School of Clinical Medicine
Department of Family Medicine & Primary Care
香港大學家庭醫學及基層醫療學系

# Improving Type 2 Diabetes Detection Among At-Risk Individuals – Effectiveness of Active Opportunistic Screening Using Spot Capillary-HbA1c Test – A Cluster Randomised Controlled Trial

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# Outline

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- Data Analyses
- Discussion
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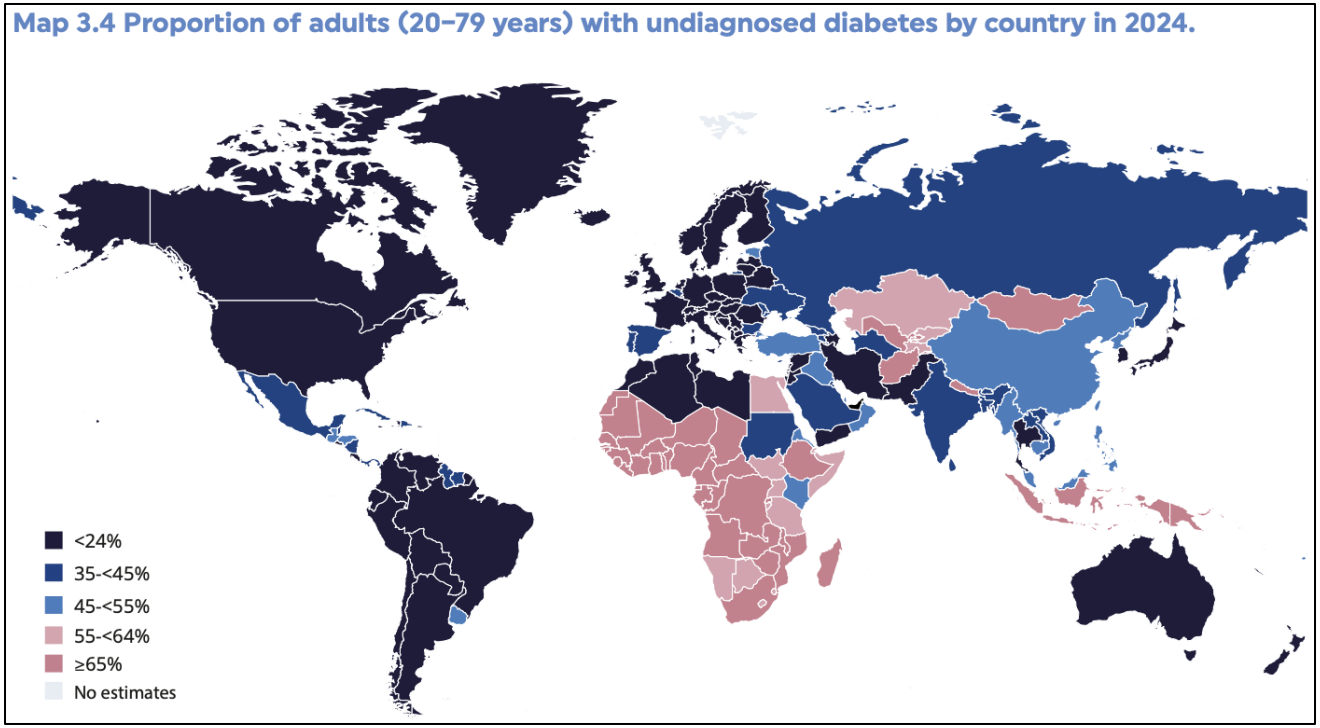
# Introduction



