeing these patients. The study design allowed us to capture
5 the perceptions and practice occurring in actual consultations in primary care settings where
6 decisions on institution of management for cardiovascular disease prevention and treatment
7 are made. This study took place in 9 different clinics and covered over a thousand patient
8 consultations.
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12 It is possible that the doctors involved in this study may have been prompted to assess
13 patients CV risk due to awareness of the research being undertaken as informed consent was
14 obtained from all participants. However, we believe that this would only have prompted them
15 to look up cardiovascular assessment. If knowledge of this study had introduced bias to the
16 results, it would likely that the direction of the bias would be towards more accurate
17 estimation of risk. Hence the rate of inaccurate risk estimation may actually be greater than
18 was found.
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36 This study used the validated Framingham risk score as the reference standard. Therefore,
37 accuracy of estimations were based on agreement with the reference score and not to actual
38 cardiovascular outcomes which would require a cohort study design. We included patients
39 aged 75 and above although the Framingham risk score is recommended for those aged 30 to
40 74 years of age. This decision was taken as it reflects the actual patient population that is seen
41 in primary care. However, we understand that the risk score is less accurate when used
42 outside the recommended age ranges. There was no adjustment for cluster effect or
43 multicollinearity.
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56 **Recommendations**

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3 In view of these findings, future studies should look at developing interventional strategies to
4 implement formal CVD risk calculation into consultation and testing the strategies in actual
5 consultations. Examples are system processes that incorporate risk calculators into electronic
6 medical records or simple displays of risk charts on clinic desks.³² Accurate risk estimations
7 should then be conveyed to patients to allow them to be fully informed when making
8 decisions regarding their management in clinical practice.
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19 **Conclusion**

20 The majority of consultations occurring between doctors and patients are being informed by
21 inaccurate cardiovascular risk estimation. Inaccuracy is mainly due to underestimation of
22 patients' CVD risks. Interventions are required to improve CVD risk estimation in order to
23 inform shared decision-making in primary care consultations.
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45 **Contributorship statement**

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3 The study was conceived by SML, WKL, EMK, IZ and HY. SML, WKL, EMK, IZ, SA, MO,
4
5 SZ, JS and HY contributed to the planning and data analysis of the study. WKL, IZ, SA, MO,
6
7 SZ, and JS assisted with data collection. NZ assisted with data analysis of the study. SML
8
9 drafted the manuscript and the final version was revised and approved by SML, WKL, EMK,
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Table 1: Socio-demography and profile of the respondents

Demographic data and profile		Frequency (%)
Mean Age ± SD (years)		57.23 ± 9.81
Mean income ± SD (RM)		1824.34 ± 2112.09
Mean body mass index ± SD (kg/m²)		28.02 ± 13.17
Gender	Female	685 (62.6)
Ethnicity	Malay	559 (51.1)
	Chinese	234 (21.4)
	Indian	161 (14.7)
	Indigenous	112 (10.2)
	Other	28 (2.6)
Smoker		185 (16.9)
Diabetes		665 (60.8)
Hypertension		840 (76.8)
Family history of Stroke		165 (15.1)
Family history of Cardiovascular Disease		158 (14.4)

Table 2: Accurate estimation of high CV risk by patient, n= 1094

Actual CV risk		
Patient's estimation	High (%)	Low/ moderate
High	112 (14.4)	54 (17.0)
Low/ Moderate	664 (85.6)	264(83.0)

Table 3: Factors associated with underestimation of high cardiovascular disease risk by patients

		Significance value	Adjusted odds ratio	95% Confidence Interval	
				Lower	Upper
SmoGenderg	Age	0.550	1.009	0.981	1.037
	Gender	0.339	1.290	0.765	2.175
	Smoker	0.167	0.616	0.310	1.224
	Income	0.280	1.000	1.000	1.000
	Systolic BP	0.482	1.006	0.989	1.023
	Diastolic BP	0.194	0.982	0.955	1.009
	Waist Circumference	0.043	0.980	0.960	0.999
	Body Mass Index	0.230	0.981	0.952	1.012

