The Second Clinical Survey of the Population-based Study on Health and Living Conditions in Regions with Sami and Norwegian Populations - the SAMINOR 2 Clinical Survey.

Performing Indigenous Health Research in a Multiethnic Landscape

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Abstract

Background

Globally, there is a huge lack of relevant research about widespread lifestyle diseases and living conditions in indigenous communities. Northern and Middle Norway have a history of multiple ethnic groups, and the Sami has been acknowledged as the indigenous people of Norway by the Norwegian State. The SAMINOR 2 Clinical Survey, a part of the SAMINOR Study, was carried out to provide health information about the Sami population in Norway.

Methods

The cross-sectional population-based SAMINOR 2 Clinical Survey consists of both questionnaires and a clinical examination performed in 10 municipalities during 2012-2014.

Results

In total, 6004 men and women (participation rate 48%) aged 40-79 years, attended. In inland Finnmark, the Sami are the majority (80-90%) as opposed to the coastline of Troms and Nordland, where the Sami population form a minority (20%). More women than men participated (54% *versus* 43%, respectively). Obesity was prevalent in this sample, and a high mean glycated hemoglobin was observed.

Conclusions

This article describes the methods and data collection of the SAMINOR 2 Clinical Survey and presents some characteristics of the sample. The definition of ethnic groups is a core question in the survey, and includes several criteria. To ensure that indigenous values and priorities are reflected in the research themes, we recommend that future research projects be directed in close collaboration with the Sami Parliament and the local communities.

Keywords: Indigenous health research, Sami, Norwegian, ethnicity, SAMINOR, Survey,

Key messages

- The SAMINOR Clinical Survey provide important insight regarding lifestyle and disease development in the indigenous Sami population, as well as the general population in these rural municipalities of Northern Norway
- The definition of ethnic groups is a core question in the survey. One main challenge is the lack of ethnic identifiers in national data systems due to legislative prohibitions against the collection of data on ethnicity. Therefore, in health research, indigenous identification relies on self-reporting
- The education level was high, including in areas in which the Sami are in the majority
- SAMINOR data are a shared resource, planned and formed together with the municipalities and the Sami Parliament in Norway

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Background

Worldwide, there is increasing focus on the health of indigenous peoples. Previous studies have reported poorer outcomes for key health indicators among indigenous populations than benchmark populations (1-4). Indigenous populations often represent a minority group in the countries in which they reside, and they suffer from a disproportionate burden of morbidity and mortality (1, 5). These health gaps may be attributed in part to differences in socioeconomic status and living conditions (1, 6). Still, there is an enormous lack of relevant research on lifestyle diseases and living conditions in indigenous communities.

The Sami are acknowledged by the Norwegian State as an indigenous people (7). Sápmi – the traditional Sami settlement area – has been inhabited by the Sami for thousands of years. Sápmi covers the northern parts of Norway, Sweden, Finland, and Russia's Kola Peninsula, with the largest proportion of the Sami population living in Norway (8). There are grave deficiencies in demographic information on the Sami population, with no existing reliable or updated records, but the estimates of the total number of Sami in Norway usually vary between 40,000 and 50,000.

Sápmi is also home to the Kvens, who are the descendants of Finnish-speaking settlers who immigrated from Sweden and Finland to Northern Norway in the 1700s and 1800s (9). The Kvens were recognized as a national minority in 1998, although they are not indigenous.

This paper presents a synopsis of the SAMINOR 2 Clinical Survey and aims to give an overview of the objectives, study design, data collection, attendance, some clinical findings

and characteristics of the participants; and highlight the study as an example of how to perform health research among indigenous populations.

Settings

Finnmark, Troms, and Nordland Counties are generally referred to as Northern Norway and consists of 87 municipalities with a population size in 2014 of 482,000 inhabitants (10). The following 10 municipalities were included in the SAMINOR 2 Clinical Survey: Kautokeino, Karasjok, Porsanger, Tana, Nesseby, Kåfjord, Storfjord, Lyngen, Skånland, and Evenes (Figure 1). These 10 municipalities were also included in the SAMINOR 1 Survey (2003-2004) (11) and the SAMINOR 2 Questionnaire Survey (2012-2014) (12). Due to limited resources, only 10 of the 24 participating municipalities in the preceding SAMINOR 1 Survey were included in the present survey. Areas where we expected to find a high proportion of people with a Sami background were selected (11). Altogether, the SAMINOR 1 Survey, the SAMINOR 2 Questionnaire Survey, and the SAMINOR 2 Clinical Survey constitute the SAMINOR Study.

In the present paper, we categorized the 10 municipalities in the SAMINOR 2 Clinical Study into four regions (Figure 1), according to their dialect, culture, geographic location, and proportion of inhabitants of Sami ethnicity. Region 1 includes the inland municipalities of Kautokeino and Karasjok in Finnmark County, where the Sami represent a large majority. Region 2 consists of the other municipalities in Finnmark County, namely Tana, Nesseby, and Porsanger, which have vast inland tundra areas in addition to coastline. Region 3 consists of three municipalities in the coastline of the northern part of Troms County: Kåfjord, Storfjord, and Lyngen. Finally, Region 4 consists of Skånland and Evenes municipalities, located on the border between Troms and Nordland Counties.

Subjects

All citizens aged 40-79 years in the selected municipalities were invited (n=12,577). After the removal of duplicates, and the exclusion of those who had moved, died, or had incorrect addresses, the final eligible study sample was 12,455. Of these, 6,004 (48.2%) men and women participated (Figure S1 in the supplementary material).

Logistics

A small team of 3-5 employees (researchers, technicians, and administrative personnel) from the Centre for Sami Health Research (CSHR) at UiT The Arctic University of Norway conducted, planned, and implemented the SAMINOR 2 Clinical Survey, along with temporarily-employed fieldworkers who were primarily local, certified health workers.

All the necessary equipment, such as individual sampling kits, instruments, computers, refrigerators, and freezers were prepared and packed at the UiT The Arctic University of Norway and transported by removal companies. The CSHR team had preparatory meetings with municipal authorities and health professionals to inform them about the survey and ensure they would promote the survey through municipal websites and other media.

Invitation

One to 2 months prior to the data collection, data on the name, postal address, and unique national personal identification number of the target population to be invited were collected from the Norwegian National Population Register at the Norwegian Tax Administration, and each invitee was assigned a unique identity code (survey ID). Three to 4 weeks before the survey began, a pamphlet was posted to inform invitees about the coming survey. Approximately 2 weeks prior to data collection, the invitation letter was posted to invitees; it included an appointment time, an informational brochure and a questionnaire, which

contained invitee's assigned study ID. Halfway through the data collection period, a reminder was sent to invitees who had not yet attended.