Almost 2 in 5 adults (42.8%; 251.7 million) with DM unaware of their status



# Delayed Diagnosis of T2DM

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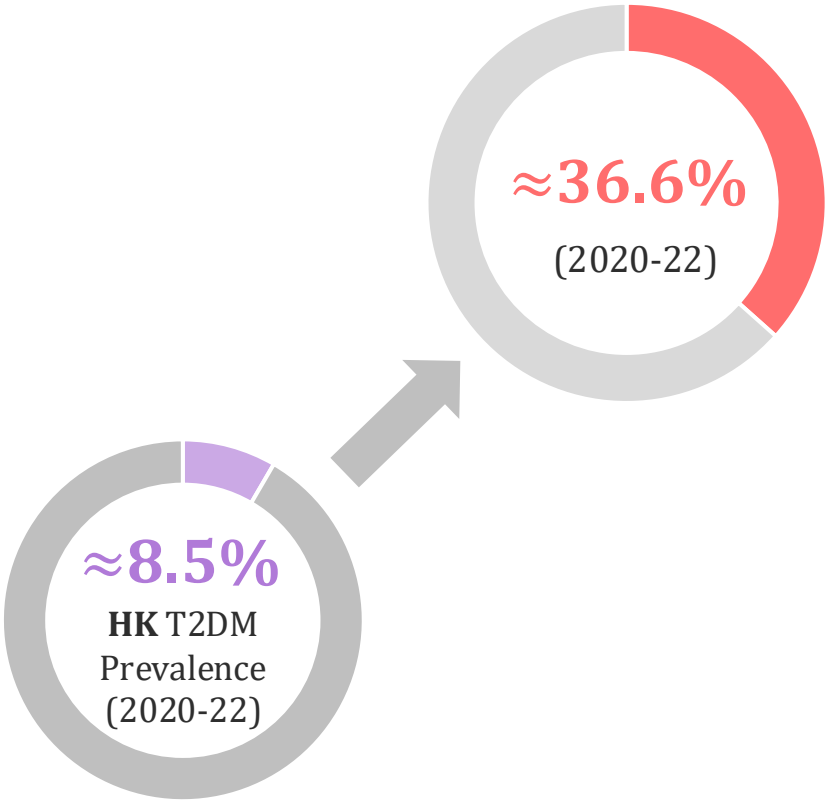


More than **1/3** of T2DM patients in HK are unaware of their diagnosis

Delayed T2DM diagnosis and treatment:

- ↑ acute and chronic macro/microvascular complications
- Negatively impacts patients' QoL
- Socioeconomic burden on both individuals and public healthcare system

# Study Background

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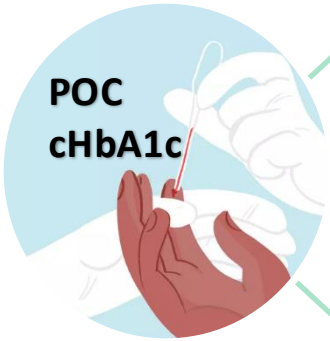
**2-Step Active Opportunistic Screening**

**Targeting**

**At-risk Individuals in Primary Care Setting**




- Stable and convenient
- **>85%** sensitivity & specificity for T2DM screening

- **Eliminate** the need for venipuncture and lab support

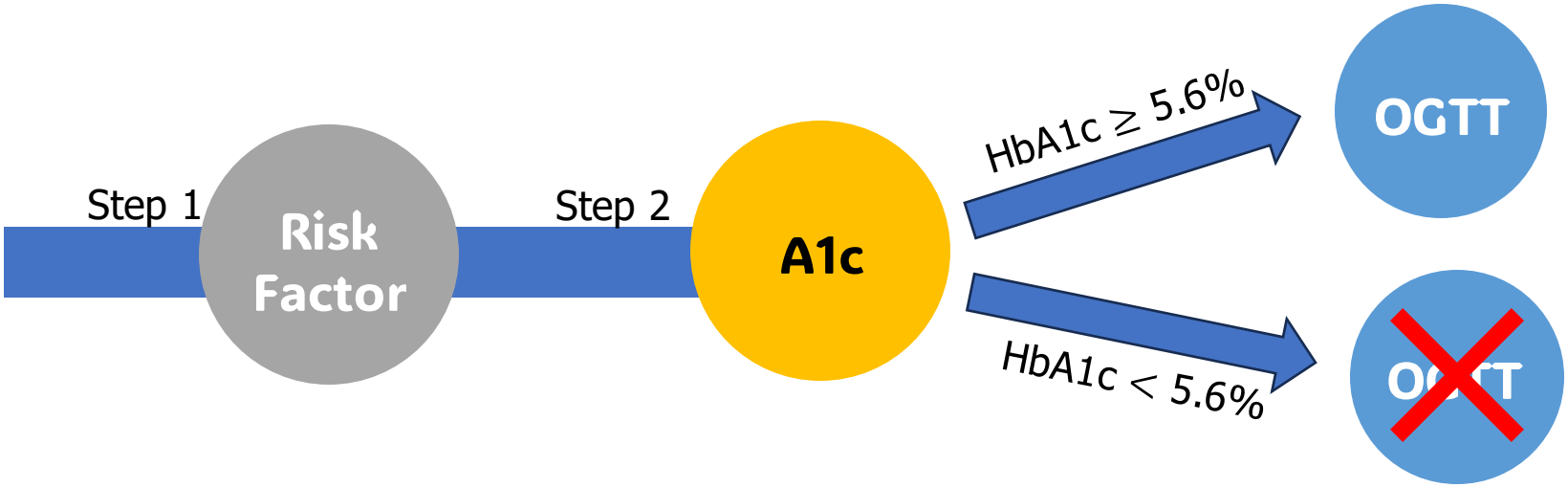

- **Immediate** feedback to patient regarding T2DM risk and need for further testing