Total Cholesterol	0.211	0.770	0.512	1.160
LDL Cholesterol	0.154	1.364	0.890	2.090
HDL Cholesterol	0.252	1.484	0.755	2.917
Ethnicity	-			
Malay				
Chinese	0.430	1.335	0.651	2.738
Indian	0.533	1.252	0.671	2.539
Indigineous	0.000	0.129	0.071	0.235
Hypertension				
Yes	-			
No	0.370	1.335	0.709	2.514
Diabetes				
Yes	-			
No	0.596	1.230	0.572	2.644
Anti-platelet use	-			
Yes	0.523	1.186	0.703	2.000
No				
Statin use				
Yes	-			
No	0.739	0.905	0.504	1.626

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	Family History with Stroke	-			
	Yes	0.198	1.494	0.811	2.753
	No				
	Family History with CVD	-			
	Yes	0.001	2.705	1.538	4.757
	No				

peer review only

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Table 4: Doctor’s estimation of patient’s CV risk vs patient’s actual risk, n=1089

Patient’s Actual risk		
Doctors estimation	High (%)	Low/ moderate
High	310 (40.2)	20 (6.3)
Low/ Moderate	462 (59.8)	297 (93.7)

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Table 5: Factors associated with doctor's underestimation of patients' actual risk

	Significance value	Adjusted odds ratio	95% Confidence Interval	
			Lower	Upper
DOCTORS' FACTORS				
Age	0.771	0.988	0.911	1.071
Experience	0.055	1.120	0.998	1.257
Gender				
Male	-			
Female	0.096	1.416	0.940	2.131
PATIENTS' FACTORS				
Age	0.000	0.908	0.886	0.930
Income	0.052	1.000	1.000	1.000
Waist Circumference	0.902	1.001	0.985	1.017
Body Mass Index	0.530	0.994	0.975	1.013
Systolic BP	0.000	0.970	0.957	0.982
Diastolic BP	0.121	1.017	0.996	1.038
Total Cholesterol	0.471	0.899	0.672	1.202
HDL Cholesterol	0.000	3.546	2.025	6.209
LDL Cholesterol	0.059	0.747	0.552	1.012
Gender				
Male	-			
Female	0.000	2.232	1.460	3.410

Ethnic				
-	-			
Malay				
Chinese	0.727	0.916	0.560	1.499
Indian	0.001	0.430	0.257	0.720
Indigenous/Others	0.004	2.498	1.346	4.636
Smoker				
Yes	-			
No	0.002	2.246	1.354	3.726
Hypertension				
Yes	-			
No	0.026	1.731	1.067	2.808
Diabetes				
Yes	-			
No	0.019	1.931	1.114	3.348
Family History with CVD				
Yes	-			
No	0.513	0.841	0.500	1.414
Family History with Stroke				
Yes	-			
No	0.740	1.091	0.652	1.825
Anti-platelet use				
Yes	-			
No	0.385	1.192	0.802	1.772

Statin use				
Yes	-			
No	0.696	0.913	0.580	1.439

Table 6: Methods used by the doctors to estimate CV risk

Methods of CV calculation	n	%
Risk factor counting	244	22.3
Paper/ chart based	250	22.9
Online risk calculator	544	50.1
None	51	4.7

	Item no.	Recommendation	Page numbers	Checklist
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title of abstract	1	✓
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3	✓
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4	✓
Objectives	3	State specific objectives, including any prespecified hypotheses	4	✓
Methods				
Study design	4	Present key elements of study design early in the paper	5	✓
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5	✓
Participants	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	5	✓
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6	✓
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	5-6	✓
Bias	9	Describe any efforts to address potential sources of bias	5-6	✓
Study size	10	Explain how the study size was arrived at	5	✓
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6	✓
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6	✓
		(b) Describe any methods used to examine subgroups and interactions	6	✓
		(c) Explain how missing data were addressed	6	✓
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	6	✓
		(e) Describe any sensitivity analyses	NA	
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,	6	✓

		completing follow-up, and analysed		
		(b) Give reasons for non-participation at each stage	6	✓
		(c) Consider use of a flow diagram	NA	
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6	✓
Outcome data	15	Report numbers of outcome events or summary measures	7	✓
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	7	✓
		(b) Report category boundaries when continuous variables were categorized	7	✓
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7	✓
Discussion				
Key results	18	Summarise key results with reference to study objectives	8	✓
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	10	✓
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9	✓
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9	✓
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	11	✓

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Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study in primary care

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Manuscripts

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3 **Can doctors and patients correctly estimate cardiovascular risk? A cross sectional study**
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5 **in primary care**
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Abstract

Objective Accurate cardiovascular risk estimations by patients and doctors are important as these affect health behaviour and medical decision-making. We aimed to determine if doctors and patients were accurately estimating the absolute cardiovascular risk of patients in primary care.

