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Science & Technology in childhood Obesity Policy

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D1.5: Ethics Report – Period 3

Author(s): Professor Amandine Garde

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Dissemination Level

PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	☒

Abbreviation	Definition
STOP	Science and Technology in childhood Obesity Policy
GDPR	General Data Protection Regulation
WP	Work Package
RCT	Randomised Control Trial
ALSPAC	Children of the 90s data set
NCD-RisC	NCD Risk Factor Collaboration
BMI	Body Mass Index
EEA	European Economic Area
EU	European Union

Science and Technology in childhood Obesity Policy

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1 Executive Summary

This report is presented as Deliverable 1.5 and details the status of the STOP project (the Project) in relation to its ethics requirements in period M37-54. The Ethics Report has been completed by the Project independent Ethics Advisor, Prof. Amandine Garde (University of Liverpool) as per the ethics requirements detailed in Deliverable D12.5 – GEN requirement no. 5. The role of the independent Ethics Advisor is to monitor the ethics issues that may arise in the project and how they are handled.

The ethics requirements within the STOP project arise from:

- national and EU regulations;
- the requirements stated in the STOP contract (including its description of action); and
- the requirements of the Horizon 2020 Grant Programme.

This is the third ethics report by the independent advisor. The first and second reports focused on M1-18 and M19-36 of the project and detailed the ethical considerations relating to informed consent, the use of personal data, cohort samples, and the management of conflicts of interest. This third report covers M37-54 and focuses specifically on:

- the impact of COVID-19 on the Project;
- ethical issues by work package (WP);
- the storage, sharing and transfer of personal data; and
- the implications of the new UK-EU relationship for the Project.

2 Project Context

The Project brings together a range of key health and food sector actors to generate scientifically sound and policy-relevant evidence on the factors that have contributed to the rise of childhood obesity in EU Member States involved in the Project[1] and on the effects of alternative policy options available to address the problem. This evidence complements, systematises and partly reframes the findings of an established body of prior research by leveraging the latest scientific findings. The Project translated the evidence gathered and generated into:

1. a comprehensive set of indicators and a measurement framework for the regular monitoring of relevant dimensions of childhood obesity, its determinants and actions to address it in all European Countries;

2. policy toolkits, providing practical guidance and tools for the design and the implementation of effective and sustainable policies and actions by governments and private sector stakeholders; and

3. a novel, evidence-based, multi-stakeholder framework to enable and promote a shared understanding of problems and solutions by key actors, relying on a structured process leveraging cognitive mapping and policy simulations validated by empirical data and empowering individual actors to take action within an agreed accountability and monitoring framework.

The Project has generated:

[1] Belgium, Croatia, Estonia, Finland, France, Germany, Italy, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom. Switzerland, New Zealand and the United States are used as comparators.

- timely, comprehensive and policy-relevant measures of childhood obesity relevant throughout Europe; and
- new, trans-disciplinary evidence of the role of key determinants of childhood obesity, emphasising the role of different environments surrounding children, from analyses of detailed multi-dimensional measurements taken on several established EU children cohorts, including epigenetic and biological mediators of obesity;

it has also assessed the impacts of policies and actions to address childhood obesity based on observations in the same children cohorts and policy simulations of the health, social and economic outcomes of policies.

Importantly, addressing health inequities has consistently been an integral part of the Project, and specific attention has been given to understanding why childhood obesity is most prevalent in disadvantaged children (primarily, but not exclusively, based on socio-economic status) and what policies can be most effective in addressing the problem for those children.

3 The Impact of COVID-19 on the Project from an Ethical Perspective

The COVID-19 pandemic has caused some delays to the Project, as outlined in the Force Majeure letter dated 21/03/2022. However, mitigation strategies have been implemented in the relevant areas of work to limit the impact of COVID-19 on the Project and each of its constituting WP.

The ethical implications of such disruptions and mitigation strategies are limited to WP8, involving a randomised controlled trial of a primary care-based approach for addressing obesity in young children, and are discussed further below. The subcontracted pilot projects in WP6 were also delayed due to COVID-19. This had implications for the independent evaluation planned in T6.4. Further details are available in D6.4. All other WPs remain unaffected by COVID-19 as regards the ethical concerns for consideration.