The pamphlet, informational brochure, invitation letter and questionnaire were developed in Norwegian, but also translated into Northern Sami by professional translators (Table S1 in the supplementary material).

The pamphlet and the informational brochure were also translated into Kven. All pamphlets, informational brochures, invitations, and questionnaires are accessible on our website (<u>www.saminor.no</u>).

Data collection

Data was collected through self-administered questionnaires, clinical examinations and blood sampling. Depending on the population size, data collection in each municipality was conducted within 2-7 weeks.

Questionnaires

An eight-page, self-administered questionnaire was posted to invitees aged 40-69 years, whereas those aged 70-79 years received a four-page questionnaire with fewer questions and larger fonts. The questionnaires were developed in collaboration with various researchers and included a combination of new questions and questions from previous SAMINOR surveys or other comparable surveys. The questionnaires covered information regarding selected diseases, as well as health-related topics, chronic pain (World Health Organization pain scale) (13, 14), socio-economic status, ethnicity, physical activity, tobacco and drug/alcohol use, and oral/dental health. For women, questions on childbirth and breastfeeding were included. In addition, the questionnaire for invitees aged 40-69 years included a food frequency questionnaire adapted from the Norwegian Women and Cancer (NOWAC) Study (15),

together with questions regarding sun-bathing habits, use of skin care products, body size perception, anxiety/depression ("The Hopkins Symptom Checklist, HSCL-5") (16), and sleeping patterns. Experiences with health care services including the use of a Sami-speaking interpreter, was included in the questionnaire addressed to invitees aged 70-79 years.

The questions regarding ethnicity were identical to those used in former SAMINOR surveys. A total of 11 questions covered language, ethnic background, and self-perceived ethnicity: "*What language(s) do/did you, your parents and your grandparents use at home?*"; The questions about home language are objective criteria used in the definition of ethnicity. "*What is your, your father's and your mother's ethnic background?*"; Ethnic background is a form of cultural identity that is created and maintained through contacts with other groups and also reflects what the surrounding define the participant to be. The last question "*What do you consider yourself to be?*" reflects the participant's own self-perceived ethnicity/identity and is a subjective criterion. On all questions the response options were: "Norwegian", "Sami", "Kven", and "Other". The questions were to be answered separately for each relative and multiple choices were allowed. Sami ethnicity can be defined in different ways, depending on the criteria. In the present paper, Sami affiliation is defined when the participant responded "Sami" to at least one of these questions. This is the widest possible definition.

Clinical examination, blood sampling, and biobanking

The procedures followed a strict protocol, in which all fieldworkers became proficient during their training.

Once called for examination, participants were registered, signed a written consent form, and completed and handed in their questionnaire. Then, height, weight, and body mass index (BMI, kg/m²) were measured using an electronic Height, Weight & Fatness Measuring System device (DS-103, Dongsahn Jenix, Seoul, Korea) with the participants wearing light clothes and no shoes. Body weight was measured in kilograms with one decimal, and height was measured in cm with one decimal. Hip and waist circumference were measured with a band to the nearest centimeter with the participant standing erect. Waist circumference was measured at the umbilicus and hip circumference was measured at level of the iliac crest (hip bone), both to the nearest cm.

Blood pressure and resting heart rate were measured, with the participant sitting with the arm resting at the level of the heart. The time interval between arrival to the examination site and blood pressure measurement was at least 15 minutes. Initially, the circumference of the upper part of the right (optimal) arm was measured to find the correct cuff. After a 2-minute rest, three measurements were taken at 1-minute intervals, using an automatic device (CARESCAPETMV100 monitor, <u>GE Healthcare, Milwaukee, Wisconsin</u>, USA). The mean of second and third measurements was used in the analysis.

Finally, blood sampling was performed, following a strict quality protocol. Non-fasting blood samples were drawn by venipuncture with participants in a seated position. Descriptions of the blood analyses are provided in Supplementary material. Blood samples were stored on site at -20°C in a manual freezer and after some weeks transported to the biobank at UiT The Arctic University of Norway. The serum samples were later stored at -70°C in manual ultra-freezers, while serum clots and serum and whole blood for persistent toxic substances and essential elements were stored at -35°C ((Table S2 in the supplementary material).

A range of blood analyses have already been performed on these samples, including indicators for cardiovascular disease, diabetes mellitus, inflammation, hematology, vitamins, environmental contaminants, and essential elements ((Table S3 in the supplementary material).

In addition, blood samples for later analyses of novel biomarkers and DNA have been stored.

Feedback to participants and medical recommendations

Immediately after the examination, participants received information on their available clinical measures (height, weight, blood pressure, heart rate, hemoglobin (Hb), and glycated hemoglobin (HbA1c)) both orally and in writing in the Norwegian or Sami language. If there was an indication of pathology, participants were recommended to contact their general practitioner for a check-up. Medical referral included high blood pressure, tachycardia, elevated Hb, anemia, and elevated HbA1c. Recommendations were given according to the degree of severity, following pre-set cut-off values (Table 1). In case of serious pathology, the local general practitioner or hospital was contacted right away.

Ethics

The Norwegian Data Protection Authority and the Regional Committees for Medical and Health Research Ethics (REC North) approved the SAMINOR Study. The REC North also approved the present study. All participants gave written informed consent, which included a consent to later linkages to national registers, previous censuses, and cardiovascular screenings. Following the Norwegian Health Research Act (17), all research projects that plan to use data from the SAMINOR 2 Clinical Survey need approval from the REC North and from the SAMINOR Project Board.

Privacy and data security

Data is stored de-identified with a unique survey ID. The linkage between the survey ID and the person's 11-digit national ID number is stored separately from the data file within the

secure EUTRO system, which is a module-based unique database solution for research, developed at the Department of Community Medicine, UiT The Arctic University of Norway.

Statistics

The participation rate is presented in numbers (n) and percent (%), stratified by sex and 5-year age groups. Sample characteristics and subjective and objective criteria of ethnicity were stratified by geographic region. Continuous variables are presented as means and standard deviations, and categorical variables are presented as number and percent. Geographic differences were tested by analysis of variance and by Pearson's χ^2 test, for continuous and categorical variables, respectively. Clinical measures and results of blood samples are presented as means and 95% confidence intervals (CI), stratified by sex and four age groups. Geometric mean was used in case of skewed distribution. All tests were two-sided with a 0.05 significance level. SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for data management and statistical analyses.