Methods A cross-sectional study was carried out in primary care clinics in Malaysia in 2014. Patients aged 35 years and above without known cardiovascular diseases were included. Face-to-face interviews with a structured questionnaire were used to collect socio-demographic and clinical data as well as patients' perception and doctors' estimate of the patients' cardiovascular disease (CVD) risk. Associations were tested using chi-square, correlation and independent T tests.

Results We recruited 1094 patients and 57 doctors. Using the Framingham Risk Score (FRS) score alone, 508 patients (46.4%) were in the high-risk group. When diabetes was included as high-risk, the number increased to 776 (70.9%). Only 34.4% of patients and 55.7% of doctors correctly estimated the patient's CVD risk in comparison to the reference FRS score.

Of the high-risk patients, 664 (85.6%) underestimated their CV risk. Factors associated with underestimation by patients included not having family history of CVD [AOR: 2.705, CI:(1.538, 4.757)], smaller waist circumference [AOR:0.979,(0.960, 0.999)] and ethnicity in comparison to the Malay as reference group [Indigenous/Others; AOR:0.129 CI: (0.071, 0.235)] Doctors underestimated risk in 59.8% of the high-risk group. Factors associated with underestimation by doctors were patients factors such as being female, [AOR:2.232;CI:1.460,3.410], younger age [AOR:0.908;CI:0.886,0.930], non-hypertensive [AOR:1.731;CI:1.067, 2.808], non-diabetic [AOR:1.931;CI: 1.114, 3.348], higher HDL levels [AOR:3.546;CI:2.025,6.209], , lower systolic BP [AOR:0.970;CI:0.957, 0.982], non-smoker [AOR:2.246;CI:1.354, 3.726] and ethnicity in comparison to the Malay as reference

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3 group [Indian; AOR: 0.430, CI: 0.257, 0.720. Indigenous/Others; AOR: 2.498, CI: (1.346,
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5 4.636).
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7 **Conclusions** The majority of consultations occurring between doctors and patients are being
8 informed by inaccurate cardiovascular risk estimation.
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11 **Article summary**

12 **Strengths and limitations of this study**

- 13 • This was a large cross-sectional study that took place in 9 different clinics and
14 covered over a thousand patient consultations.
- 15 • It captured the perceptions and practice occurring in actual consultations in primary
16 care settings where medical decisions were being made.
- 17 • Participants' behaviour may have been affected due to awareness of the research
18 being undertaken
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32 **Background**

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34 Despite international efforts, cardiovascular disease (CVD) remains the leading cause of
35 death worldwide, killing more than 17 million people a year.¹ Affordable, feasible and
36 effective global actions capable of averting millions of deaths from non-communicable
37 diseases have been identified to tackle this continuing crisis.² Yet, the rate of non-
38 communicable diseases, of which CVD is a major contributor, is increasing and this increase
39 is disproportionately greater in developing countries.³ Out of five interventions identified as
40 priority actions for the non-communicable disease crisis,² only one addressed individual
41 clinical services that is, access of essential drugs and technologies. This was deemed essential
42 especially for those identified to be at high risk of CVD.
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3 People at high risk of CVD can be identified using tools such as cardiovascular risk scores.
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5 These were designed to calculate an individual's risk of developing a cardiovascular (CV)
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7 event from risk factors obtained from history, physical examination or investigations. Most
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9 guidelines recommend the use of risk scores to predict global risk rather than focusing on
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11 single risk modification. The majority advocates the use of Framingham risk scores or scores
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13 that have been calibrated from the Framingham study data.⁴⁻⁶ A systematic review identified
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15 21 risk scores for use in adults with no history of previous cardiovascular disease.⁷ However,
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17 the use of the risk score is surprisingly limited. Studies have reported rates of use ranging
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19 from 17-65%.⁸⁻¹⁰ Studies have shown that subjective estimation of cardiovascular risk by
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21 doctors is inaccurate.¹¹⁻¹⁶ They tended to underestimate risk when the study used actual
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23 patients¹¹⁻¹⁶ and overestimate risk for case reports or vignettes¹²⁻¹⁵ Patients have also been
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25 found to be inaccurate in estimating their own CV risk.⁸ About 40% of the general population
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27 underestimates their CV risk and 20% overestimated it.^{11,17,18,19} In studies on those at
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29 established high CV risk, only about 40% were aware of their increased risk.²⁰ Higher CV
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31 risk perception has been shown to be associated with better acceptance towards medical
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33 management regardless of whether the perception accurately reflected actual CV risk or not.²¹
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Accurate estimations of CV risk by both patients and doctors are important as these affect health behaviour and medical decision-making. The proliferations of mobile health technology including online risk calculators and guidelines have shown potential in increasing awareness and use of CV risk scores in clinical consultations.²² But has this led to a corresponding improvement in the use of CV risk scores in practice? Our study aimed to determine if doctors and patients were able to accurately estimate the absolute cardiovascular risk of patients in a primary care health setting.