4 Ethical Issues by Work Package

Due to the type of research undertaken in certain WPs (e.g. primary data collection, or research involving children), the section below details the ethical considerations that have been considered in each of these WPs.

4.1 WP2 – Measuring childhood obesity, disparities and geographical variations

WP2 leveraged the NCD-RisC[2] data pooling and analytical approach to estimate, for the first time, mean BMI and prevalence of BMI categories, including overweight and obesity in children, including adolescents, of different ages and gender in all European countries, based on measured data on height and weight, from at least 1975.

The study was implemented in accordance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects[3]. Depending on local circumstances, ethical permission was requested from relevant ethical committees.

2 NCD-RisC (NCD Risk Factor Collaboration) is a network of health scientists around the world that provides rigorous and timely data on major risk factors for non-communicable diseases for all of the world's countries.

3 International ethical guidelines for biomedical research involving human subjects. Geneva, Council for International Organizations of Medical Sciences/World Health Organization, 1993.

Prior to the child's enrolment in the study, parents were fully informed of all study procedures, and their informed consent for the measurements and for data treatment (all written in local language) obtained on a voluntary basis. This was done either through a letter or through a school information meeting. The objectives of the study, anthropometric measurements and data treatment were explained. Depending on local laws and regulations, countries had the option of choosing passive or active informed consent.

Confidentiality of all collected and archived data is ensured. Identification numbers are assigned to the children and each register mentions only those numbers. No information on the subjects is given to anyone external to the research. Forms are stored in safes at the national coordinating centre.

The children's names are not included in the electronic data files.

It is vital that field workers carrying out the anthropometric measurements work in a way that avoids stigmatisation and bullying and that they acknowledge the rights of children and parents to withhold and to withdraw consent from the project at any time.

School-specific results are not provided to the schools.

4.2 WP4 – Regulation and fiscal policies

WP4 has pursued two objectives:

- Firstly, to provide a comprehensive inventory of the effects of regulatory and fiscal policies.
- Second, to conduct simulation-modelling analyses to assess fiscal and nutritional labelling policies on children consumption, weight loss and health by focusing on socio-economically disadvantaged children, in different European countries.

Work concluded on Task 4.4 to assess the potential impacts of new fiscal and regulatory policies on added sugar in Europe.

As a part of this research, expert panels were created with individuals specialising in public health, nutrition, food- or health policy, obesity or chronic diseases. They were invited to participate in an online rating survey, and workshops to identify recommendations and their level of priority. All experts consented to take part in the panel and declared the existence of potential conflicts of interest. Representatives from industry were excluded in the Food-EPI process except in Finland, where the Finnish Food and Drink Industries' Federation and Finnish Grocery Trade Association participated in the workshops.

A full list of the experts who consented to include this information is available in Appendix 1 of D4.4. Ethics approvals were carried out independently by each participating country.

Ethical committee approvals for each country:

Estonia:

- The permission of the Ethics Committee was not required as no personal data is processed.

Finland:

- The permission of the Ethics Committee is not required as no personal data is processed.

Portugal:

- In Portugal, the experts signed a consent form which indicated their consent to participate in all the phases of the Food-EPI evaluation.

Slovenia:

- No personal data were collected or assessed in the study.

Spain:

- Clinical Research Ethics Committee of the Balearic Islands, Palma de Mallorca, Spain (ref. IB/3814/18PI).

Italy:

- The permission of the Ethics Committee was not required as no personal data is processed.

4.3 WP5 – Consumer Behaviour: Creating Demand for Healthy Lifestyles

WP5 aims to evaluate how national and local governments have created and promoted demand for health through social marketing and behavioural insights.

Work concluded in Task 5.3 to carry out a series of behavioural experiments to test hypotheses around children's and parents' responses to social marketing incentives and behavioural interventions, in the context of obesity policies. These experiments took place in two primary schools in Slovenia (one for the experiment, and one for the control group) with children from the 1st to the 4th grade (ages 6-10), where each has a high proportion of children with the highest BMI. The STOP task leader, HEC, partnered with the Institute for Health and Environment (IHE) in Ljubljana, Slovenia to conduct the intervention in schools in Slovenia.

The closure of schools due to the COVID-19 pandemic delayed the start of the behavioural experiments. WP5 partners ran the experiment in September 2021 – July 2022, when COVID-19 was considered to be at a manageable level and external researchers were permitted into schools.

