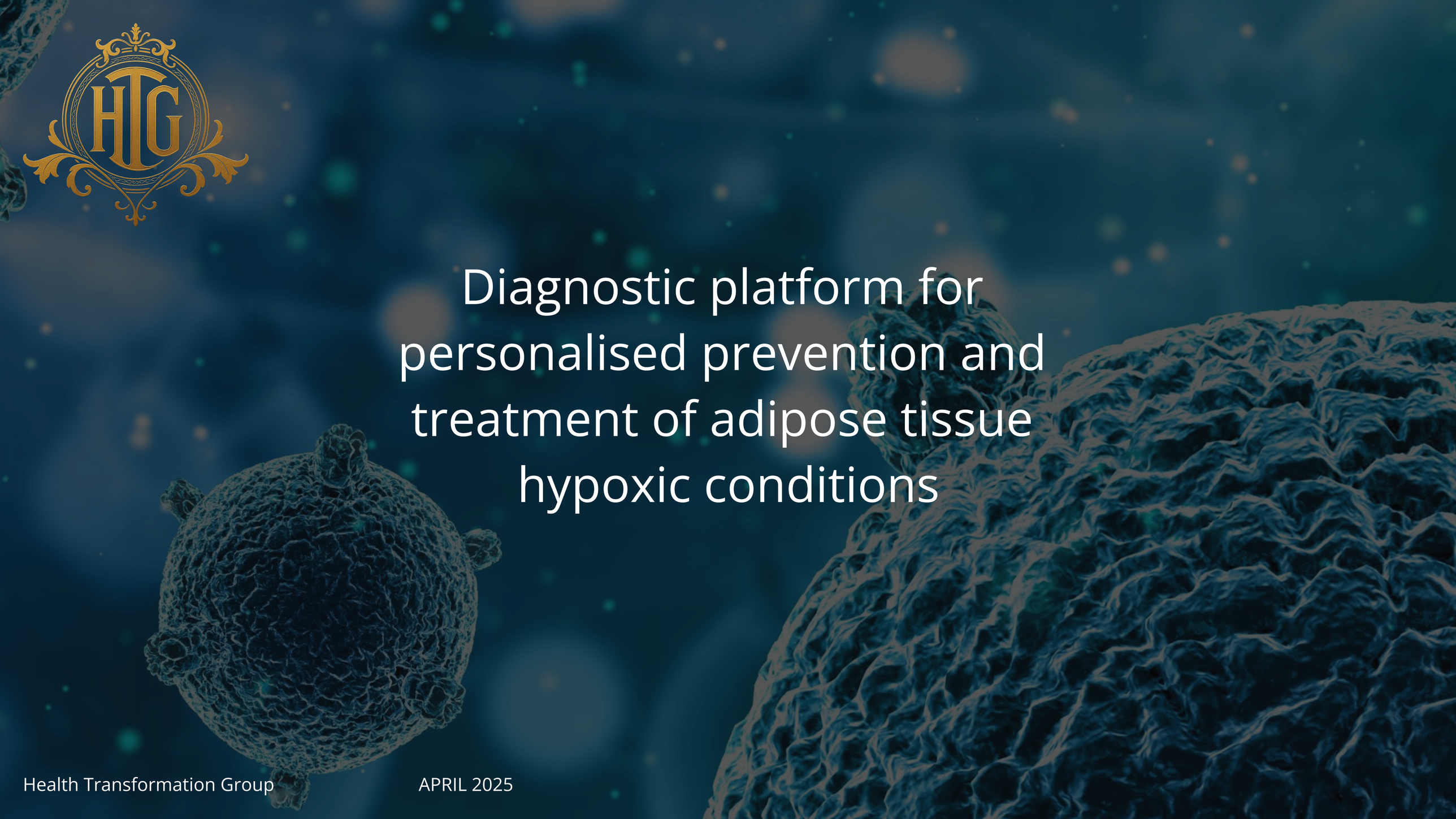
Diagnostic platform for personalised prevention and treatment of adipose tissue hypoxic conditions



Health Transformation Group

APRIL 2025

Call for Global Action Plan on Obesity at World Health Assembly in May 2022

The World Obesity Atlas 2022, published by the World Obesity Federation, predicts that one billion people globally, including 1 in 5 women and 1 in 7 men, will be living with obesity by 2030

WHO About Obesity and Overweight

KEY FACTS

- Worldwide obesity has more than quadruple since 1975
- Globally more than 3.1 billion people were overweight in 2024. Of these over 1 billion were obese
- 41 million children under the age of 5 were overweight or obese
- Over 340 million children and adolescents aged 5-19 were overweight or obese
- Most of the world's population live in countries where overweight and obesity kills more people than underweight
- 10% of global deaths were attributed to obesity in 2024
- Obesity is treatable and preventable

- Overweight is a BMI > 25
- Obesity is a BMI > 30

COMMON HEALTH CONSEQUENCES

Raised BMI is a major risk factor for noncommunicable diseases such as:

- cardiovascular diseases, the leading cause of death in the world
- type 2 diabetes
- musculoskeletal disorders (especially osteoarthritis – a highly disabling degenerative disease of the joints)
- some cancers (including endometrial, breast, ovarian, prostate, liver, gallbladder, kidney, and colon)

Global Economic Burden

- In per capita terms, the costs of obesity in 2019 ranged from US$17 in India to US$940 in Australia. The global economic costs were an estimated US$2.0 trillion or 2.8% of the global gross domestic product (GDP)
- By 2060, with no significant changes to the status quo, the economic impacts from obesity are projected to grow to **3.6%** of the GDP on average
- Moderate obesity as a health risk factor alone reduce life expectancy by **3 years** on average.
- **8.4%** of the health budget will be spent to treat the consequences of overweight over the next thirty years.
- Overweight also negatively impacts educational outcomes, as children with a healthy weight are **13%** more likely to report good performance in schools.
- For each 1 USD dollar invested in tackling overweight, up to **5.6 USD** will be returned in economic benefits.

https://www.worldbank.org/en/topic/nutrition/publication/obesity-health-and-economic-consequences-of-an-impending-global-challenge

https://www.oecd.org › health › health-systems

https://gh.bmj.com/content/6/10/e006351

How can excessive weight be reduced?