**Early T2DM Diagnosis and Referral for Early Management**

# Study Aims & Objectives



Determine the effectiveness of ***active opportunistic 2-step T2DM screening strategy*** in general out-patient clinics




Using point-of-care capillary HbA1c (**POC cHbA1c**) vs conventional venous HbA1c (**vHbA1c**) testing in improving T2DM detection among at-risk primary care patients

# Study Outcomes



## Primary Outcomes

1. The difference in **proportion of T2DM detected** between the intervention group (POC cHbA1c testing) and control group (conventional vHbA1c testing)
2. The **uptake rate of POC cHbA1c testing vs. vHbA1c testing** among consented participants

## Secondary Outcomes

1. The **proportion of subjects with high-risk HbA1c concentration (HbA1c ≥ 5.6%)** among the studied at-risk group
2. The difference in **uptake rate of diagnostic OGTT** (intervention vs. control group)
3. The Number-Needed-to-Screen **(NNS)** for POC cHbA1c to detect one more case with T2DM compared to vHbA1c testing
4. The **proportion of patients who refuse to join** the study (among all eligible subjects)

# Study Flow



**Recruitment**

**Primary Care Patients**
Recruited from 8 different public primary care clinics in HK

**Step 1 Active Opportunistic Risk Factor Screen**

**Eligibility Screen by Trained Research Assistants**

***Inclusion criteria (any below):***
- **Age ≥ 45**
- **First-degree relatives with T2DM**
- **History of Gestational DM**
- **Hypertension**
- **IFG/IGT**
- **Lipid disorder**
- **Obesity (BMI ≥ 25 kg/m$^2$)**

***Exclusion criteria:***
- Known DM / on OHA Rx
- Received T2DM screening test within 12 months
- Pregnant / breast-feeding
- Active thyroid diseases or anaemia
- On iron / systemic steroid Rx
- History of blood donation/ blood transfusion within 3 months

Excluded if met any exclusion criteria

# Study Flow

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**Enrollment**

**852** Eligible patients who provided written consent to join study

**Step 2** HbA1c screen for abnormal glycaemic status (random allocation by clinic 1 : 1)

**Intervention clinics**
**(N=433; from 4 clinics)**

- ✓ **On-site** POC cHbA1c testing offered
- ✓ **Immediate face-to-face** notification of HbA1c level and risk of T2DM

If HbA1c **≥ 5.6%**

- ✓ **On-site immediate invitation** to schedule OGTT visit at the same clinic within 2 – 4 weeks

**Control clinics**
**(N=419; from 4 clinics)**

- ✓ **vHbA1c** testing offered, scheduled on a separate clinic visit within 2 weeks
- ✓ **Phone contact** to inform HbA1c level and risk of T2DM when result available

If HbA1c **≥ 5.6%**

- ✓ **Phone invitation** to schedule OGTT visit at the same clinic within 2 – 4 weeks