Methodology

This was a cross sectional study carried out in nine public primary care clinics in Malaysia in 2014 with the period of recruitment from the 1st to the 30th November 2014. The nine clinics were chosen conveniently from five regions of Malaysia: two clinics each from the northern (Ipoh), southern (Melaka) and western regions (Klang Valley), and one clinic from the eastern region (Kelantan) of Peninsular Malaysia and two clinics from East Malaysia (Sabah). All patients attending these clinics aged 35 years and above with cardiovascular (CV) risks assessments done within the past year were included. Patients with known cardiovascular diseases (CVD) for example ischaemic heart disease and strokes were excluded.

Based on a study, which found that 40-52% of patients correctly estimated their CV risk, we used 50% to calculate the sample size, giving a total of 384 participants.¹⁷ After stratifying by regions, and taking into account a 30% non-responder rate, a sample size of 998 was needed. About 200 patients were recruited from each region.

A face to face interview was conducted using a structured questionnaire to collect patients' data on socio-demography, CV risk factors including age, gender and family history of CVD. Patients were asked to rate their risk of having a heart attack or stroke within the next 10 years as being low, moderate or high. The doctors then filled in patients' data on smoking status in the last one month, history of diabetes and hypertension, lipid profile within the last one year, antihypertensive, statin and antiplatelet use, and estimated patients' CVD risk in the next 10 years as per usual practice namely low (<10%), moderate (10-20%) and high (>20%). Measurements were also taken for weight, height, waist circumference, and blood pressure using a validated digital blood pressure machine (OMRON HEM-7121). Doctors were also

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3 asked to fill up a questionnaire on their socio-demography, years of practice, and the methods
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5 they used to estimate patients' CV risks, if any.
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10 We used the D'Agostino 2008 Framingham General CVD Score (FRS) as the reference CVD
11 risk.²² This has been validated for use in Malaysia without requiring adjustment for
12 demographic variables such as ethnicity.²³⁻²⁴ The 10-year CVD risk is classified into low
13 (<10%), moderate (10-20%) and high (>20%) risk. In this study, high CVD risk group was
14 defined as FRS >20% and/or presence of diabetes mellitus (DM). Estimations made by the
15 patients and doctors were deemed to be correct when there was agreement with the
16 Framingham score as calculated by the research team; underestimation occurred when
17 estimations were low or moderate in those scored as high risk by the research team.
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29 **Analysis**

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31 Data were entered and analysed using Statistical Program for Social Sciences (SPSS) version
32 22.0 (SPSS Inc., 20). Complete-case analysis was used meaning those with missing values
33 were excluded. Frequencies were reported using percentages and proportions. Associations
34 between categorical data were tested using chi-square tests while continuous data were tested
35 using independent T test and correlation test. Kappa value was calculated to determine the
36 agreement between CV risks estimated by patient and actual risk, and CV risks estimated by
37 doctors and actual risk. Univariate and multivariate binary logistic analyses were used, with
38 underestimation of those at high risk as the outcome of interest. The intracluster correlation
39 coefficient (ICC) was calculated to determine the homogeneity of the clusters. Values of ICC that are
40 close to 0 indicate that the design effect is 1 and that the clusters are homogenous.²⁵ The correlation
41 estimates and the variant inflation factors (VIF) were used to determine multicollinearity among the
42 explanatory variables.
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Ethical approval

This study was registered in the National Medical Research Registry, Malaysia. (NMRR-13-962-17898) and approved by the Malaysian Research Ethics Committee. Potential participants were given verbal and written information regarding the study and informed consent was obtained from those who were recruited.