World Health Organization

At the individual level, people can:

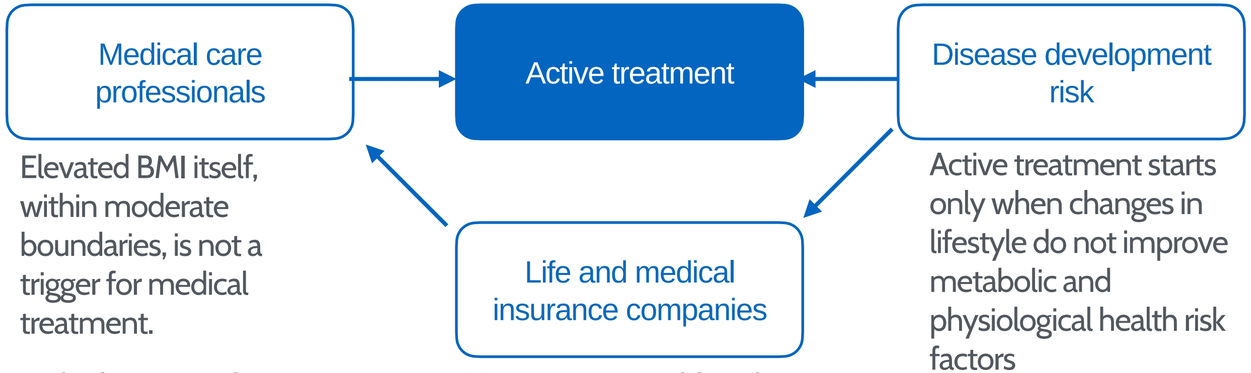
- limit energy intake from total fats and sugars and processed food
- increase consumption of fruit and vegetables, as well as legumes, whole grains and nuts
- engage in regular physical activity (60 minutes a day for children and 150 minutes spread through the week for adults)

The food industry can play a significant role in promoting healthy diets by:

- reducing the fat, sugar and salt content of processed foods
- Replacing “bad” fat with “good” fat
- ensuring that healthy and nutritious choices are available and affordable to all consumers
- restricting marketing of foods high in sugars, salt and fats, especially those foods aimed at children and teenagers
- ensuring the availability of healthy food choices and supporting regular physical activity practice in the workplace

Not All Obesity Cases Require Treatment

Today a BMI is an only informational parameter, it's a prerequisite but not legal or medical reason for practitioners to oblige person to make efforts to loose the weight or change the insurance plan in case of it's avoidance



Elevated BMI itself, within moderate boundaries, is not a trigger for medical treatment.

Only diagnosis of accompanying metabolic and physiological health risk factors leads to healthcare intervention starting with recommendations to changes of lifestyle.

Can not insist on lifestyle changes based on BMI alone

Active treatment starts only when changes in lifestyle do not improve metabolic and physiological health risk factors

About 30% of overweight or obese people do not have metabolic or physiological health risk factors, and do not require medical attention.

Others have to correct their lifestyle and start support their health when their BMI exceeds 25, and especially over 30.

Hence it is important to find a way to differentiate "healthy" from "unhealthy" excess in BMI

Global Statistics and Forecast

Table 1.0: Estimated global prevalence and numbers of adults living with obesity in 2010–2030

	2010		2025		2030	
Adult obesity prevalence	% adults	number	% adults	number	% adults	number
Obesity (Class I, II and III) BMI ≥30kg/m²	11.4%	511m	16.1%	892m	17.5%	1,025m
of which, severe obesity (Class II and III) BMI ≥35kg/m²	3.2%%	143m	5.1%	284m	5.7%	333m
and of these, severe obesity (Class III) BMI ≥40kg/m²	0.9%	42m	1.7%	93m	1.9%	111m

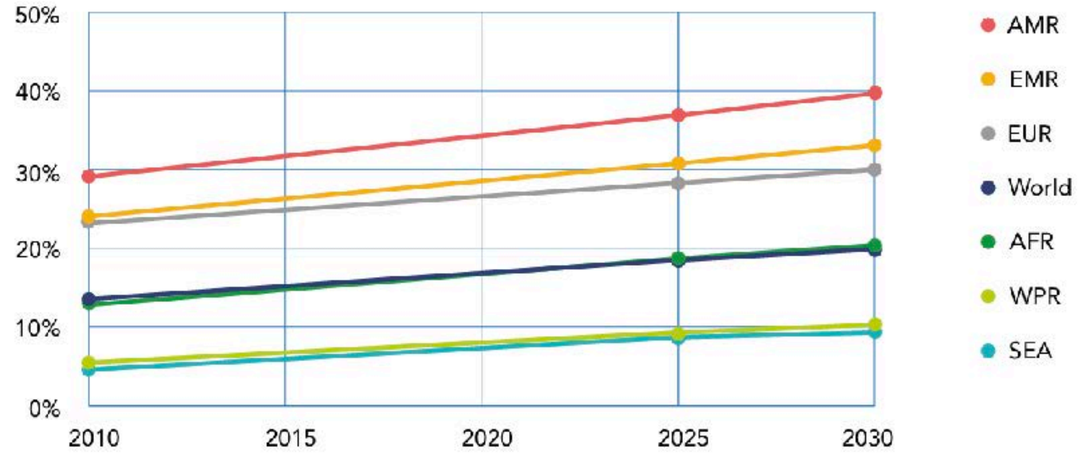
Source: NCD Risk Factor Collaboration (2017), UN Population Division and World Obesity Federation projections

Table 2.0: Estimated global prevalence and numbers of people with obesity and severe obesity in 2010, 2020, 2025 and 2030

Obesity prevalence defined by BMI	2010		2020		2025		2030	
	%	n	%	n	%	n	%	n
Women								
Obesity (Class I, II and III) ≥30kg/m²	14	304m	17	445m	18	512m	20	586m
Severe obesity (Class II and III) ≥35kg/m²	4	100m	6	159m	7	188m	7	219m
Severe obesity (Class III) ≥40kg/m²	1	32m	2	54m	2	65m	3	77m
Men								
Obesity (Class I, II and III) ≥30kg/m²	9	207m	13	324m	14	380m	15	439m
Severe obesity (Class II and III) ≥35kg/m²	2	44m	3	79m	3	96m	4	114m
Severe obesity (Class III) ≥40kg/m²	0.5	11m	1	22m	1	28m	1	34m
All adults								
Obesity (Class I, II and III) ≥30kg/m²	11	511m	15	764m	16	892m	18	1,025m
Severe obesity (Class II and III) ≥35kg/m²	3	143m	5	238m	5	284m	6	333m
Severe obesity (Class III) ≥40kg/m²	1	42m	2	77m	2	93m	2	111m

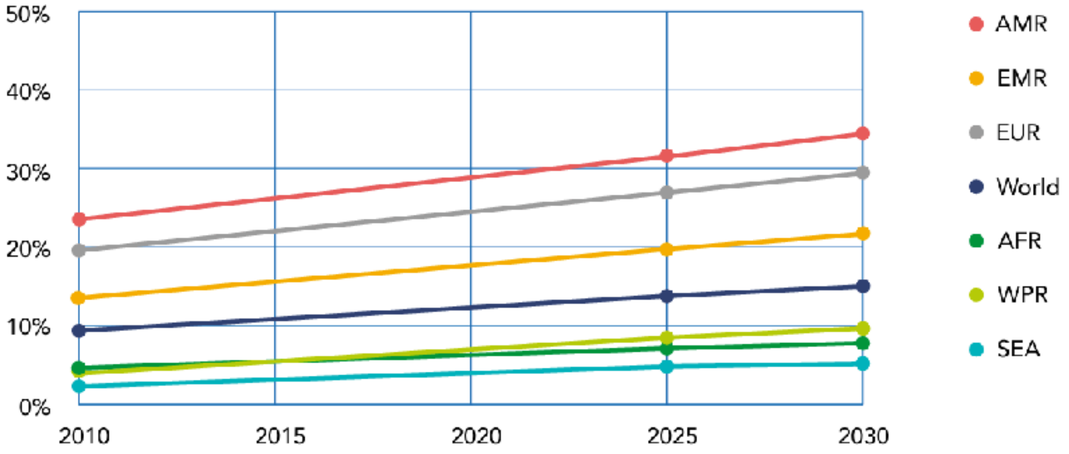
Source: NCD Risk Factor Collaboration (2017), UN Population Division and World Obesity Federation projections