Results

Overall, more women than men participated (54.4% *versus* 42.5%, respectively) (Table 2). Participation increased with increasing age in both sexes, except for a lower participation for those aged 75-79 years. Participation was highest in Kautokeino municipality (56%) and lowest in Evenes municipality (41%). Participation was particularly high among women in Kautokeino (67%) (Figure 2).

The highest mean age was among participants in Region 3 (60.2 years) and the lowest mean age was observed in Region 1 (58.3 years) (Table 3). The age group 60-69 years constituted one-third of the study sample. There were significant differences regarding marital status between regions, with the highest proportion of married couples in Region 4 and lowest

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in Region 2. Cohabitation was most common in Region 2 and most infrequent in Region 3. The education level was high in this population, as 40% had 13 years or more of schooling. Region 3 stood out with a significantly lower education level than the other regions.

In total, 54% of the study sample reported Sami affiliation. In Region 1, almost 90% of the participants had Sami affiliation. In contrast, Regions 3 and 4 had 39% and 20% Sami affiliation, respectively. In Region 1, a vast majority of the sample reported "Sami" as their domestic language, ethnic background, and self-perceived ethnicity, and reported to have four grandparents who spoke Sami at home (Table 4).

The mean BMI among men was 28.3 kg/m^2 . The highest mean BMI was found in the youngest age group. The mean BMI among women was also high (28.0 kg/m^2), and it was highest in the age group 60-69 years (27.9 kg/m^2). Central obesity was also pronounced both for men and women, with mean waist circumferences of 99.6 cm and 93.2 cm, respectively (Table 5).

Discussion

This paper presents the background, objective, and implementation of the SAMINOR 2 Clinical Survey, which comprises a multi-ethnic population aged 40-79 years from 10 municipalities of Northern Norway during 2012-2014. The scientific program of the survey includes several large public health issues, including cardiovascular diseases, diabetes mellitus, mental health, and health services, which are also national health priorities.

The SAMINOR 2 Clinical Survey achieved a response rate of 48%, which is acceptable due to the short period of data collection in each municipality. The participation rate was lower than that in the SAMINOR 1 Survey (61%), conducted 10 years earlier. Declining response rates have also been observed in other population-based studies (18, 19). This decline can partly be explained by a change in design. In the SAMINOR 1 Survey, those in Finnmark and Troms counties who had not attended the clinical examination received a second invitation a couple of months later (11). Due to limited resources, a second chance to participate was not possible in the SAMINOR 2 Clinical Survey. Access to register-based data for non-responders is limited, due to strict regulations. However, information on sex, age, and municipality was available for all invitees, and non-responders were dominated by the youngest invitees and by men. The legislative prohibitions against the collection of data on ethnicity in national registers hinders our ability to assess whether the ethnic distribution in the survey reflects that of the actual population in the selected geographic area. Low participation and the fact that the survey only covered 10 municipalities raise questions about external validity. Indeed, all epidemiological studies raise concerns about generalizability from a specific study sample to the entire target population (20). Accordingly, it is unknown to what extent the results from the SAMINOR 2 Clinical Survey illustrate the real health status and disease burden of the total Sami population or other inhabitants in Northern Norway. However, the internal validity can be high. In upcoming publications, potential

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selection bias, internal validity, and generalizability issues and sensitivity analyzes, must be carefully discussed, in relation to each specific study focus.

The history and development of the Sami people is considerably different from that of the benchmark population in Norway. Like other indigenous peoples, the Sami have been exposed to the pressure of colonization and assimilation for more than 100 years (21, 22). The assimilation process included prohibitions against using the Sami language in schools and other public places, promotion of Norwegian settlements in coastal Sami areas so the coastal Sami became a minority in their traditional settlement areas, in addition to several other initiatives to promote assimilation(23). This was later termed "Norwegianization". (24, 25). According to the late Johan Albert Kalstad, this process can be described figuratively as a tsunami, where the devastating effect was most striking at the coast and declined toward the inland areas (personal communication). This historical backcloth is a challenge when collecting data. It is still controversial to focus on issues facing the Sami population in several of the municipalities included in the survey, and it is not known whether the historical trauma of Norwegianization influenced study participation. A focus on Sami language and ethnicity and the fact that the survey was performed by a Sami research center may have contributed to low participation in some regions. Non-Sami invitees may have perceived the survey as intended for people of Sami origin only, while Sami invitees may have found the questions too personal and invasive. On the other hand, Sami invitees may have felt reassured by the fact that the researchers were of their own people, as suggested by the high response rate in Sami majority areas (Kautokeino, Tana, and Nesseby). Overall participation was low in the coastal regions (Regions 3 and 4), where the assimilation process heavily influenced Sami self-identification and made any focus on Sami ethnicity controversial (21). The education level in our sample was high, including in areas in which the Sami are in the majority. This is in line with previous findings from the SAMINOR 1 Survey (11).

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Educational opportunities increased in the decades following World War II, with the establishment of a university in Tromsø in 1968, in addition to several district colleges, which gave youth from Northern Norway the opportunity to pursue higher education in their own region. A Sami activist wave in the 1960s and 1970s caused young Sami adults, especially women, to pursue higher education (26, 27). Furthermore, the establishment of the Sami Parliament and other Sami institutions during the past 25–30 years increased the job opportunities for educated Sami in their home municipalities.

Due to the heterogeneity of the population being studied, use of ethnicity as an independent variable in epidemiological research is challenging (28). The definition of ethnic groups is a core question in the SAMINOR Study, ascertained by 11 different questions. However, operationalization of the target population must be handled with care. As the questions include both objective and subjective criteria: Sami language, ethnicity, and identity, it is possible to categorize the participants into indigenous *versus* non-indigenous groups in several different ways. In this paper, we have shown some examples. It is recommended that each research project create ethnic categories based on what is most suitable for their specific topic. However, despite the complexities of identifying the Sami population, it is essential to collect indigenous health data for use in the development of better health services.

In the present paper, we present only an overview of some central clinical measures. Mean BMI and waist circumference were rather high in all age groups and both sexes. High prevalence of obesity and metabolic syndrome was already verified in this population in the SAMINOR 1 Survey (11, 29). Obesity is recognized as a risk factor for metabolic syndrome and chronic lifestyle diseases like type 2 diabetes mellitus. Additional attention is consistently given to chronic diseases and unfavorable health factors, but also to factors that contribute to overall health in areas with both Sami and non-Sami population. This knowledge is important to the health care system, health politicians, health researchers, and the public in general (30, 31).