Results

Out of the 1107 patients approached, 7 refused to participate and 6 did not fulfil the inclusion criteria, giving a total of 1094 patients recruited. The mean age was 57.2 years (SD 9.8) with a range of 35 to 86 years. There were 62.6% females, 60.8% had diabetes and 76.9% had hypertension (Table 1). A total of 57 doctors participated in the study. The mean age of the doctors was 32.3 years (SD 5.5) with a mean duration of work experience of 6.5 years (SD 3.8). Women comprise 63.4% of the doctors.

Using the FRS score alone, 508 patients (46.4%) were in the high risk group. When diabetes was included, the number increased to 776 (70.9%). Of all the consultations, only 34.4% of patients and 55.7% of doctors correctly estimated the patient's CVD risk group.

The ICC values calculated for all the variables were small, ranging from 0.001 to 0.086, indicating that the clusters are homogenous. The highest correlation between the variables is < 0.85 (the highest being 0.780) while the highest variance Inflation Factor (VIF) is < 5 . Hence, there is no multicollinearity within the variables.

Patients' estimation

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3 Table 2 shows patients' estimation of their CV risks. Among patients in high CV risk group,
4 only 112 (14.4%) correctly estimated their risks. The remaining 664 (85.6%) underestimated
5 their CV risk. The correlation between patients' perceived CV risk and their actual risk was
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7 Kappa = -0.016. Factors associated with underestimation by patients included not having
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9 family history of CVD [AOR: 2.747, CI:1.566, 4.818], smaller waist circumference
10 [AOR:0.980; CI: 0.960, 0.999] and ethnicity in comparison to the Malay as reference group.
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12 [Indigenous/Others; AOR:0.129 CI: 0.071, 0.235]. (Table 3)
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20 21 **Doctors' estimation**

22 Table 4 shows doctors' estimation of patients' CV risks. Among patients in high CV risk
23 group, doctors correctly estimated 40.2% and underestimated 59.8%. The correlation between
24 doctors' estimation of patient's CV risk versus patient's actual CV risk was Kappa = -0.084.
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26 Factors associated with underestimation of high CV risk by doctors were patients factors such
27 as being female, [AOR:2.232; CI:1.460,3.410], younger age [AOR:0.908; CI:0.886,0.930],
28 non-hypertensive [AOR:1.731; CI:1.067, 2.808], non-diabetic [AOR:1.931; CI:1.114, 3.348],
29 higher HDL levels [AOR:3.546; CI:2.025,6.209], , lower systolic BP [AOR:0.970; CI:0.957,
30 0.982], non-smoker [AOR:2.246; CI:1.354, 3.726] and ethnicity in comparison to the Malay
31 as reference group [Indian; AOR: 0.430, CI: 0.257, 0.720. Indigenous/Others; AOR: 2.498,
32 CI: (1.346, 4.636).]. (Table 5)
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47 Table 6 summarises the methods used by doctors to estimate patients' CV risk. About half
48 used online risk calculators while a quarter each used risk factor counting or manual
49 calculation. Risk scores used included Framingham, QRISK and ACC-AHA risk scores.
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56 **Discussion**

