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FH Europe
The European FH Patient Network

DIAGNÓZA FH, z.s.

SENÁT
PARLAMENTU ČESKÉ REPUBLIKY

The Time is Now: Achieving FH Paediatric Screening Across Europe

The Prague Declaration

6 September 2022

“On behalf of the Czech Government, and the Czech EU Presidency, I am delighted to support the Prague Declaration on FH Paediatric Screening. This is the key outcome of a meeting in the Czech Senate on 6th September 2022 under the auspices of our Presidency, which gathered leading experts from the field and from the wider public health and digital health arena.

Addressing the human burden of Familial Hypercholesterolaemia is critical. This inherited condition leads to premature heart attacks and even death if not detected early enough and subsequently treated. But we also need to look at the human and economic burden both at individual/family and at systems level and the cost effectiveness, short and long term, of paediatric screening for inherited high cholesterol. This is clearly an investment that can reap dividends in lives, the quality of those lives and societal impact.

I see also an important wider context here. One of our EU Presidency priorities is prevention, and FH paediatric screening is a prime example of prevention – and a critical shift away from cardiovascular disease towards cardiovascular health. The Declaration could not be timelier as the EU invests in Non-Communicable Diseases prevention.

We live in highly complex times – with global conflict and the aftermath of the Pandemic. We are still grappling, as a society, on how to deal with the immediate threats, but also how to build back better, with more resilience, more humanity and more hope. I see the Prague Declaration as a symbol of this. More practically, it is a North Star, that will help us all steer towards universal FH Paediatric Screening in our respective countries.“

Mr Jakub Dvořáček
Czech Deputy Minister of Health

“As representative of the Czech Senate, and Chair of the Healthcare Committee of Senate, I am proud to support the Prague Declaration on FH Paediatric Screening. The Declaration embodies the rich content and the passion we heard at the landmark Senate meeting on the topic on 6 September which I was delighted to host.

I have borne witness to the major progress that has taken place to date on FH paediatric screening in the Czech Republic, but also very aware that we are on a journey and can aspire to greater impact. In some other countries, the journey is just beginning – and there is just cause for optimism, that we learned during our meeting.

We have the science, we have the treatment pathway, we have the opportunity to create awareness among the general public regarding the importance of screening – we have the innovation towards a more personalised approach, and with digitalisation and a new health data space – we can also transform health systems to integrate FH paediatric screening seamlessly. Perhaps more importantly, this is a human rights', and specifically a children's rights issue. It is quite simply, unconscionable not to implement FH paediatric screening – knowing the profoundly tragic and deepseated consequences of complacency in this area.

I believe the implementation of the Prague Declaration will enable many, many more to live longer, healthier, and happier lives and manage their condition through the life course. It will avoid deaths, disability, family trauma and in the case of HoFH, very early deaths in childhood. We have a duty and a responsibility to move forward and put the Prague Declaration into practice.“

Mr Roman Kraus M.D.
Member of the Czech Senate
Chair of the Healthcare Committee of the Senate

PREAMBLE

Familial Hypercholesterolaemia (FH) is severely under-recognized, under-diagnosed and under-treated in Europe, leading to a significantly higher risk of premature cardiovascular diseases in those affected. FH stands for inherited, very high cholesterol and affects 1:300 individuals regardless of their age, race, sex, and lifestyle, making it the most common inherited metabolic disorder and a non-modifiable cardiovascular disease risk factor in the world.

With a 50% chance of inheriting the condition, every individual with an FH-causing variant also has at least one parent, and often siblings, with the same variant, presenting a cardiovascular health burden for affected families. In Europe, there are over 500,000 children and 2,000,000 adults affected by FH. However, 5% of these children are identified and only a small fraction of all affected individuals receives life-saving treatment.

Homozygous FH (HoFH) is the rare and the most severe form of FH. Untreated, HoFH often causes heart disease (heart attacks and aortic valve disease) in early childhood. As treatment beginning early in life is highly efficacious in preventing cardiovascular diseases in these individuals and cost-effective [1–3], early detection of FH is crucial.

The Prague Declaration is a call to action for national and European/international policymakers and decision-makers, building on a considerable body of quality evidence to date. It also reflects the outcomes of a meeting dedicated to FH paediatric screening under the auspices of the Czech EU Presidency on 6 September 2022, during which outstanding barriers to the implementation of FH paediatric screening systematically across Europe were addressed, bringing tangible solutions to move forward:

- **Recognising the WHO Consultations on FH in 1998 which, for the first time, called on governments and public health systems to address the risk factors linked to inherited lipid disorders [4];.**

- **Acknowledging that the Council of the European Union in December 2015 presented FH as "a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data [5]);**

- **Recalling the Global Call for Action on FH published in 2020 under the title "Reducing the Clinical and Public Health Burden of Familial Hypercholesterolemia", a global FH advocacy community effort of adopting the 9 (out of the initial 11) updated WHO public policy recommendations, covering awareness; advocacy; screening, testing, and diagnosis; treatment; family-based care; registries; research; and cost and value [6];.**