The design of the SAMINOR 2 Clinical Survey makes it possible to identify the indigenous population as well as other ethnic groups, enabling ethnicity-specific analyses. By collecting information on self-reported ethnicity, the survey provides a unique opportunity to link a person's ethnicity to information in national health registers, facilitated by the national 11-digit unique personal identification number. In addition, the survey can be linked with other health surveys, including the SAMINOR 1 Survey and the SAMINOR 2 Questionnaire Survey.

SAMINOR data are a shared resource, planned and formed together with the municipalities and the Sami Parliament in Norway. Good communication with each municipality and the Sami Parliament - before, during, and after data collection - was and is highly prioritized. Indeed, one main aim of the CSHR is to give research information back to the communities where the research is performed. Therefore, anonymous results on group level from the SAMINOR 2 Clinical Survey are communicated to each of the municipalities through health reports and population meetings. We emphasize that understanding and respect of Sami and non-Sami diversity, and people's needs and aspirations, are essential in all research. It is of particular importance that the researcher obtain insight into the wide variety of life in the communities where research is done.

This article presents only an overview of some of the data collected in the SAMINOR 2 Clinical Survey. Upcoming publications from the survey will address lifestyle diseases and indicators, and nutritional topics. We recommend that future research projects be done in close collaboration with the Sami Parliament and local communities to ensure that indigenous values and priorities are reflected in the themes.

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Conclusion

The SAMINOR Clinical Survey has the potential to provide important insight regarding lifestyle and disease development in the indigenous Sami population, as well as the general population in these rural municipalities of Northern Norway. Self-reported ethnicity information enables comparisons between Sami and non-Sami participants. In the future, this data will be used in a wide range of studies, with a special focus on the health of the Sami population. All use of the data must be done with respect for the Sami people and with an understanding of the ethnic heterogeneity of the studied population.

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Authors' Contributions

ARB is the Head of the SAMINOR Study and research leader of the SAMINOR 2 Clinical Survey. She conceived the study, made some of the tables, and wrote the manuscript. MM prepared tables and figures and performed the statistical analyses, contributed to conception and design, and critically revised the paper. SH contributed to conception and design and revised the paper. MM, and SH reviewed subsequent versions, read, and approved the final manuscript. All authors contributed to the interpretation of data and approved the final version of manuscript.

Conflict of interest

Conflict of Interest: none declared.

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Table 1. Cut-offs for medical referral with related recommendations. The SAMINOR 2 Clinical Survey(2012-2014).

	Cut-off for medical referral	Action/recommendation
Systolic BP	≥155 mmHg	Consult your GP within 1-2 months
	≥180 mmHg	Consult your GP within a week
Diastolic BP	≥90 mmHg	Consult your GP within 1-2 months
	≥110 mmHg	Consult your GP within a week
	≥120 mmHg	Emergency action
Pulse	≥100 BPM	Consult your GP within 1-2 months
	≥120 BPM	Consult your GP within 1-2 weeks
	Irregular	Consult your GP within 1 month
Hb	Women: >17.5 g/dl, men: >18.5 g/dl	Consult your GP within 2 months
	Women: <9 g/dl, men: <10 g/dl	Consult your GP within 1-2 weeks
	≤8 g/dl	Emergency action
HbA1c	≥6.2%	Consult your GP within 3 months
	≥12.0%	Consult your GP within 1 months

hemoglobin

 Table 2. Participation by sex and age group. The SAMINOR 2 Clinical Survey (2012-2014, n=12,455)*.

	Men		\	Women		Total	
Age (years)	Invited	Attended (%)	Invited	Attended (%)	Invited	Attended (%)	
40–44	867	255 (29.4)	836	388 (46.4)	1,703	643 (37.8)	
45–49	907	283 (31.2)	795	364 (45.8)	1,702	647 (38.0)	
50–54	883	319 (36.1)	777	406 (52.3)	1,660	725 (43.7)	
55–59	897	372 (41.5)	848	481 (56.7)	1,745	853 (48.9)	
60–64	970	481 (49.6)	872	535 (61.4)	1,842	1,016 (55.2)	
65–69	930	488 (52.5)	817	504 (61.7)	1,747	992 (56.8)	
70–74	591	336 (56.9)	550	333 (60.5)	1,141	669 (58.6)	
75–79	424	213 (50.2)	491	246 (50.1)	915	459 (50.2)	
Total	6,469	2,747 (42.5)	5,986	3,257 (54.4)	12,455	6,004 (48.2)	

* The total population aged 40-79 years in 10 municipalities were invited.

	Region 1	Region 2	Region 3	Region 4		
		Tana	Kåfjord			
	Kautokeino	Nesseby	Lyngen	Evenes		
	Karasjok	Porsanger	Storfjord	Skånland	Total	
	(n=1,289)	(n=2,011)	(n=1,665)	(n=1,039)	(n=6,004)	P-value
Age (years), mean (SD)	58.3 (10.4)	59.2 (10.4)	60.2 (10.6)	60.1 (10.2)	59.4 (10.5)	<0.0001
Age groups, n (%)						<0.0001
40–49 years	310 (24.0)	442 (22.0)	351 (21.1)	187 (18.0)	1,290 (21.5)	
50–59 years	374 (29.0)	540 (26.9)	388 (23.3)	276 (26.6)	1,578 (26.3)	
60–69 years	401 (31.1)	664 (33.0)	569 (34.2)	374 (36.0)	2,008 (33.4)	
70–79 years	204 (15.8)	365 (18.2)	357 (21.4)	202 (19.4)	1,128 (18.8)	
Total	1,289	2,011	1,665	1,039	6,004	
Sex, n (%)						0.06
Men	551 (42.7)	947 (47.1)	757 (45.5)	492 (47.4)	2,747 (45.8)	
Women	738 (57.3)	1,064 (52.9)	908 (54.5)	547 (52.6)	3,257 (54.2)	
Total	1,289	2,011	1,665	1,039	6,004	
Education (years), mean (SD)	12.2 (4.6)	12.2 (3.8)	11.5 (3.8)	12.4 (3.7)	12.0 (4.0)	<0.0001
Education, n (%)						<0.0001
≥13 years	528 (43.7)	822 (42.5)	546 (34.2)	425 (42.9)	2,321 (40.5)	
<13 years	680 (56.3)	1,114 (57.5)	1,051 (65.8)	565 (57.1)	3,410 (59.5)	
Total	1,208	1,936	1,597	990	5,731	
Marital status, n (%)						<0.0001
Married	698 (54.9)	1,009 (50.6)	1,026 (62.8)	668 (65.2)	3,401 (57.4)	
Cohabiting	173 (13.6)	361 (18.1)	195 (11.9)	130 (12.7)	859 (14.5)	
Divorced	110 (8.6)	243 (12.2)	121 (7.4)	79 (7.7)	553 (9.3)	
Unmarried	208 (16.4)	267 (13.4)	164 (10.0)	83 (8.1)	722 (12.2)	
Widow(er)	83 (6.5)	113 (5.7)	128 (7.8)	65 (6.3)	389 (6.6)	
Total	1,272	1,993	1,634	1,025	5,924	

Table 3. Sample characteristics by geographic regions. The SAMINOR 2 Clinical Survey (2012-2014, n=6,004).