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3 Our findings indicate that both patients and doctors were underestimating the patient's
4 cardiovascular risk. Of those at high CV risk, only 1 in 7 patients could identify themselves
5 as being at high risk. More worryingly, only 2 out of 5 doctors seeing these high CV risk
6 patients could correctly identify them. This implies that medical decision-making during
7 these consultations were poorly informed due to inaccurate CV risk estimation.
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16 How can this occur with the easy availability of online risk calculators and guidelines
17 recommending use of risk estimation? It is likely that risk estimation for CVD is still poorly
18 understood. Many CVD risk scores recommended using baseline levels of risk factors for risk
19 calculation prior to the initiation of medication. For some risk scores such as the ATP-III risk
20 calculator and the Pooled Cohort Risk score, diabetes is automatically taken as high CV risk
21 without the need for calculation. However, new risk calculators such as QRISK and
22 D'Agostino now consider the effect of treatment and incorporate variables such as present
23 use of antihypertensive or lipid lowering agents into the calculation.^{26,27} Differences in the
24 methods used by different risk scores and over time have led to misunderstandings, confusion
25 and uncertainty by users.
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41 A study that explored general practitioners' use of cardiovascular risk scores found that
42 doctors had great uncertainty over the use of CVD scores in treated patients.²⁸ Use of
43 patient's risk factor levels when patient is on treatment would lead to an under-estimation of
44 the true CVD risk. Prolonged exposure to previous high levels and the presence of
45 established chronic changes would mean that maximal reduction may take longer than 5
46 years and may never reach the level of a treatment naïve patient. However, doctors find it
47 difficult to obtain pre-treatment levels and over-estimation would occur if the patient's risk
48 factor had been controlled over a long period of time.
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3 Shared medical decision-making through proper risk communication ensures patients and
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5 doctors are able to weigh the risk and benefits of treatment options. The underestimation of
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7 risk as seen in this study population is likely to have significant impact on their management.
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9 Over-optimism has also been noted in other studies which described the tendency for people
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11 to be unrealistically optimistic about future life events.²⁹ The research showed that subjects
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13 tended to be optimistic of their chances for negative events when the event is perceived to be
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15 controllable. This appears to mirror our finding where patients and doctors perceived the risk
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17 for CVD as being low because of the availability of treatment and behavioural lifestyle
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19 modification steps that can be taken. The mainstay of treatment of risk factors is to prevent
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21 progression of disease. Yet, patients and doctors must understand that residual risk remains
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23 and that treatment should be continued for most despite normalisation of risk factor levels.
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25 This understanding is potentially jeopardised by optimism bias as adherence to medication
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27 and preventive behaviour have been shown to be associated with higher risk perception.³⁰⁻³²
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34 The findings also suggest that patients and doctors estimated risk by risk factor profile or risk
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36 factor counting as opposed to absolute risk calculation. It appears that there is good
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38 awareness of some of the risk factors for cardiovascular disease as risk perception was found
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40 to be associated with these factors namely age, gender, co-morbidities and smoking. However,
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42 focusing on individual risk factors or risk factor counting tends to underestimate risk in those
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44 who may have slightly elevated levels of multiple risk factors that synergistically increased
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46 the overall absolute CV risk.³³ This is why most cardiovascular disease guidelines advocate
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48 the use of risk calculators to estimate individual risk.^{5, 6, 34-35} Patients appeared to be more
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50 aware of family history and having a higher waist circumference as conferring risk compared
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52 to other risk factors. Family history and obesity have been shown to be associated with
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54 increased self-perception of risk.¹² It is useful to identify factors that have greater meaning to
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3 patients. Otherwise, a mismatch between doctors' and patients' perception on the importance
4 of particular risk factors can affect the communication of risk. The very low correlation
5 between provider and patient estimates that we found in this study indicates that this
6 mismatch is occurring.
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14 Ethnicity also was found to be significantly associated with underestimation of risk. The
15 AOR for underestimation of risk by doctors for patients of Indian ethnicity was 0.430, CI:
16 0.257, 0.720 compared to the reference group (Malay patients). This indicates that in
17 comparison to the Malay patients, underestimation of risk by doctors was less in patients of
18 Indian ethnicity. It is possible that this is linked to training that those of South Asian ethnicity
19 are at higher CVD risk.³⁶ This finding can be used to target those at greater risk of inaccurate
20 estimations for intervention.
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30 31 32 **Strengths and limitations of the study**

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34 This is a cross-sectional study that examined the risk perceptions of individual patients by
35 both the patients and the doctors seeing these patients. The study design allowed us to capture
36 the perceptions and practice occurring in actual consultations in primary care settings where
37 decisions on institution of management for cardiovascular disease prevention and treatment
38 are made. This study took place in 9 different clinics and covered over a thousand patient
39 consultations.
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50 It is possible that the doctors involved in this study may have been prompted to assess
51 patients' CV risk due to awareness of the research being undertaken as informed consent was
52 obtained from all participants. However, we believe that this would only have prompted them
53 to look up cardiovascular assessment. If knowledge of this study had introduced bias to the
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3 results, it would likely that the direction of the bias would be towards more accurate
4 estimation of risk. Hence the rate of inaccurate risk estimation may actually be greater than
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7 was found.
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11 This study used the validated Framingham risk score as the reference standard. Therefore,
12 accuracy of estimations was based on agreement with the reference score and not to actual
13 cardiovascular outcomes which would require a cohort study design. We included patients
14 aged 75 and above although the Framingham risk score is recommended for those aged 30 to
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This study used the validated Framingham risk score as the reference standard. Therefore, accuracy of estimations was based on agreement with the reference score and not to actual cardiovascular outcomes which would require a cohort study design. We included patients aged 75 and above although the Framingham risk score is recommended for those aged 30 to 74 years of age. This decision was taken as it reflects the actual patient population that is seen in primary care. However, we understand that the risk score is less accurate when used outside the recommended age ranges.