Proceed to confirmatory OGTT for T2DM if HbA1c ≥ 5.6%

**Follow-up OGTT**
T2DM if : **FG ≥ 7.0** mmol/L +/or **2h PG ≥ 11.1** mmol/L

# Recruitment Flow Chart

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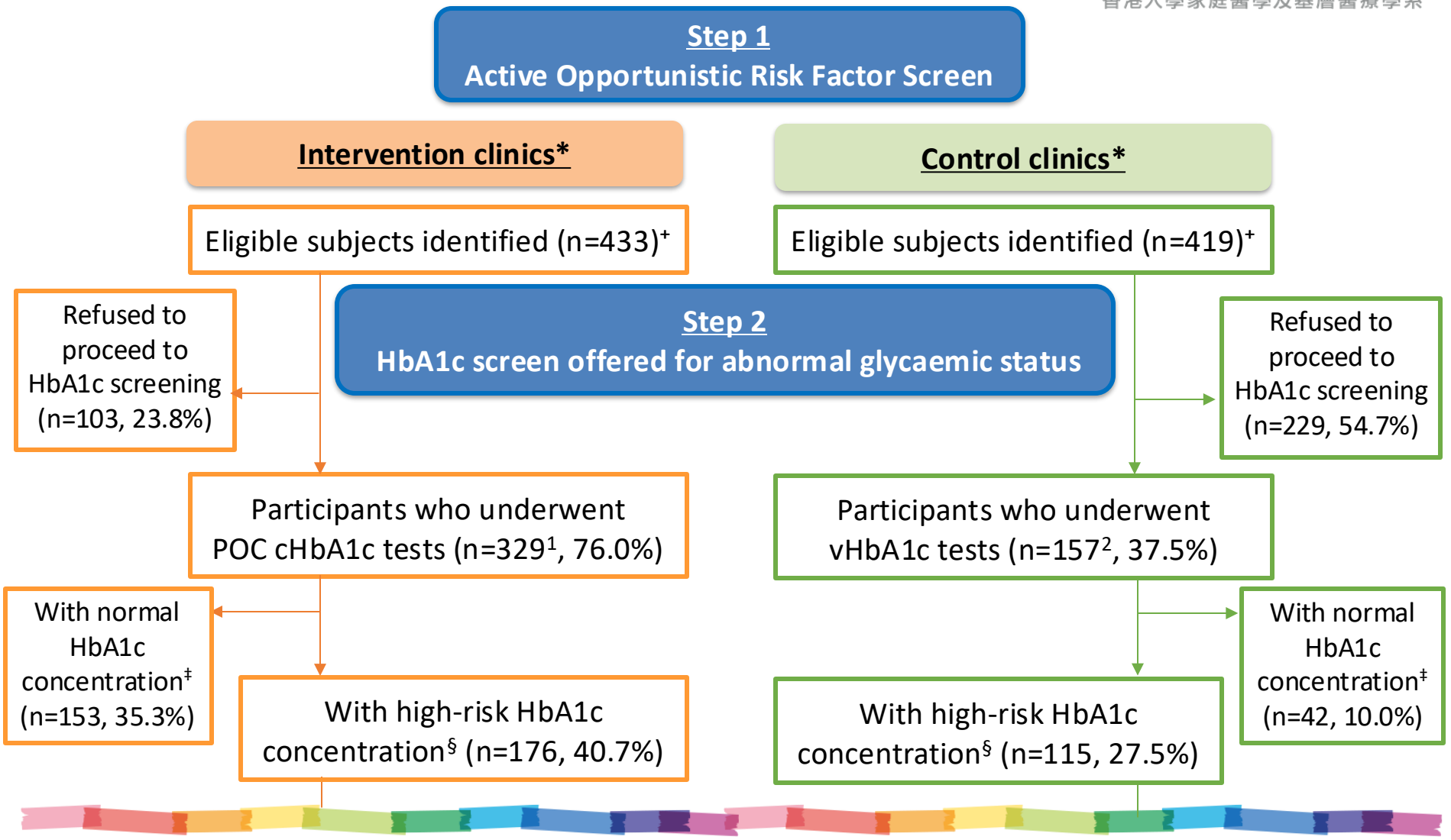


醫院管理局 HOSPITAL AUTHORITY

*Hong Kong West Cluster*

# Recruitment Flow Chart Cont.

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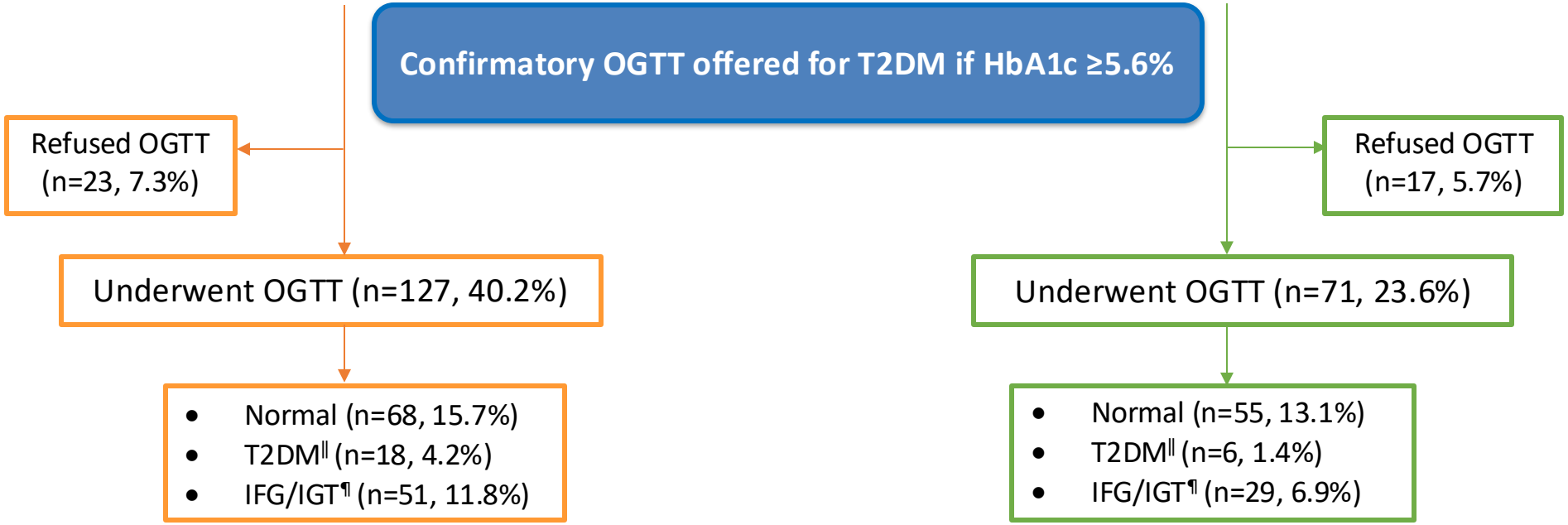