Figure 2.0: Prevalence of obesity (BMI ≥30kg/m²) amongst women by regions in 2010–2030



Source: NCD Risk Factor Collaboration (2017) and World Obesity Federation projections

Figure 2.1: Prevalence of obesity (BMI ≥30kg/m²) amongst men by regions in 2010–2030



Source: NCD Risk Factor Collaboration (2017) and World Obesity Federation projections

Target Market

Total Addressable Market - 1025 mln people

Table 2.1: Estimated regional prevalence of obesity amongst women in 2030

	≥30kg/m²		≥35kg/m²		≥40kg/m²	
	%	N	%	N	%	N
AFR	20%	74m	8%	28m	3%	11m
AMR	40%	164m	19%	80m	8%	32m
EMR	33%	84m	14%	36m	5%	13m
EUR	30%	113m	12%	45m	4%	15m
SEA	9%	69m	2%	16m	0.5%	4m
WPR	10%	79m	2%	16m	0.5%	4m
World	20%	586m	7%	219m	3%	78m

Source: NCD Risk Factor Collaboration (2017), UN Population Division and World Obesity Federation projections

Table 2.2: Estimated regional prevalence of obesity amongst men in 2030

	≥30kg/m²		≥35kg/m²		≥40kg/m²	
	%	N	%	N	%	N
AFR	8%	27m	2%	6m	1%	2m
AMR	34%	134m	13%	49m	4%	17m
EMR	22%	59m	6%	16m	2%	5m
EUR	29%	102m	8%	27m	2%	6m
SEA	5%	40m	1%	5m	0.2%	1m
WPR	10%	75m	1%	10m	0.3%	2m
World	15%	439m	4%	114m	1%	34m

Source: NCD Risk Factor Collaboration (2017), UN Population Division and World Obesity Federation projections

Table 2.4: Estimated number of adults with BMI ≥30kg/m² - top 20 countries globally for women and men by 2030

Women			Men		
Country	Number	Prevalence %	Country	Number	Prevalence %
GLOBAL	586m	20	GLOBAL	434m	15
United States of America	64m	47	United States of America	61m	47
China	60m	10	China	55m	10
India	40m	8	India	24m	4
Brazil	29m	33	Brazil	21m	26
Mexico	21m	41	Mexico	15m	32
Egypt	18m	52	Russian Federation	12m	24
Russian Federation	18m	30	Egypt	11m	31
Turkey	16m	50	Turkey	11m	34
Indonesia	14m	14	Germany	10m	32
Iran	14m	42	United Kingdom	10m	37
Pakistan	13m	17	Iran	9m	28
Nigeria	13m	20	Indonesia	8m	8
South Africa	11m	50	Pakistan	7m	9
United Kingdom	10m	37	France	7m	29
Germany	9m	25	Saudi Arabia	7m	41
Algeria	7m	46	Italy	6m	26
France	7m	26	Canada	6m	39
Colombia	7m	34	Spain	6m	32
Argentina	6m	36	Argentina	6m	35
Iraq	6m	45	South Africa	5m	23

Source: NCD Risk Factor Collaboration (2017), UN Population Division and World Obesity Federation projections

Challenges in Diagnostics of Health Risk Changes in Adipose Tissue

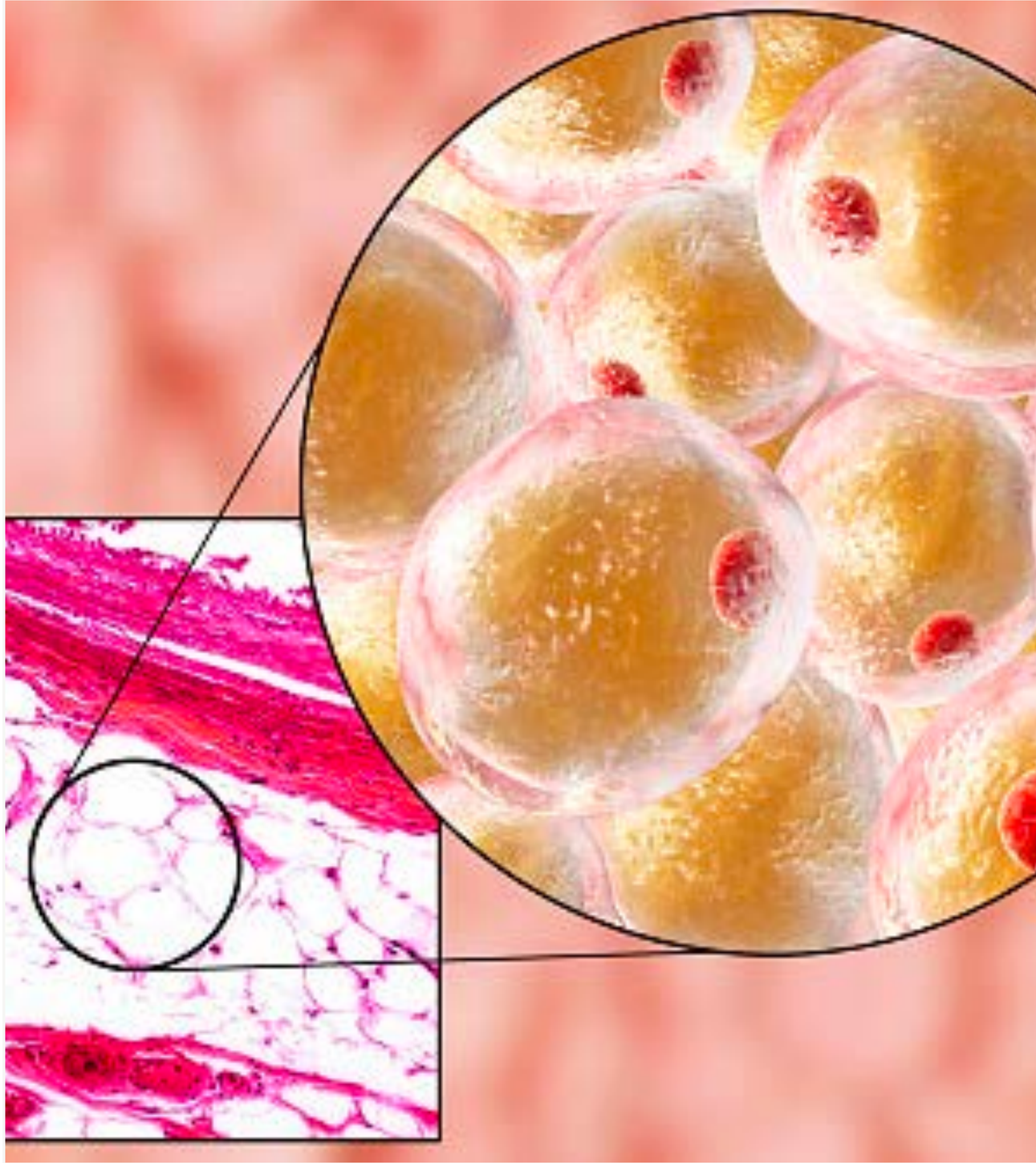
One of the main factors responsible for pathological metabolic and physiological changes in adipose tissue is a disruption in tissue oxygen supply and consequent development of hypoxic conditions therein.