- **Acknowledging that FH paediatric screening was recognized in 2021 by the European Commission Public Health Best Practice Portal as one of the best practices in non-communicable disease prevention [7];.**

- **Noting the Lancet article published in September 2021 entitled "Familial Hypercholesterolaemia – too many lost opportunities" [8];.**

- **Having regard to the high-level technical meeting under the Slovenian EU Presidency in October 2021 and the resulting scientific and political consensus on FH Paediatric Screening and recommendations therefrom [9,10];**

- **Having regard to the World Heart Federation Whitepaper "Improving Prevention and Control of Raised Cholesterol" published in 2022, which references the importance of FH paediatric screening [11];**

- **Recognizing the lack of awareness among decision makers and citizens in general regarding the burden of FH, the need for knowledge building and a policy framework to make this disease a priority;**

- **Recognizing the European Commission´s "Healthier Together" Initiative addressing non-communicable diseases, including cardiovascular diseases [12];**

- **Welcoming the Czech EU Presidency's focus on prevention and rare diseases, highly relevant in the context of HoFH, a rare form of FH [13].**

THE FH EUROPEAN COMMUNITY CALLS FOR

1. Political leadership and commitment to make FH paediatric screening a reality

Political leaders should commit to deliberate and bold efforts to make FH paediatric screening a reality in their country, acknowledging the unequivocal scientific evidence base, cost effectiveness analyses and a (children's) rights' perspective, in the spirit of leaving no-one behind.

A multi-stakeholder approach is also needed, to ensure health systems can integrate FH paediatric screening effectively. This includes enablers such as digitalisation, responsible health data sharing, and healthcare professionals' (HCPs) education.

2. Investment and a policy framework for raising awareness of FH amongst medical practitioners and the public, to build trust and responsiveness

National governments in the EU should mobilise significant investment and create appropriate policy guidance to raise awareness amongst the public and healthcare professionals about FH and associated risks, applying the latest knowledge about personalised prevention, behavioural science, health literacy and the social determinants of health.

Awareness-raising campaigns and initiatives should be co-created through meaningful engagement of patient organisations, healthcare professionals and citizens.

3. Comprehensive early detection, screening, diagnosis and life course care programmes in every country

Every country should establish systematic early detection screening and diagnosis for FH, with an appropriate care programme focused on childhood identification and treatment.
The programme should be aligned with the "Best Practices on How to Establish a Screening Programme" [7] and in particular, to those defined by the European Commission´s public health best practice portal for FH.

Country/region-wide lipid referral centres should coordinate screening and promote family-based care.

Lipid referral centres should be guided by the experience of European Reference Networks and the European Atherosclerosis Society Lipid Clinics Network [14].

Each screening programme should incorporate universal, cascade and opportunistic strategies.

These may be based initially on cholesterol testing; however, FH genetic testing or ideally a combination of both should be developed as soon as feasible.

They should be country/region-specific and in accordance with the organisational structure of respective health care systems.

The screening could occur in the context of regular health care visits (such as vaccinations) or routine healthy children's follow-up, in community settings, or around the perinatal period.

4. Specific actions to address the barriers to successful large-scale uptake of screening programmes and subsequent treatment

Positive action is needed to ensure the success of screening, including public information campaigns and personalised health advice. It is also important to ensure that a positive diagnosis has no adverse effects on access to treatment for patients and their immediate families.

Cost-benefit models should be developed that can be tailored to specific national scenarios to show the long-term cost advantages of FH screening as well as the benefits to individual citizens and their families of early diagnosis.

5. Targeted research and development to address knowledge gaps

Research to support childhood FH identification should include:

- new methods for early identification, diagnosis (including genetic diagnosis), personalised treatments and follow-up;
- registries that document FH care, monitor progress in achieving guideline-based treatment goals, and measure health outcomes. These should be developed in the context of the European Health Data Space and the European Reference network and in conjunction with the international FH registry [15];.
- long-term clinical trials (3–5 years) and longitudinal studies in children and young people to further assess health outcomes, complications, cost-effectiveness, affordability, and feasibility, that allows full Health Technology Assessments to support decision-making processes;
- implementation of science to facilitate guideline-based FH care and assess citizen satisfaction with programmes;
- innovation in personalised prevention and treatment in FH;

New research and development should be supported through adaption of the appropriate policies.

6. Building the capacity of health professionals and empowering patients on how to best support individuals and families with FH

Based on the best available evidence and good practice, capacity-building programmes, and training materials should be created for professionals and individuals, to better deal with the pathology and its burden.

Dialogues should take place with patients and healthcare professionals to discuss last advances and evidence.

