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Prevalence of type 2 diabetes mellitus (T2DM) in the adult Russian population (NATION study)



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ABSTRACT

Aim: To estimate type 2 diabetes mellitus (T2DM) prevalence in Russian adults.

Methods: NATION is a national, epidemiological, cross-sectional study, conducted in Russia.

In adults (aged 20–79 years), recruitment was stratified by age, sex, geographic region and settlement type to obtain a representative sample. Recruitment was in public areas with high numbers of people. T2DM was diagnosed by glycated haemoglobin A1c (HbA1c) levels

(diabetes: HbA1c \geq 6.5% [\geq 48 mmol/mol]; pre-diabetes: HbA1c \geq 5.7 to <6.5% [\geq 39 to <48 mmol/mol]). Socio-demographic and anthropometric data were collected.

Results: Blood samples from 26,620 subjects were available. Overall, 5.4% were diagnosed with T2DM (previously diagnosed: 2.5%; previously undiagnosed: 2.9%); 19.3% were prediabetic. T2DM prevalence increased with age (up to 70 years) and was higher among females than males (6.1% vs. 4.7%, p < 0.001). The estimated proportion of subjects with prediabetes and T2DM tended to increase with increasing body mass index. T2DM prevalence was higher in rural versus urban populations (6.7% vs. 5.0%, p < 0.001).

Conclusion: In the Russian adult population, 19.3% had pre-diabetes, T2DM prevalence was 5.4%, and 54% of subjects with diabetes were previously undiagnosed. These results may help to develop a new T2DM predictive, preventative and management programme in Russia.

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1. Introduction

Prevalence of diabetes mellitus (DM) is growing worldwide and has reached epidemic proportions in many developing and most developed countries [1,2]. A recent report noted an

estimated prevalence of diabetes of 9.2% (uncertainty interval 4.7–13.3%) for the adult population aged 20–79 years in Russia [2]. According to this estimated prevalence, in Russia, ~12.1 million (uncertainty interval 6.2–17.0 million) people aged 20–79 years old are thought to have DM in 2015 [2]. Thus, Russia is ranked fifth in the top 10 countries with the largest

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population living with DM. However, this estimate might not be reliable as it is extrapolated from diabetes prevalence in the neighbouring countries. An earlier report gave a rather conservative estimate of DM prevalence (3.2%, 3.5 million/110 million adult population of Russia) [3], but sample populations previously evaluated were not representative of the general Russian population [4]. Furthermore, more recently, epidemiological studies in several Russian regions have shown that DM prevalence may be greater than previously reported [5]. The inconsistencies in reporting DM prevalence has led to an assumption that a substantial number of individuals in Russia remain undiagnosed. Given the growing economic burden of type 2 DM (T2DM), there is a need to conduct a well-designed, epidemiological study to improve the accuracy of prevalence estimates.

In 2013, Russian and French officials met to discuss the prospect of co-operation for conducting a large-scale, epidemiological study, the NATION study, to evaluate accurately T2DM prevalence in Russia [6]. Results of this study would be useful for Public Health authorities in decision making to define health priorities, to develop healthier lifestyles and better diabetes care to eventually reduce T2DM and its complications.

The aim of the NATION study was to evaluate the prevalence of T2DM in the adult Russian population, the relationship of T2DM with age, sex and body mass index (BMI), and to compare the prevalence between urban and rural populations. A sampling model was developed to adequately represent the Russian adult population using population data from the Russian Population Census [7].

2. Materials and methods

2.1. Study design and recruitment

NATION is a national, epidemiological, cross-sectional study, which was conducted across the eight districts of the Russian Federation from September 2013 to February 2015. Sixty-three regions were included and 188 settlements comprised of 90 cities/towns (urban) and 98 rural settlements. Urban and rural settlements were defined as per the Federal State Statistics Service [7]. Details of the recruitment method are shown in Supplementary Table 1. Adults aged 20-79 years were recruited by age, sex, geographic distribution and type of settlement. Recruitment was conducted in public places with a high concentration of people (e.g. streets, squares, parks and other community areas) in urban areas, and in the streets of rural areas. Subjects were consecutively recruited until quotas for sex, age and settlement type were reached. Any subject who, when asked, stated that they had T1DM was excluded from recruitment. Subjects were asked to complete a survey on socio-economic status, health and lifestyle habits. All subjects provided written informed consent prior to study participation. The study was performed in accordance with applicable ethical principles outlined in the Helsinki Declaration and guidelines for Good Clinical Practice [8,9]. Ethical approval was provided by the Independent Multidisciplinary Committee on Ethical Review of Clinical Trials of the Russian Federation.

2.2. Sampling

For the NATION study, a representative sample frame was constructed based on the general population profile of Russia, i.e. the distribution of the whole Russian population (aged 20–79 years) and based on Russian regions (population structure based on age, sex, and settlement type). These population data were sourced from the Russian Population Census [7].

A sample size of 26,000 subjects was required so that the diabetes prevalence could be estimated to within 0.6 percentage points of the true value with 95% confidence, assuming an expected prevalence of diabetes equal to 5%. A multi-stage selection method with quotas for age, sex and settlement type was used to design the appropriate sampling frame (see Supplementary Table 2 for full details).

2.3. T2DM evaluation methodology

A survey based on a structured questionnaire was conducted (Aston Consulting, Moscow, Russia), BMI (without any outer clothing and shoes) was assessed, and whole venous blood samples (2 mL, EDTA tubes; fasting status was not necessary) were collected during laboratory/mobile unit visits. Blood samples were kept at 2-8 °C and transported to a central laboratory (INVITRO, Moscow, Russia) within a maximum of 5 days from collection. HbA1c levels were analyzed by capillary electrophoresis of whole blood [10] using a Capillarys 2 Flex-Piercing instrument (Sebia Inc, Norcross, GA, USA). An internal quality control (QC) was performed daily and the between-run coefficient of variability (CV) was <4%, and the mean internal QCs were 5.1% and 5.3%. An external QC of the analysers in the central laboratory compared with all other laboratories in the European Reference Laboratory database in 2013, demonstrated excellent repeatability (CV 1.2%) and linearity (CV 0.9983) of the method.

Following data collection, several groups were identified: (1) subjects previously diagnosed as T2DM subjects (anamnestic information), pharmacologically treated or not; (2) subjects previously undiagnosed as T2DM subjects based on HbA1c \geq 6.5% (\geq 48 mmol/mol); (3) subjects defined as having prediabetes based on HbA1c \geq 5.7% and <6.5% (\geq 39 to <48 mmol/mol) and without a previous T2DM diagnosis.

2.4. Objectives

The primary objective of the NATION study was to evaluate the prevalence of previously diagnosed and previously undiagnosed T2DM, and pre-diabetes in the adult Russian population. Secondary objectives included evaluation of the urban and rural distributions of T2DM, and T2DM relationship with demographic characteristics (age and sex) and BMI.

2.5. Statistical analyses

All data (socio-demographic determinants, anthropometric measurements, HbA1c results, and survey responses) were entered into a unified database after the field phase. Statistical analyses were performed using standard data processing packages (SPSS statistical software, version 20.0; SPSS Inc.,

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