The absence of affordable, simple to use diagnostic tests to measure tissue oxygenation facilitates development of pathological metabolic complications in unchecked overweight and obese pandemic.

The earlier the detection of a disruption in tissue oxygen supply the sooner the person could start to take measures to improve this parameter by changing their lifestyle and diet and start to take dedicated clinically validated supplements. For doctors, this early diagnosis of asymptomatic tissue hypoxic conditions would justify additional medical investigation and if necessary intervention.

It is important to determine the risk of development of metabolic and physiological complications in overweight and obese persons at the earliest stages possible by assessing tissue oxygen supply and detecting its potential disruption.

To maximise the efficacy of this approach, diagnostics for self-testing at home or by a doctor need to be developed.

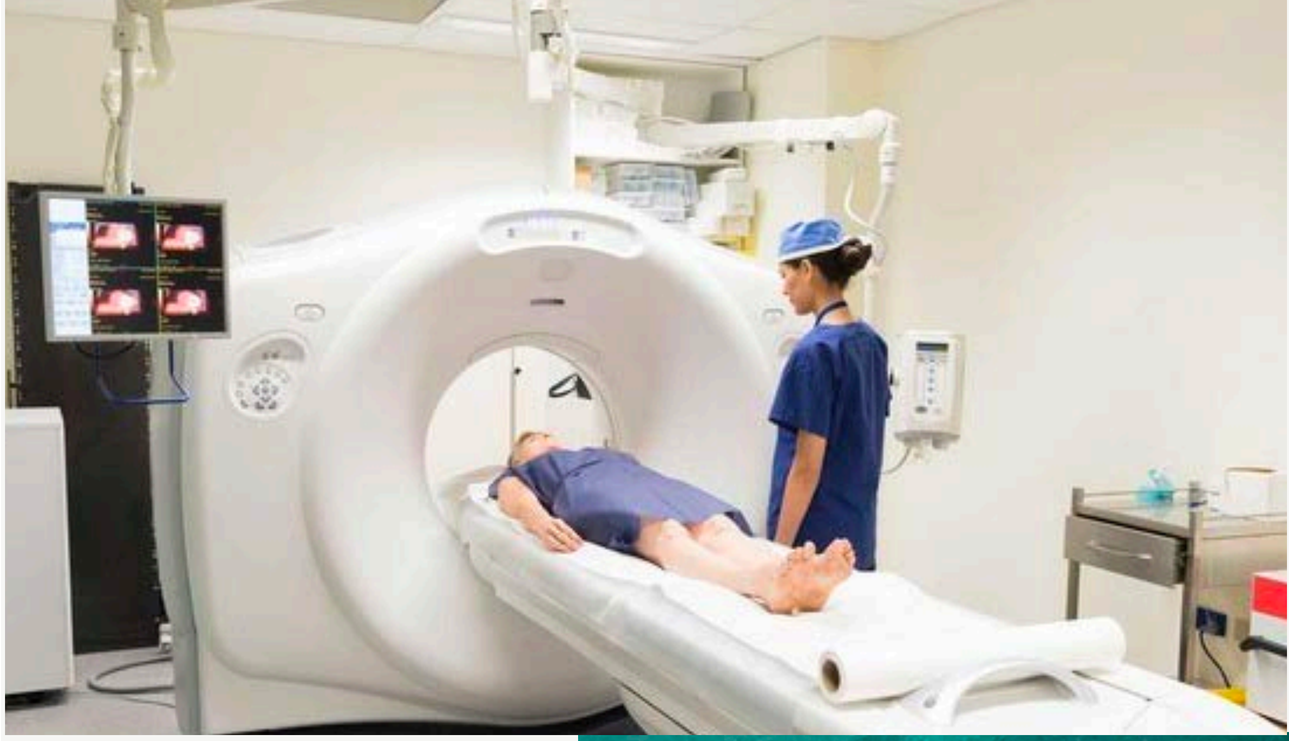


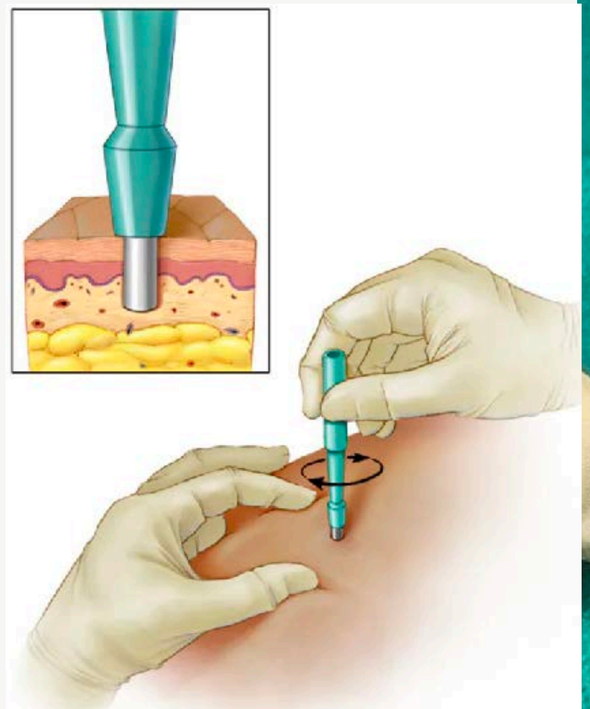
TISSUE OXYGENATION - CURRENT METHODOLOGY LIMITATIONS

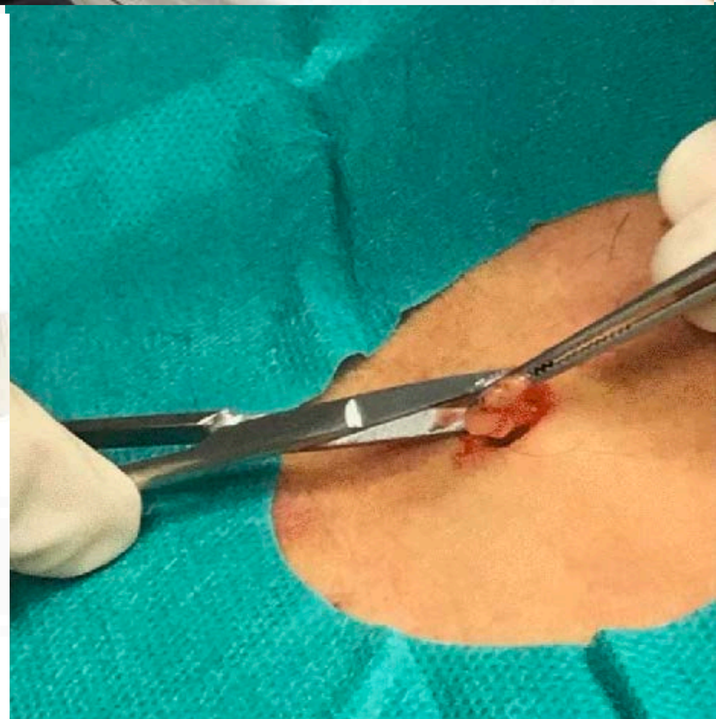
Three methods today are used to diagnose tissue hypoxia.

1. Positron emission tomography (PET) scan, which is an imaging technique using radioactive metabolic tracers.