SD, standard deviation

	Region 1	<u>Region 2</u> Tana	<u>Region 3</u> Kåfjord	Region 4	
	Kautokeino	Nesseby	Lyngen	Evenes	
	Karasjok	Porsanger	Storfjord	Skånland	Total
	(n=1,269)	(n=1,990)	(n=1,624)	(n=1,025)	(n=5,908)
	n (%)	n (%)	n (%)	n (%)	n (%)
Domestic language (What lan	guage do you spe	ak at home?)			
Sami	909 (72.0)	418 (21.2)	21 (1.3)	19 (1.9)	1,367 (23.4
Sami and Norwegian	129 (10.2)	198 (10.1)	66 (4.1)	37 (3.6)	430 (7.4
Norwegian	199 (15.8)	1,234 (62.7)	1,472 (92.1)	937 (92.0)	3,842 (65.7
Other	25 (2.0)	118 (6.0)	40 (2.5)	25 (2.5)	208 (3.6
Total	1,262	1,968	1,599	1,018	5,847
Ethnic background (Please ind	dicate your ethnic	background.)			
Sami	1,022 (81.3)	584 (30.4)	71 (4.5)	118 (11.7)	1,795 (31.2
Sami and Norwegian	74 (5.9)	297 (15.5)	193 (12.3)	50 (5.0)	614 (10.7
Norwegian	129 (10.3)	870 (45.3)	1,232 (78.5)	812 (80.7)	3,043 (52.9
Other	32 (2.5)	168 (8.8)	73 (4.7)	26 (2.6)	299 (5.2
Total	1,257	1,919	1,569	1,006	5,75
Self-perceived ethnicity (Who	ıt (ethnicity) do yo	u consider yours	self to be?)		
Sami	958 (76.1)	444 (22.5)	43 (2.7)	60 (5.9)	1,505 (25.7
Sami and Norwegian	136 (10.8)	361 (18.3)	157 (9.7)	68 (6.7)	722 (12.3
Norwegian	140 (11.1)	1,042 (52.9)	1,366 (84.6)	872 (85.5)	3,420 (58.3
Other	25 (2.0)	122 (6.2)	48 (3.0)	20 (2.0)	215 (3.7
Total	1,259	1,969	1,614	1,020	5,86
Sami affiliation ¹					
Sami	1,136 (89.5)	1,225 (61.6)	629 (38.7)	206 (20.1)	3,196 (54.1
Non-Sami	133 (10.5)	765 (38.4)	995 (61.3)	819 (79.9)	2,712 (45.9
Total	1,269	1,990	1,624	1,025	5,90
Number of grandparents with	n Sami as their dor	nestic language			
4	955 (76.1)	608 (31.6)	252 (16.3)	114 (11.5)	1,929 (33.7
1-3	147 (11.7)	502 (26.1)	299 (19.3)	52 (5.3)	1,000 (17.5
0	153 (12.2)	815 (42.3)	997 (64.4)	824 (83.2)	2,789 (48.8
Total	1,255	1,925	1,548	990	5,71

Table 4. Subjective and objective criteria of Sami heritage by geographic regions. The SAMINOR 2Clinical Survey (2012–2014, n=5,908).

¹ Sami affiliation is used when the at least one of the following criteria were met: a) at least one parent, grandparent, or the respondents themselves spoke Sami as a domestic language, <u>or</u> b) the ethnic background of respondents or one of their parents was reported to be Sami, <u>or</u> c) the respondents considered themselves to be Sami. This is the widest possible definition.

Age groups	40–49 years	50–59 years	60–69 years	70–79 years	Total
	Mean (95%	Mean (95%	Mean (95%	Mean (95%	Mean (95%
	CI)	CI)	CI)	CI)	CI)
Men					
Smallest n–largest n ¹	536–538	686–691	966–969	546–549	2,737–2,746
Height (cm)	176.1	174.0	172.5	170.0	173.1
	(175.4–	(173.5–	(172.1–	(169.4–	(172.8–
	176.7)	174.5)	173.0)	170.6)	173.4)
Weight (kg)	88.5 (87.2–	86.0 (85.0–	84.4 (83.5–	80.0 (78.9–	84.7 (84.2–
	89.7)	87.1)	85.3)	81.1)	85.3)
Body mass index	28.6 (28.2–	28.4 (28.1–	28.3 (28.1–	27.6 (27.3–	28.3 (28.1–
(kg/m²)	28.9)	28.7)	28.6)	27.9)	28.4)
Waist circumference	99.4 (98.5–	99.2 (98.4–	100.1 (99.4–	99.6 (98.7–	99.6 (99.2–
(cm)	100.4)	100.0)	100.7)	100.5)	100.0)
Hip circumference	102.7	101.7	101.8	101.8	101.9
(cm)	(102.1–	(101.2–	(101.3–	(101.2–	(101.7–
	103.4)	102.2)	102.2)	102.4)	102.2)
Systolic blood	128.6	131.8	137.2	140.7	134.8
pressure (mmHg)	(127.4–	(130.6–	(136.1–	(139.1–	(134.2–
	129.8)	133.0)	138.3)	142.3)	135.5)
Diastolic blood	77.9 (77.1–	78.5 (77.7–	77.8 (77.2–	74.9 (74.1–	77.4 (77.0–
pressure (mmHg)	78.7)	79.2)	78.4)	75.7)	77.8)
Pulse (BPM)	69.8 (68.8–	69.6 (68.7–	68.9 (68.1–	67.5 (66.5–	69.0 (68.5–
	70.7)	70.5)	69.7)	68.5)	69.4)
HbA1c (%) ²	5.51 (5.47–	5.68 (5.64–	5.84 (5.80–	5.89 (5.83–	5.74 (5.72–
	5.54)	5.72)	5.89)	5.96)	5.77)
Hb (g/dl)	15.28	14.97	14.88	14.48	14.90
	(15.20–	(14.90–	(14.82–	(14.38–	(14.86–
	15.36)	15.04)	14.95)	14.59)	14.94)
Women					
Smallest n–largest n ¹	747–752	879–887	1,037–1,039	577–579	3,245–3,254
Height (cm)	162.1	161.2	159.3	156.8	160.0
	(161.6–	(160.8–	(158.9–	(156.2–	(159.8–
	162.5)	161.6)	159.7)	157.4)	160.2)
Weight (kg)	72.8 (71.7–	72.2 (71.3–	70.8 (70.0–	, 70.5 (69.5–	71.6 (71.1–
	73.8)	73.0)	71.6)	71.5)	72.0)
Body mass index	27.7 (27.3–	27.8 (27.5–	27.9 (27.6–	28.7 (28.3–	28.0 (27.8–
(kg/m^2)	28.1)	28.1)	28.2)	29.1)	28.1)
Waist circumference	91.7 (90.8–	92.8 (92.0–	93.3 (92.6–	95.6 (94.6–	93.2 (92.8–
(cm)	92.7)	93.6)	94.0)	96.5)	93.6)
Hip circumference	102.8	102.8	103.2	105.2	103.4
(cm)	(102.0–	(102.2–	(102.6–	(104.4–	(103.0-
. ,	103.6)	103.5)	103.8)	106.0)	103.7)
Systolic blood	119.8	127.5	134.5	142.9	130.7
pressure (mmHg)	(118.7–	(126.3–	(133.5–	(141.3–	(130.0–
	120.8)	128.6)	135.6)	144.5)	131.3)