*Note*. HbA1c=Glycated haemoglobin; POC cHbA1c=Point-of care capillary HbA1c; vHbA1c=venous HbA1c; OGTT=Oral glucose tolerance test; T2DM=Type 2 diabetes mellitus; IFG=Impaired fasting glucose; IGT=Impaired glucose tolerance.

[1]In total, 330 enrolled patients agreed to proceed to POC cHbA1c screening, yet one patient refused to undergo POC cHbA1c testing later.

[2]In total, 190 enrolled patients agreed to proceed to vHbA1c screening, yet 33 patients refused to undergo vHbA1c testing due to personal circumstances.

[*] Point-of care capillary HbA1c testing for intervention; venous HbA1c testing for control.

[†] Cases with missing data are removed from the analysis.

[‡]Normal HbA1c concentration refers to HbA1c <5.6%.

[§]High-risk HbA1c concentration refers to HbA1c ≥5.6%.

[‖]T2DM refers to fasting glucose ≥7.0 mmol/L and/or 2-hour post-challenge plasma glucose concentration (2h PG) ≥11.1 mmol/L according to the American Diabetes Association.

[¶]IFG (impaired fasting glucose) refers to fasting glucose between 5.6-6.9 mmol/L, and IGT (impaired glucose tolerance) refers to 2h PG between 7.8-11.0 mmol/L according to the American Diabetes Association.

# Primary Outcomes

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## Primary Outcomes

| Intervention (POC cHbA1c) | Control (vHbA1c) |
|---|---|
|  |  |
| 1 Proportion of ***T2DM*** detected = 4.2% | 1 Proportion of ***T2DM*** detected = 1.4% |
| 2 Uptake rate of ***POC cHbA1c*** = 76.0% | 2 Uptake rate of ***vHbA1c*** = 37.5% |
| 3 IFG/IGT = 11.8% | 3 IFG/IGT = 6.9% |

# Secondary Outcomes

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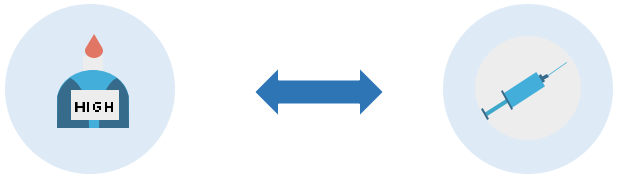
## Secondary Outcomes




| | | | |
|---|---|---|---|
| 1 | Proportion of ***HbA1c concentration*** $\geq 5.6\%$ = | 40.7% | 27.5% |
| 2 | Uptake rate of diagnostic ***OGTT*** = | 33.5% | 22.7% |
| 3 | Proportion of **patient refused** = | 23.8% | 54.7% |

**NNS** to detect one more T2DM case using POC cHbA1c vs. vHbA1c

# Major Findings (POC cHbA1c)

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## 7.06 Higher Odds of Uptake

Our study supports POC cHbA1c's acceptability among at-risk population, highlighting its time-efficient and feasible nature

## Screening Efficiency & Effectiveness

61
NNS

11.8%
Pre-DM

4.2%
T2DM

## Factors Associated with Overall Detection Rate (T2DM & Pre-DM)

1. History of Gestational Diabetes: OR=3.67, 95% CI [1.34-10.03], $p$=0.012
2. Obesity: OR=2.76, 95% CI [1.68-4.54], $p$<0.001
3. Age: OR=1.04, 95% CI [1.02-1.06], $p$<0.001

# Implications



Novel POC cHbA1c testing can enhance efficiency & effectiveness of T2DM screening services

Potential to improve T2DM detection among hard-to-reach patients


Earlier Management

↓ **Micro/macrovascular** complications
↓ **Burdens** on patient, family and healthcare system

Well-accepted by patients, accessible & feasible T2DM screening test

Enhances service-wide applicability of POC cHbA1c

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# Thank You!