2. Near-infrared spectroscopy combined with vascular occlusion test, which measure tissue oxygen saturation, but applicable only for assessment of skeletal muscle but not for adipose or other tissue respiration.
3. Tissue biopsy.

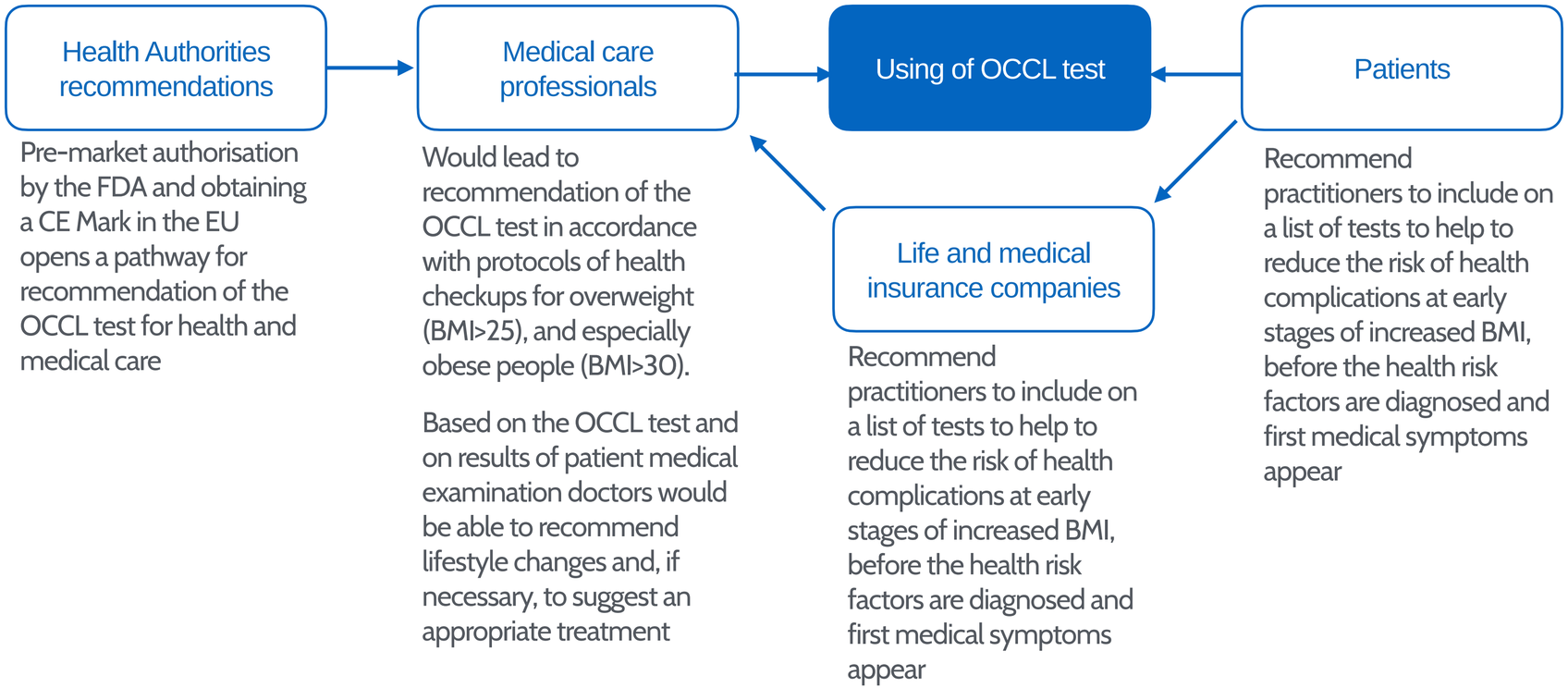
All these methods require hospital admission, specialised equipment and highly trained medical and laboratory professionals to undertake the procedures and interpret the results.







High BMI Has To Become A Prerequisite For The OCCL Test



42%
Percent of adults aged over 20 are Overweight or obese

74%
Percent of adults aged over 20 with overweight and obesity

23%
Percent of adolescents aged 12-19 years are obese

37M
Adults do not need to change their lifestyle

88M
Adults with an increased BMI need to change their lifestyle

US statistics for 2024

Oxygen in Plasma. How to Measure It?

Challenge in obtaining of tissue oxygenation data.

Oxygen transported from the blood to the tissue may be reduced or impaired due to inflammation or age-related oxidative tissue damage build-up.

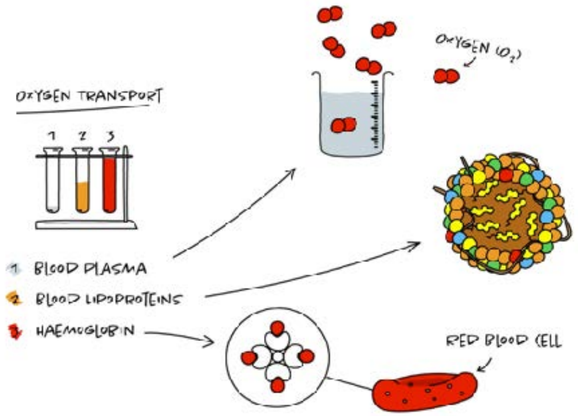
This would cause tissue hypoxia even with a high oxygen level in the blood

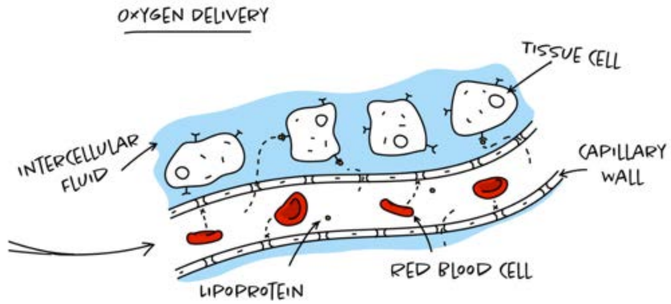
Oxygen Carrying Capacity of blood plasma Lipoproteins (OCCL) test – a diagnostic test which measures the plasma part of the total blood oxygen, part of a PaO2 parameter, which couldn't be extracted from the PaO2 measurement before