Table 5. Clinical measures reported to the participants, by sex and age group, means and 95%confidence intervals (CI). The SAMINOR 2 Clinical Survey (2012–2014, n=6,000).

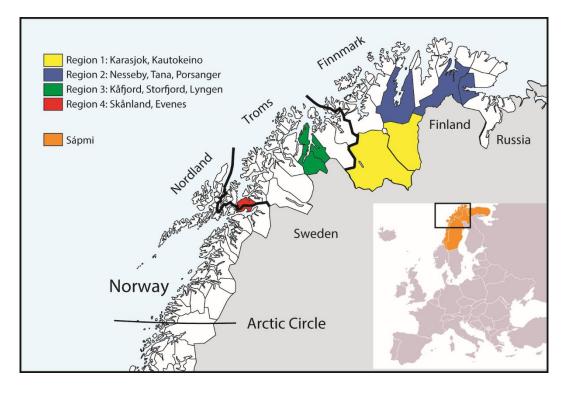
Diastolic blood	71.3 (70.6–	72.6 (72.0–	71.9 (71.4–	72.7 (72.0–	72.1 (71.8–
pressure (mmHg)	72.0)	73.2)	72.5)	73.5)	72.4)
Pulse (BPM)	71.6 (70.8–	71.3 (70.6–	71.2 (70.6–	71.5 (70.4–	71.8 (71.0–
	72.4)	72.1)	71.9)	72.5)	71.8)
HbA1c (%) ²	5.42 (5.39–	5.64 (5.61–	5.77 (5.74–	5.94 (5.88–	5.68 (5.66–
	5.44)	5.67)	5.80)	5.99)	5.70)
Hb (g/dl)	13.48	13.73	13.75	13.56	13.65
	(13.40-	(13.67–	(13.69–	(13.47–	(13.61–
	13.56)	13.80)	13.81)	13.65)	13.69)

¹ Numbers vary due to missing values. Smallest and largest n are therefore provided.

² Geometric mean due to skewed distribution.

Cl, confidence interval; BPM, beats per minute; HbA1c, glycated hemoglobin; Hb, hemoglobin;

Figure 1. Geographical regions and municipalities included in the SAMINOR 2 Clinical Survey 2012–2014



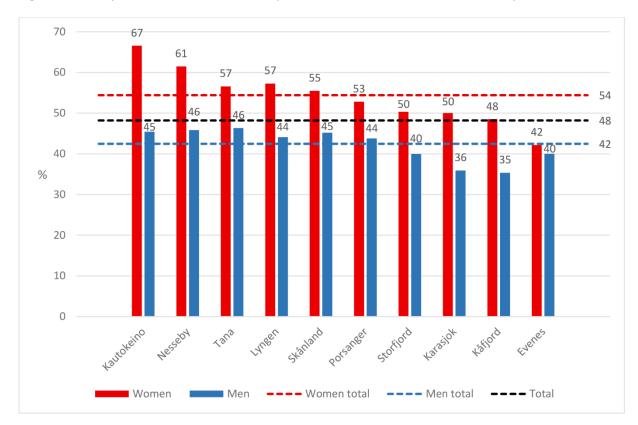


Figure 2. Participation rate in the 10 municipalities in the SAMINOR 2 Clinical Survey.

SUPPLEMENTARY MATERIAL

Biobanking and blood analyses

This appendix shows an overview of the data collection and sampling (Table S1 and Figure S1). In addition, it describes the biobank and the analyses performed on blood samples (Tables S2 and S3). Glycated hemoglobin (HbA1c) and hemoglobin (Hb) were analyzed immediately on whole blood collected in a BD Vacutainer[®] K₂ ethylene diamine tetraacetic acid (EDTA) 7.2 mg, 4 ml, REF# 368861). Remaining blood samples were sequentially processed into cryo-vials or pre-rinsed glass vials (serum PTS only): whole blood from one BD Vacutainer[®] (Trace element, K₂ EDTA 10.8 mg, 4 ml, Ref# 368381; BD, Franklin Lakes, USA); and, serum and clot, both extracted from centrifuged (38 X for 10 minutes) 3 x BD Vacutainer[®] (SST[™] II Advance, 10/8.5 ml, Ref# 367953).

Almost all laboratory analyses were performed at the Laboratory of the Department of Clinical Chemistry, University Hospital of North Norway (UNN), Tromsø from September 2014 to November (Table 2). Vitamin D was analyzed at the Department of Food and Environmental Sciences, University of Helsinki, Finland. Contaminants and toxic and essential elements were analyzed on parts of the sample at the Norwegian Institute for Air Research (NILU), Tromsø, Norway, and National Institute of Occupational Health (STAMI), Oslo, Norway, respectively.

Information about the different blood samples, dates of analysis and total numbers are included in Tables 1 and 2 of this appendix.