Recommendations

In view of these findings, future studies should look at developing interventional strategies to implement formal CVD risk calculation into consultation and testing the strategies in actual consultations. Examples are system processes that incorporate risk calculators into electronic medical records or simple displays of risk charts on clinic desks.³² Accurate risk estimations should then be conveyed to patients to allow them to be fully informed when making decisions regarding their management in clinical practice.

Conclusion

The majority of consultations occurring between doctors and patients are being informed by inaccurate cardiovascular risk estimation. Inaccuracy is mainly due to underestimation of patients' CVD risks. Interventions are required to improve CVD risk estimation in order to inform shared decision-making in primary care consultations.

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Contributorship statement

SML- Liew Su May, WKL- Lee Wai Khew, EMK- Khoo Ee Ming, IZ- Irmis Zarina Ismail, SA- Subashini Ambigapathy, MO- Mimi Omar, SZ- Siti Zaleha Suleiman, JS- Juwita Saaban, NZ- Nurfarhana Zaidi, HY- Harny Yussof

The study was conceived by SML, WKL, EMK, IZ and HY. SML, WKL, EMK, IZ, SA, MO, SZ, JS and HY contributed to the planning and data analysis of the study. WKL, IZ, SA, MO, SZ, and JS assisted with data collection. NZ assisted with data analysis of the study. SML drafted the manuscript and the final version was revised and approved by SML, WKL, EMK, IZ, SA, MO, SZ, JS, NZ and HY.

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Table 1: Socio-demography and profile of the respondents

Demographic data and profile		Frequency (%)
Mean Age ± SD (years)		57.23 ± 9.81
Mean income ± SD (RM)		1824.34 ± 2112.09
Mean body mass index ± SD (kg/m²)		28.02 ± 13.17
Gender	Female	685 (62.6)
Ethnicity	Malay	559 (51.1)
	Chinese	234 (21.4)
	Indian	161 (14.7)
	Indigenous	112 (10.2)
	Other	28 (2.6)
Smoker		185 (16.9)
Diabetes		665 (60.8)
Hypertension		840 (76.8)
Family history of Stroke		165 (15.1)
Family history of Cardiovascular Disease		158 (14.4)

Table 2: Accurate estimation of high CV risk by patient, n= 1094

Actual CV risk		
Patient's estimation	High (%)	Low/ moderate
High	112 (14.4)	54 (17.0)
Low/ Moderate	664 (85.6)	264(83.0)

Table 3: Factors associated with underestimation of high cardiovascular disease risk by patients

		Significance value	Adjusted odds ratio	95% Confidence Interval	
				Lower	Upper
	Age	0.550	1.009	0.981	1.037
	Gender (female)	0.339	1.290	0.765	2.175
	Smoker (Non smoker)	0.167	0.616	0.310	1.224
	Income	0.280	1.000	1.000	1.000
	Systolic BP	0.482	1.006	0.989	1.023
	Diastolic BP	0.194	0.982	0.955	1.009
	Waist Circumference	0.043	0.980	0.960	0.999
	Body Mass Index	0.230	0.981	0.952	1.012
	Total Cholesterol	0.211	0.770	0.512	1.160
	LDL Cholesterol	0.154	1.364	0.890	2.090