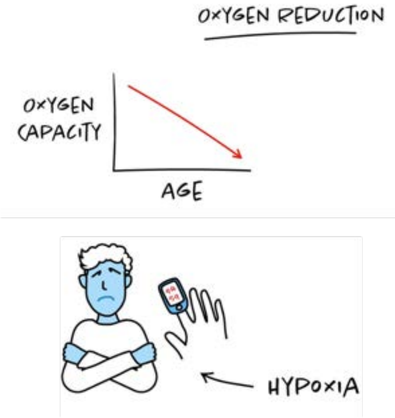
Plasma oxygen during cardiopulmonary bypass: a comparison of blood oxygen levels with oxygen present in plasma lipid →

PUBMED.NCBI.NLM.NIH.GOV

Discovery of Oxygen Carrying Capacity of Lipoproteins (OCCL)







It has been demonstrated that plasma lipoproteins can carry a significant amount of oxygen gas

This property is due to the crystalline hydrophobic structure of lipids, which provides a more favourable environment for O2 solubility than in an aqueous medium

Haemoglobin in erythrocytes is the much more superior and main transporter of oxygen in the blood

However, erythrocytes cannot pass the capillary wall and deliver O2 themselves to tissue cells. Therefore, plasma lipoproteins may be the only carrier of O2 in intercellular or interstitial fluid

In more than 10 years of clinical research, after this discovery, it was demonstrated that the oxygen-carrying capacity of lipoproteins (OCCL) could be affected by a number of factors, including inflammatory damage and oxidative stress

Decline in OCCL may result in a reduction of O2 supply to tissues and depression in their respiration, which together may contribute to the development of tissue hypoxia

Recognition of the Innovation in Liver Metabolic Pathologies and Disease

Lipoproteins are predominantly generated and oxidised in the liver.

Dr. Ivan Petyaev and the CNL scientific team have sufficient expertise in diagnostics and treatment of lipoprotein pathologies

Lipoprotein

From Wikipedia, the free encyclopedia

For proteins covalently linked to lipids, including bacterial/transmembrane "lipoproteins", see Proteolipid.

A **lipoprotein** is a biochemical assembly whose primary function is to transport hydrophobic lipid (also known as fat) molecules in water, as in blood plasma or other **extracellular fluids**. They consist of a triglyceride and cholesterol center, surrounded by a phospholipid outer shell, with the hydrophilic portions oriented outward toward the surrounding water and lipophilic portions oriented inward toward the lipid center. A special kind of protein, called apolipoprotein, is embedded in the outer shell, both stabilising the complex and giving it a functional identity that determines its role.

Many enzymes, transporters, structural proteins, antigens, adhesins, and toxins are lipoproteins. Examples include **plasma lipoprotein particles** (HDL, LDL, IDL, VLDL and chylomicrons). Subgroups of these plasma particles are primary drivers or modulators of atherosclerosis.[1]

https://en.wikipedia.org/wiki/Lipoprotein

Oxygenation [edit]

One of the main roles of extracellular fluid is to facilitate the exchange of molecular oxygen from blood to tissue cells and for carbon dioxide, CO_2, produced in cell mitochondria, back to the blood. Since carbon dioxide is about 20 times more soluble in water than oxygen, it can relatively easily diffuse in the aqueous fluid between cells and blood.[15]

However, hydrophobic molecular oxygen has very poor water solubility and prefers hydrophobic lipid crystalline structures.[16][17] As a result of this, plasma lipoproteins can carry significantly more O_2 than in the surrounding aqueous medium.[18][19]

If hemoglobin in erythrocytes is the main transporter of oxygen in the blood, plasma lipoproteins may be its only carrier in the ECF.

The oxygen-carrying capacity of lipoproteins, OCCL, reduces in ageing or in inflammation. This results in changes of ECF functions, reduction of tissue O_2 supply and contributes to development of tissue hypoxia. These changes in lipoproteins are caused by oxidative or inflammatory damage.[20]

https://en.wikipedia.org/wiki/Extracellular_fluid

Mission and Objective

OUR MISSION

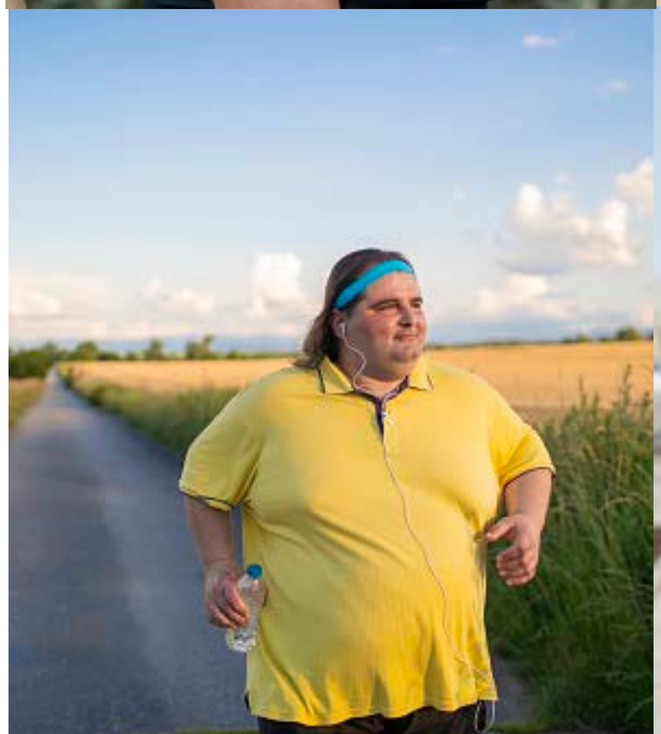
Point-of-care diagnostics - anywhere and anytime

We believe in a future where people will easily assess their key health parameters as they now check their smartphone battery level

OUR SOCIAL OBJECTIVE

Improve the quality of life for overweight and obese people

Tissue oxygenation is an essential body health parameter



OCCL Adipose Tissue Test

- Can help to assess the health status of adipose tissue in overweight and obese people
- Can help to assess tissue oxygenation which is important to support the health of adipose tissue

Recommended regimen of test application

- Overweight: once a year
- Obese: twice a year

1bn+

People
obese or overweight globally in 2020

30%

Of overweight people
do not have metabolic health risk factors

IP Protection

Test platform — “Hardware”

- International Publication Number WO 2023/095140 A1 for DEVICE AND METHOD FOR DRY CHEMISTRY OXYGEN CATALYMETRY

Test utility — “Software”

- WOPCT/GB2019/050333
- WOPCT/GB2019/051169

Know-how

- Technology secrets
- Laboratory and clinical data

Plasma oxygen during cardiopulmonary bypass: a comparison of blood oxygen levels with oxygen present in plasma lipid →