		Invitation materials				
Municipalities	Collection	Number of	Pamphlet/informational	Questionnaire	Invitation letter	
	period ¹	fieldworkers	brochure			
Skånland/Evenes	2012 Sept. 17 th	11	Norwegian	Norwegian	Norwegian	
	– Oct. 25 th					
Karasjok	2013 Jan. 28 th –	14	Norwegian/Sami	Norwegian/Sami	Norwegian/Sami	
	Febr. 21 th					
Kautokeino	2013 Febr. 25 th	10	Norwegian/Sami	Norwegian/Sami	Norwegian/Sami	
	– Mar. 21 th					
Porsanger	2013 Apr. 15 th –	9	Norwegian/Sami/Kven	Norwegian ²	Norwegian/Sami	
	May. 30 th					
Kåfjord	2013 Sept. 16 th -	9	Norwegian/Sami	Norwegian ²	Norwegian	
	Oct. 11 th					
Storfjord	2013 Oct. 16 th –	7	Norwegian/Sami/Kven	Norwegian ²	Norwegian	
	Nov. 7 th					
Nesseby	2014 Febr. 12 th	6	Norwegian/Sami	Norwegian/Sami	Norwegian/Sami	
	– Febr. 25 th					
Tana	2014 Febr. 27 th	11	Norwegian/Sami	Norwegian/Sami	Norwegian/Sami	
	– Apr. 3 th					
Lyngen	2014 May. 7 th –	10	Norwegian/Sami	Norwegian ²	Norwegian	
	June. 12 th					

Table S1. Overview of the data collection. The SAMINOR 2 Clinical Survey (2012-2014).

¹ In some municipalities the health examination site was closed from 1 up to 4 weekdays due to public holidays

² The Sami questionnaire was available on request

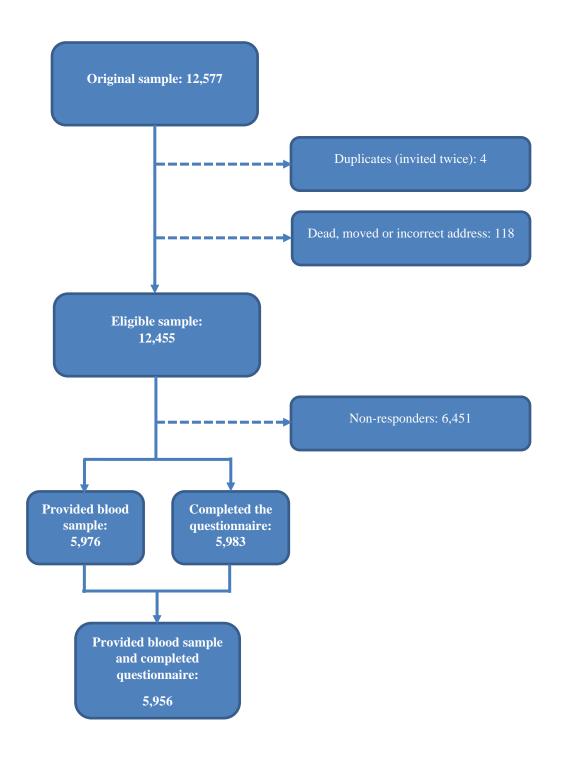


Figure S1. Sample description of the SAMINOR 2 Clinical Survey (2012 – 2014)

	n	Type of tube	Amount	Stored at
Total number of participants	6004			
Agreed to blood sampling	5998			
Blood sampling performed	5996			
Whole blood designated for Hb	5991	EDTA	4ml	-
Whole blood designated for HbA1c	5982	EDTA	4ml	_
Whole blood designated for metal analyses	5974	Cryo	2ml	-20°C/-35°C
Serum designated for lipid analyses	5976	Cryo	<2ml	-20°C/-70°C
Serum designated for Vitamin D analyses	5954	Cryo	1ml	-20°C/-70°C
Serum designated for contaminant analyses	5953	Cryo	2ml	-20°C/-70°C
Whole blood for storage in biobank	5978	Cryo	2ml	-20°C/-35°C
Serum sample 1 for storage in biobank	5921	Cryo	2ml	-20°C/-70°C
Serum sample 2 for storage in biobank	5829	Cryo	2ml	-20°C/-70°C
Serum sample 3 for storage in biobank	4039	Cryo	2ml	-20°C/-70°C
Clot (DNA) for storage in biobank	5975	SST	10ml	-20°C/-70°C

 Table S2. Collected blood samples. The SAMINOR 2 Clinical Survey (2012-2014).

Table S3. Overview of the analyzed blood samples. The SAMINOR 2 Clinical Survey (2012-2014).

Table	n	Date of analysis
At least one blood analysis available	5996	
Hb	5991	17 Sep 2012-12 Jun 2014
HbA1c	5982	17 Sep 2012-12 Jun 2014
Serum analyzed UNN	5975	6 Sep 2014-9 Nov 2014
s-Ferritin	5975	6 Sep 2014-9 Nov 2014
s-Transferrin	5972	6 Sep 2014-9 Nov 2014
s-Iron	5974	6 Sep 2014-9 Nov 2014
Vitamin B12	5974	6 Sep 2014-9 Nov 2014
Folate	5866	6 Sep 2014-9 Nov 2014
HS-CRP	5972	6 Sep 2014-9 Nov 2014
Random plasma glucose	5974	6 Sep 2014-9 Nov 2014
Apolipoprotein-A	5974	6 Sep 2014-9 Nov 2014
Apolipoprotein-B	5973	6 Sep 2014-9 Nov 2014
Total cholesterol	5974	6 Sep 2014-9 Nov 2014
LDL cholesterol	5939	6 Sep 2014-9 Nov 2014
HDL cholesterol	5974	6 Sep 2014-9 Nov 2014
Triglycerides	5975	6 Sep 2014-9 Nov 2014
Transferrin saturation	5971	6 Sep 2014-9 Nov 2014
25-hydroxy-vitamin D analyzed at Helsinki University	5953	2 Jun 2016
Toxic and essential elements analyzed at STAMI	470	27 Apr 2016
Contaminants analyzed at NILU	462	20 Apr 2017

Description of blood analyses

Reagents were purchased from the same company.

Hemoglobin

Hb was analyzed by the hemoglobincyanide (HiCN) method on a HemoCue Hb 201+¹. A drop of blood was placed on a hydrophobic surface, e.g., plastic fil, using a pipette, and a microcuvette was filled. The internal and external quality controls showed values within established control limits. Internal quality control was conducted daily with heamolysate.