HDL Cholesterol	0.252	1.484	0.755	2.917
Ethnicity				
Malay (reference)		1.0		
Chinese	0.430	1.335	0.651	2.738
Indian	0.533	1.252	0.671	2.539
Indigenous	0.000	0.129	0.071	0.235
Hypertension				
Yes (reference)	-	1.0		
No	0.370	1.335	0.709	2.514
Diabetes				
Yes(reference)	-	1.0		
No	0.596	1.230	0.572	2.644
Anti-platelet use				
Yes (reference)	-	1.0		
No	0.523	1.186	0.703	2.000
Statin use				
Yes (reference)	-	1.0		
No	0.739	0.905	0.504	1.626
Family History with				
Stroke				
Yes (reference)	-	1.0		
No	0.198	1.494	0.811	2.753

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	Family History with CVD				
	Yes (reference)	-	1.0		
	No	0.001	2.705	1.538	4.757

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Table 4: Doctor's estimation of patient's CV risk vs patient's actual risk, n=1089

Patient's Actual risk		
Doctors estimation	High (%)	Low/ moderate
High	310 (40.2)	20 (6.3)
Low/ Moderate	462 (59.8)	297 (93.7)

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Table 5: Factors associated with doctor's underestimation of patients' actual risk

	Significance value	Adjusted odds ratio	95% Confidence Interval	
			Lower	Upper
DOCTORS' FACTORS				
Age	0.771	0.988	0.911	1.071
Experience	0.055	1.120	0.998	1.257
Gender				
Male (reference)	-	1.0		
Female	0.096	1.416	0.940	2.131
PATIENTS' FACTORS				
Age	0.000	0.908	0.886	0.930
Income	0.052	1.000	1.000	1.000
Waist Circumference	0.902	1.001	0.985	1.017
Body Mass Index	0.530	0.994	0.975	1.013
Systolic BP	0.000	0.970	0.957	0.982
Diastolic BP	0.121	1.017	0.996	1.038
Total Cholesterol	0.471	0.899	0.672	1.202
HDL Cholesterol	0.000	3.546	2.025	6.209
LDL Cholesterol	0.059	0.747	0.552	1.012
Gender				
Male (reference)	-	1.0		
Female	0.000	2.232	1.460	3.410

Ethnic				
Malay (reference)		1.0		
Chinese	0.727	0.916	0.560	1.499
Indian	0.001	0.430	0.257	0.720
Indigenous/Others	0.004	2.498	1.346	4.636
Smoker				
Yes (reference)	-	1.0		
No	0.002	2.246	1.354	3.726
Hypertension				
Yes (reference)	-	1.0		
No	0.026	1.731	1.067	2.808
Diabetes				
Yes (reference)	-	1.0		
No	0.019	1.931	1.114	3.348
Family History with CVD				
Yes (reference)	-	1.0		
No	0.513	0.841	0.500	1.414
Family History with Stroke				
Yes (reference)	-	1.0		
No	0.740	1.091	0.652	1.825
Anti-platelet use				
Yes (reference)	-	1.0		
No	0.385	1.192	0.802	1.772

Statin use				
Yes	-	1.0		
No	0.696	0.913	0.580	1.439

Table 6: Methods used by the doctors to estimate CV risk

Methods of CV calculation	n	%
Risk factor counting	244	22.3
Paper/ chart based	250	22.9
Online risk calculator	544	50.1
None	51	4.7

	Item no.	Recommendation	Page numbers	Checklist
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title of abstract	1	✓
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3	✓
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4	✓
Objectives	3	State specific objectives, including any prespecified hypotheses	4	✓
Methods				
Study design	4	Present key elements of study design early in the paper	5	✓
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5	✓
Participants	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	5	✓
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6	✓
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	5-6	✓
Bias	9	Describe any efforts to address potential sources of bias	5-6	✓
Study size	10	Explain how the study size was arrived at	5	✓
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6	✓
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6	✓
		(b) Describe any methods used to examine subgroups and interactions	6	✓
		(c) Explain how missing data were addressed	6	✓
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	6	✓
		(e) Describe any sensitivity analyses	NA	
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,	6	✓

		completing follow-up, and analysed		
		(b) Give reasons for non-participation at each stage	6	✓
		(c) Consider use of a flow diagram	NA	
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6	✓
Outcome data	15	Report numbers of outcome events or summary measures	7	✓
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	7	✓
		(b) Report category boundaries when continuous variables were categorized	7	✓
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7	✓
Discussion				
Key results	18	Summarise key results with reference to study objectives	8	✓
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	10	✓
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9	✓
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9	✓
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	11	✓