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Micellar acceleration of oxygen-dependent reactions and its potential use in the study of human low density lipoprotein →

SCIENCEDIRECT.COM/SCIENCE

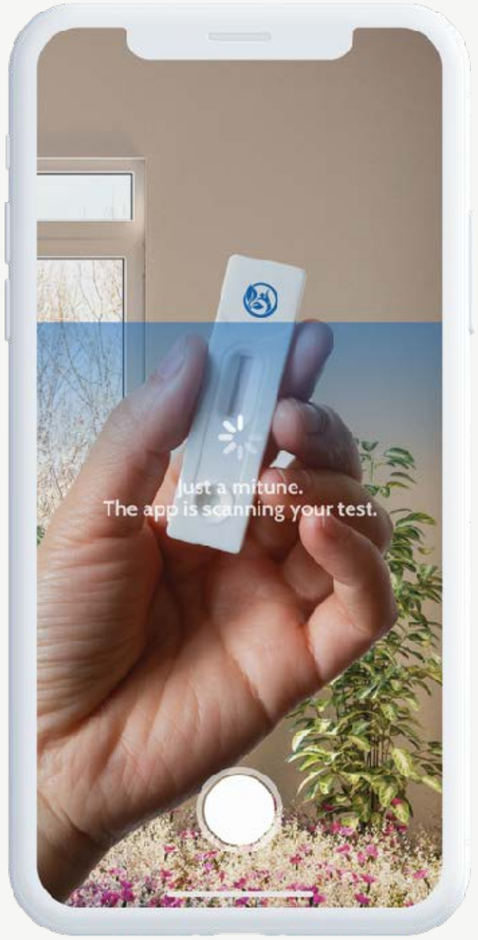
Collaboration of Global Leaders

Cambridge Nutranostics Ltd (CNL) is developing a point-of-care diagnostic test in collaboration with leading medical science and technology centres. Medical science and development of Oxygen Carrying Capacity of blood plasma Lipoproteins (OCCL) test technology:

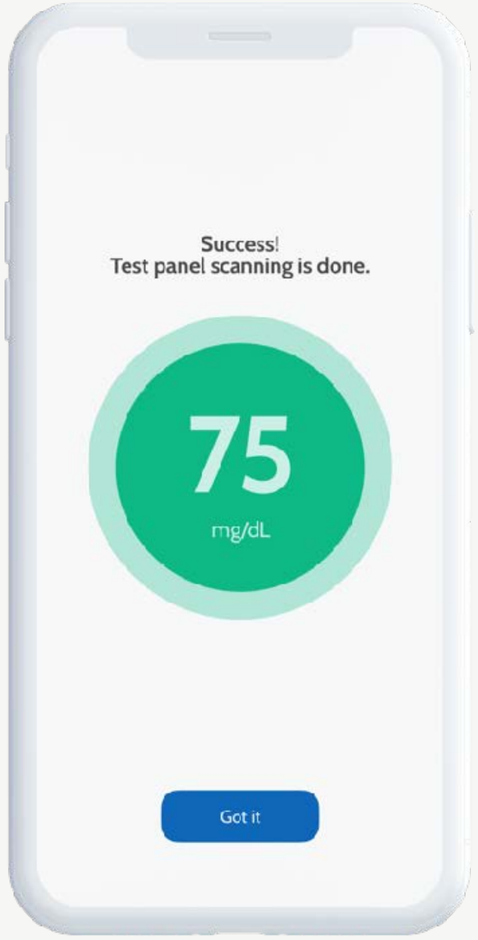
- **University of Cambridge** — discovery in oxygen physiology and pathology
- **Harvard Medical School** — advanced theranostic clinical validation
- **Charite Hospital** — advanced nutranostic clinical validation
- **Royal Papworth Hospital (NHS)** — first clinical validation of the OCCL discovery
- **Lycotec Ltd** — role of OCCL in health and pathology, new diagnostics and treatment
- **IVD Solutions** — leading US developer of dry chemistry point-of-care diagnostics with successful track record, its scientists helped bring 10 FDA approved products to market.