Glycated haemoglobin

HbA1c was analyzed with The DCA Vantage[™] (Siemens Medical Solutions Diagnostics, Tarrytown, NY), which is based on latex agglutination inhibition immunoassay methodology and provides results in 6 minutes ². This is the successor of the DCA 2000[™]. Internal and external quality controls showed values within established control limits. The internal quality control was conducted daily or when new reagents were opened. The inter-assay coefficient for variations (CV) for HbA1c was <3% ³.

Serum ferritin

Serum ferritin (s-ferritin) was measured on the Cobas 8000 system from Roche/Hitachi with an electrochemiluminescense immunoassay (ECLIA) ⁴ using the sandwich principle. Ferritin (REF 04491785) has been a standardized against the Ferritin assay (REF 11820982). The Ferritin assay (REF 11820982) has been standardized against the Enzymun – Test Ferritin method. This in turn has been standardized against the 1st International Standard (IS) National Institute for Biological Standards and Control (NIBSC) "Reagent for Ferritin (human liver)" 80/602 ⁵. The analyzer automatically calculates the analyte concentration of each sample in μ g/I.

Serum transferrin

Transferrin was measured on the Cobas 8000 system from Roche/Hitachi with a by immunoturbidimetric assay using human transferrin, which forms a precipitate with a specific antiserum ^{6,7}. This system automatically calculates the analyte concentration of each sample in mg/dlx 0,01=g/l. This method has been standardized against the reference preparation of the Institute for Reference Materials and Measurements (IRMM) BCR470/CRM470 (Reference Preparation for Proteins in Human Serum, RPPHS) ^{5,8}.

30

Serum iron

Serum iron was measured on the Cobas 8000 system from Roche/Hitachi with a colorimetric method. This method has been standardized against a primary reference material (SRM 937) ^{5,9}.

Vitamin B12

Vitamin B12 was measured on the Cobas 8000 system from Roche/Hitachi with by ECLIA ^{5,10,11} using the competitive principle. Results were determined via a calibration curve, which is an instrument specifically generated by 2-point calibration and a master curve provided by the reagent barcode. This method has been standardized against the Vitamin B12 assay (REF 11820753) ⁵. The analyzer automatically calculates the analyte concentration of each sample in pmol/l or pg/mL.

Folate

Folate was measured on the Cobas 8000 system from Roche/Hitachi with ECLIA ¹¹ using the competitive principle. The method has been standardized against World Health Organization International Standard NIBSC-code:03/178, where earlier generations are traceable to "Bio-Rad Quantaphase IIB12/Folat Radioassay ⁵.

Glucose

Glucose was measured on the Cobas 8000 system from Roche/Hitachi using an *in vitro* test for the quantitative determination of glucose in human serum. The test principle is an ultraviolet test with enzymatic references method with hexokinase ¹². Glucose values for human serum obtained on the Roche/Hitachi c 701 analyzer (y) were compared with those determined using the same reagent on the Roche/Hitachi cobas 501 analyzer (x). This method has been standardized against **isotope dilution mass spectrometry reference measurement procedure** ⁵. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dl x 0.0555= mmol/l.

High-Sensitivity C-Reactive Protein

<u>High-Sensitivity C-Reactive Protein</u> was measured on the Cobas 8000 system from Roche/Hitachi with an immunoturibidimetric assay ^{13,14}. The method has been standardized against the reference preparation of the IRMM BCR470/CRM470 (RPPHS)^{5,15,16}. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/Ll x 9.52= nmol/L.

Apolipoprotein A

Apolipoprotein A was measured on the Cobas 8000 system from Roche/Hitachi with an immunoturibidimetric assay ^{17,18}. The method has been standardized against the IFCC SP1-01 reference standard (WHO-IRP October 1992) ⁵. The analyzer automatically calculates the analyte concentration of each sample in by conversion factor mg/dL x 0.01= g/L.

Apolipoprotein B

Apolipoprotein B was measured on the Cobas 8000 system from Roche/Hitachi with a immunoturibidimetric assay ^{17,18}. The method has been standardized against the IFCC SP3-07 reference standard (World Health Organization-IRP October 1992) ⁵. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dL x 0.01= g/L.

Cholesterol

Cholesterol was measured on the Cobas 8000 system from Roche/Hitachi with a homogeneous enzymatic colorimetric method ^{19,20}. The method has been standardized against the designated Centers for Disease Control reference method (designated comparison method). The standardization meets the requirements of the "HDL Cholesterol Method Evaluation Protocol for Manufactures" of the US national Reference System of Cholesterol, (Cholesterol Reference Method Laboratory Network, CRMLN), November 1994 ⁵. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dL x 0.0259=mmol/L.

Low-density lipoprotein Cholesterol

Low-density lipoprotein (LDL) Cholesterol was measured on the Cobas 8000 system from Roche/Hitachi with a homogeneous enzymatic colorimetric method ²⁰⁻²². The method has been

standardized against the beta quantification method as defined in the recommendations in the LDL Cholesterol Certification Protocol for Manufacturers ⁵. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dL x 0.0259= mmol/L.

High-density lipoprotein Cholesterol

High-density lipoprotein (HDL) Cholesterol was measured on the Cobas 8000 system from Roche/Hitachi with a homogeneous enzymatic colorimetric method. The method has been standardized against the designated CDC reference method (designated comparison method) ²³. The standardization meets the requirements of the "HDL Cholesterol Method Evaluation Protocol for Manufacturers" of the US National Reference System of Cholesterol, Cholesterol Reference Method Laboratory Network (CRMLN), November 1994 ⁵. The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dL x 0.0259=mmol/L.

Triglycerides

Triglycerides were measured on the Cobas 8000 system from Roche/Hitachi with a homogeneous enzymatic colorimetric method. The method has been standardized against the designated ID/MS method 5,14,24 . The analyzer automatically calculates the analyte concentration of each sample by conversion factor mg/dL x 0.0113=mmol/L.

25-hydroxy-vitamin D

25-hydroxy-vitamin D [25(OH)D] was measured by the IDS-iSYS 25-Hydroxy Vitamin D^s assay on the IDS-iSYS analyzer (IDS Ltd., Boldon, UK). 25(OH)D analysis in serum blood samples was performed at the Department of Food and Environmental Sciences, University of Helsinki. The laboratory method is standardized, validated and certified by "The vitamin D Standardization Program" (VDSP) <u>https://ods.od.nih.gov/Research/vdsp.aspx</u>.

Contaminants

For details of chemicals analyses of contaminants, we refer to former ²⁵ and up-coming publications.

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