7. Commitment to shared learning and monitoring through exchange and comparisons beyond borders in- and outside the EU

Through funding programmes such as EU4Health, there should be investment in the transferability and uptake of best practice models in FH paediatric screening from other countries, and country level 'score cards' to measure progress according to safety, efficacy, cost and cost-effectiveness, organisational, ethical, legal and social criteria.

The experience of FH paediatric screening should be carefully observed and documented for analysis in the context of wider efforts towards better cardiovascular health (CVH) through collaboration with relevant national, European and Global alliances.

We invite national and regional policymakers across the EU, medical societies, patient and public health organisations, and individual experts to support this declaration and to help ensure that FH Paediatric Screening becomes a reality in Europe, as part of European and national strategies to prevent cardiovascular diseases, and to promote cardiovascular health.

ENDORSED BY

International

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EACH - European Alliance for Cardiovascular Health, https://www.cardiovascular-alliance.eu
EAS FHSC - European Atherosclerosis Society FH Studies Collaboration, www.eas-society.org/page/fhsc
EAS - European Atherosclerosis Society, www.eas-society.org
EHN - European Heart Network, https://www.ehnheart.org
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Global Heart Hub, https://globalhearthub.org
IAS - International Atherosclerosis Society, www.athero.org
International HealthTechScan, https://www.i-hts.org
ILEP - International Lipid Expert Panel, https://ilep.eu
ISPAD - International Society for Pediatric and Adolescent Diabetes, https://www.ispad.org
MEDizzy, https://medizzy.com
ScreenPro FH, http://screenprofh.com
The Digital Health Society, https://thedigitalhealthsociety.com
WHF - World Heart Federation, www.world-heart-federation.org

Austria

FHChol, https://fhchol.at

Bulgaria

Bulgarian Hypertension League, http://www.hypertensionleaguebg.info/about-bhl

Cyprus

Cyprus Atherosclerosis Society/CyFH Patient Registry, https://cas.org.cy/cyfh-info

Czech Republic

Center of Cardiovascular Surgery and Transplantation Brno, https://www.cktch.cz
Czech Society for Atherosclerosis, https://athero.cz
Czech Society of Cardiology, http://www.kardio-cz.cz
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General University Hospital in Prague, https://www.vfn.cz
Institute of Health Information and Statistics of the Czech Republic, https://www.uzis.cz
Masaryk University, www.muni.cz

France

NSFA - French Society of Atherosclerosis, https://www.nsfa.asso.fr
ANHET.F - Association Nationale des Hypercholestérolémies familiales et Lipoprotéines(a), https://www.anhet.fr

Germany

CholCo - Cholesterin & Co: Patientenorganisation für Patienten mit Familiärer Hypercholesterinämie oder anderen schweren genetischen Fettstoffwechselstörungen, www.cholco.de
DigiMed Bayern, https://www.digimed-bayern.de

Germany, Austria, Switzelrnad

D•A•CH-Gesellschaft Prävention von Herz-Kreislauf-Erkrankungen e.V., www.dach-praevention.eu

Greece

LDL Greece, https://www.ldlgreece.gr

Hungary

SZÍVSN / Heartily Hungary, https://szivsn.hu

Iraq

ILCN - Iraqi Lipid Clinics Network, http://www.iraqilcn.com

Ireland

Croí, The Heart and Stroke Charity, https://croi.ie

Italy

LIPIGEN - Fondazione SISA, www.sisa.it/LIPIGEN

Latvia

ParSirdi.lv, www.parsirdi.lv

Lithuania

LŠA - Lithuanian Heart Association, www.heart.lt
SVEIKA SIRDIS - The Healthy Heart, www.sveikasirdis.com

Norway

NKT for FH, http://nktforfh.no

Poland

Association of Patients with Family Hyperlipidemia in Gdańsk, https://www.facebook.com/hipercholesterolemia
ECO Serce, Poland, http://ecoserce.pl
KCHR - National Center for Family Hypercholesterolaemia, http://www.hipercholesterolemia.com.pl
PTL - Polish Lipids Society, https://ptlipid.pl

Portugal

National Institute of Health Doutor Ricardo Jorge, www.insa.min-saude.pt
Portuguese Atherosclerosis Society, http://spaterosclerose.org

Romania

InoMed - Centre for Innovation in Medicine, www.ino-med.ro

Slovakia

MEDPED - Coordination Center for Familial Hyperlipidemias, Slovak Medical University, www.medpedfh.sk
SAA - Slovak Association of Atherosclerosis, www.saa.sk
Srdce rodiny,n.f, www.medpedfh.sk

Slovenia

University Medical Centre Ljubljana, www.kclj.si
ZA SRCE - Slovenian Heart Foundation, www.zasrce.si

Spain

FHF - Fundación Hipercolesterolemia Familiar Spain, www.colesterolfamiliar.org

The Netherlands

Amsterdam UMC, www.amc.nl
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CSAT CZECH SOCIETY FOR ATHEROSCLEROSIS

ISPAD International Society for Pediatric and Adolescent Diabetes

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