OCCL Fat Health Test

Blood collection at home, using a kit with a cassette to analyse blood sample



Taking a photo of the developed colour in the cassette by smartphone

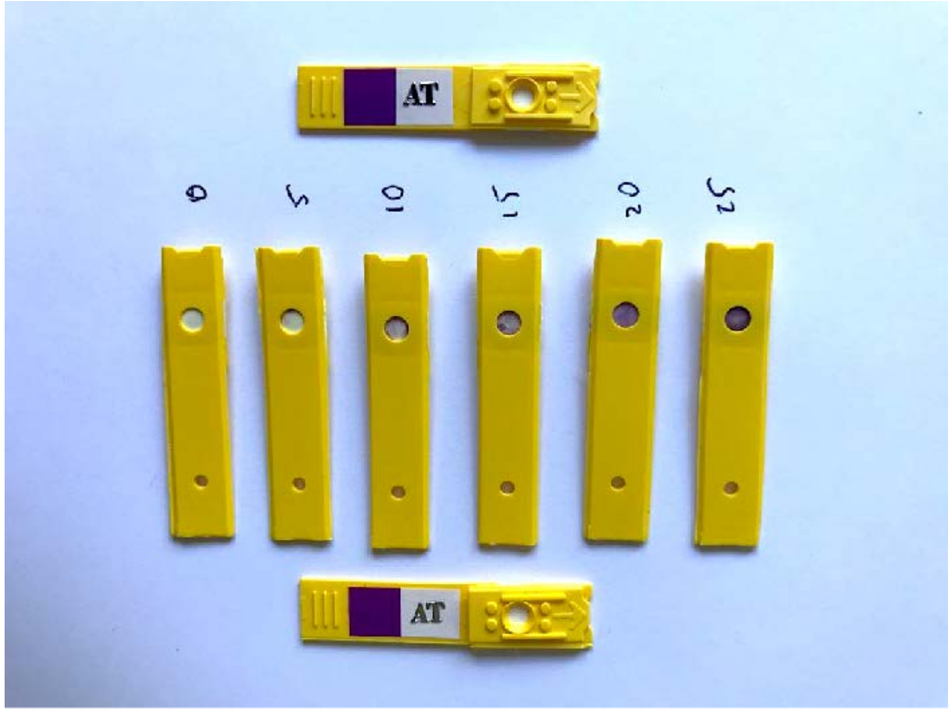


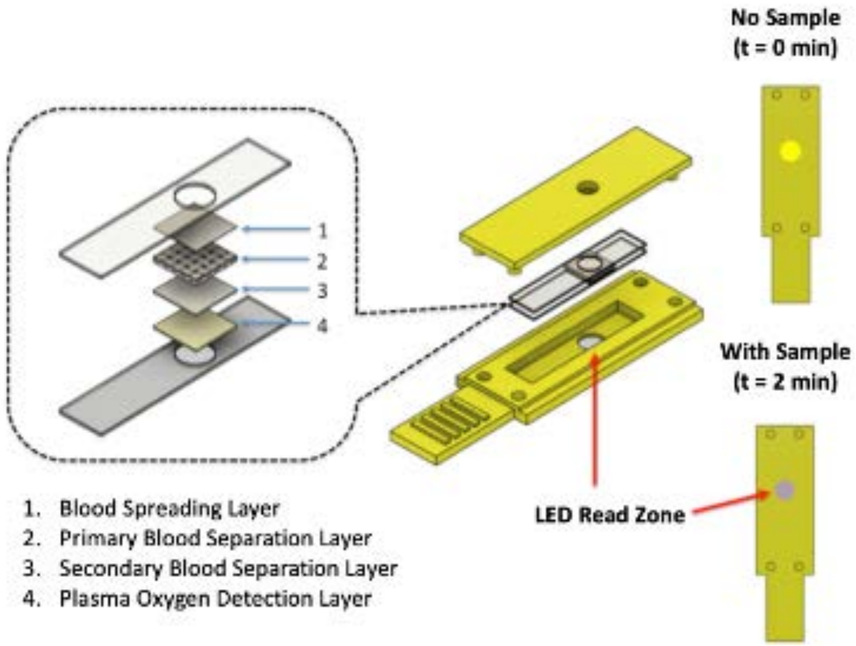
Immediate result by mobile application

Clinical validation and Optimisation of Dry Chemistry OCCL Fat Health Test

- 1st working prototype of the OCCL test in initial clinical validation
- Protocol development to optimise capillary blood volume, time exposure and colour development
- Validation in parallel assessment with other established oxygen metabolism parameters: liquid based OCCL and PaO2
- Validation in clinic in persons of different age, gender and BMI
- Validation in healthy persons and with clinically confirmed hypoxic conditions

Over 1000 OCCL test cassettes would be needed to optimise perfomance, reproducibility and accurancy. This will be achieved in Q3 2025





Regulatory Requirements

To enter a market and be commercialized (could be sold without prescription), the OCCL test does not require an approval by the FDA in the USA or a Notified Body in the EU.

To enter the professional market (could be prescribed and recommended by doctors for health diagnostics) the test needs to have a pre-market authorisation in the USA and have a CE Mark in the EU

The FDA pre-market authorisation and obtaining of a CE Mark require submission of dossiers on the safety and efficacy performance of the OCCL test, which will include:

1. Clinical trial and laboratory data
2. Production facility certification

USA	European Union and UK
FDA	In Vitro Diagnostic Regulation 2017/746 compliance
OCCL test - Class II device Requires dossier - safety and efficacy	OCCL test - Class B device Requires "self-declared" conformity
To bring the test to market a submission needs to be made to FDA for premarket authorisation.	In vitro diagnostic (IVD) devices sold in the European Union require a CE mark to certify that the device complies with the current European In-Vitro Diagnostic Devices Directive (IVDD 98/79/EC). The CE mark is a quality certification indicating that the device may be legally commercialized in the European Union.

Regulatory Partner

PARTNERS FOR FDA
REGULATORY AUTHORISATION

Robert Harper

CEO of IVD Solutions – co-developer and manufacturer of the dry chemistry cassettes for the OCCL test.

IVDS scientists have helped bring 10 FDA-approved products to the market over their careers in diagnostics

Our partner for FDA Regulatory Approval confirmed the submission track for the OCCL test premarket authorisation

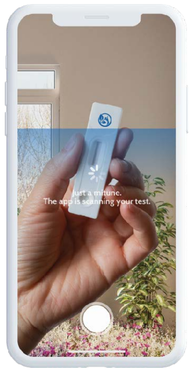
Partnership

Healthcare Authorities

- United States Department of Health and Human Services
- NHS UK
- Ministry of Health of the People's Republic of China
- Ministry of Health, Labour and Welfare of Japan

Commercial partners:

- Health, diet and fitness trackers
- Vitamin and supplement apps



For apps and services:

- **Personalised supplementation** and solutions with tracked results
- **Connection with health apps and wearables** for health data enrichment
- **Co-Branding** of the test scanner
- **API** for the results

Team

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Dr Ivan Petyaev
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Chief of Strategy Officer

Dmitry Malyanov
Chief Business Development Officer

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Dennis Sandris Nielsen
Professor, PhD
University of Copenhagen, Denmark

Roadmap 2H 2025 - 1H 2026

Q1 2025

100 patients with blood samples to be analysed with the 1st OCCL test prototype

Q2 2025

100 patients with blood samples to be analysed with the 2nd OCCL test prototype

Expansion of clinical validation of the OCCL test in Europe

Q3 2025

300 patients with blood samples to be analysed with the 2nd OCCL test prototype

Initiation of clinical validation of the OCCL test in the US

Test validation for a US FDA pre-market authorisation Dossier

Working on a Dossier for a CE Mark in Europe

Adapt the OCCL test for dry chemistry lateral-flow diagnostic combined with smartphone diagnostic

CNL mobile app first integrations with health tracking apps

Q4 2025

Completion of a Dossier for the US FDA pre-market authorisation

Completion of a Dossier for a CE Mark in Europe

Obtaining approval for US FDA pre-market authorisation

Expansion of clinical validation of the OCCL test in the US

Q1-Q2 2026

Launch to the market with US FDA authorisation

Launch to the market with the CE Mark

Prenatal Health Bonds issuance

CNL Inner Circle

CNL IN-HOUSE

Business development

Partnerships

B2B sales

CNL LABORATORY

R&D for the test diversification

R&D for US FDA and CE Mark Dossiers

COMPANY PARTNERS (LYCOTEC AND IVDS)

Setting up test production and QC FDA compliance

CAMBRIDGE DIAGNOSTIC IMAGING (CADI)

Development of the mobile app and algorithms

Promotion and sales in social media

CNL Financial Projections

What confirms CNL performance:

- Point-of-care technology – we have a patent protected IP which secures a monopoly for oxygenation, lipid quality assessment and hypoxia risk assessment using dry chemistry
- Low regulatory risk – the OCCL test does not require authorisation from FDA but only pre-market authorisation in the US, and needs only a self-certification CE Mark for IVD in Europe.
- Diversification of the point-of-care setup for the test application - clinical validation of the OCCL test in nutranostics and theranostics was made on 760 persons with impaired plasma lipoproteins and low tissue oxygenation
- Entrance into different diagnostic markets mitigates the commercial risk in all main economic markets: US, EU, CH and the Middle East.

Investment Required

Current investment round - for commercialisation: regulatory clearance, smartphone diagnostic upgrade and production set-up:

- Capital investment required: $XXM

Previous funding

- $8.4M from own funds

Funds Distribution:

- 45% - FDA/IDVR approval
- 20% - Operation
- 20% - IP and software development
- 10% - Marketing and business development
- 5% - Manufacturing

What important truth do very few people agree with you on?

PETER THIEL

Our genetic code determines from which disease we may die but we can influence and control when

IVAN PETYAEV

Thank you