The experiment utilised an opt-in method in obtaining consent for participation for all parts of the research, unless a particular school preferred the opt-out method. Both options of consent were explained to the participating schools. The sample pool options depended therefore on the method relied upon to obtain consent. It was first made clear to the schools that no child would have to participate in the research activities without their consent, and clear information sheets were provided, based on which of the research activities were to be presented to children. To minimise the risk of personal bias of the researchers in choosing overweight children out of the potential sample pool, the researchers strove towards a balanced sample without positive or negative discrimination of participants.

The research focused on school lunches and snacks that children ate on their way to school, in school, or on their way home from school. Interviews were carried out with children to find out what food items they chose for school lunch, what they actually ate, and to ascertain if and/or why they did not eat certain food items. These interviews were carried out in the form of focus groups of three to six children, in order to create a friendly setting for the participants. If a child did not actively participate in the conversation and was uncooperative, researchers considered this as their revoked consent. The child was immediately escorted to the teacher, who was informed of what had happened. There were concerns of potential unwanted invasion of the research into the children's

home environment, especially with snack diaries, which needed to be partially filled in at home to document after-class snacks. This could have overlapped with dietary practices in the home environment, which were not the subject of the research. To avoid possible misunderstandings, the purpose of the snack diary was clearly explained orally, as well as the time frame of the data required for entry.

The social marketing intervention was based on the results of the first phase of research activities. The focus of the intervention was to target the eating of unhealthy snacks. The specific goal was to reduce the consumption of unhealthy snacks, and in doing so, increase the consumption of healthier snacks, in particular, the consumption of healthy vegetable snacks. With the intervention, the researchers strove to establish a positive attitude towards healthy components of school lunches and the well-being of children. Special attention needed to be paid to planning the intervention so that it respected the personal rights of children to privacy and data protection, and took account of cultural and individual diversity (e.g. specific dietary limitations resulting from religious beliefs).

4.4 WP6 – Healthy Food and Food Choice Environments

WP6 seeks to identify ways of effectively promoting the supply and delivery of healthy foods through appropriate food reformulation and formulation programmes and through a redesign of key aspects of food environments to make them conducive to healthy food choices.

A further component of WP6 involved the funding of four industry-led pilot projects, which aimed to make a positive impact on childhood obesity through technological innovations and the reformulation of food products.

The four funded projects are:

- FlavorID, an app-based recipe recommender based off individual tastes and preferences with the aim to incorporate more vegetables into children's diets;
- MilaCel, a food reformulation project which uses apple fibre paste to reduce the fat and sugar content of food whilst retaining satiety and taste;
- the SWEET App, an app-based technology which delivers educational content to families with the ability to also browse and self-refer to non-medical sources of support in their own communities ('community assets') which focus on obesity prevention and physical activity; and
- Shift, a meal delivery service which aims to offer a healthy and affordable alternative to current takeaway options in two London boroughs.

Each project team was granted 150,000 EUR by the Project and implemented a pilot project over an 18-month period with input from relevant Project partners and third parties. The success of all four projects will be comprehensively evaluated at the end of the 18-month period by Project partners and independent experts. Moreover, where possible, Imperial College London undertook a separate evaluation of the pilot projects as part of the final reporting period of the Project. However, COVID-19 delayed the progress of the pilots, and this had knock-on impacts for the evaluations. Where required, ethics approval was sought from ICREC (Imperial College Research Ethics Committee). However, I have not been involved and have not seen the report, so am unable to comment further.

FlavorID:
For the ICL evaluation of the FlavorID innovation, ICL will conduct an evaluation of their 'Happy Plate' platform, which uses 'FlavorID' technology. The evaluation includes a quantitative component (based on data from a 4-week randomised control trial on cooking and a 3-month follow-up) and a

qualitative component (based on semi-structured interviews immediately after the end of the cooking trial).

MilaCel:
In order to understand the potential of the MilaCel apple fibre paste to tackle childhood obesity, Pennotec conducted an experimental evaluation on reduced-calorie recipes of school lunch desserts with year 5 and year 6 children in three primary schools in Gwynedd. The evaluation started with a seven-week school lunch trial, followed by a focus group interview with randomly selected participating children. It aims to understand:

- Children's acceptance of adapted school lunch desserts when a proportion of the fat that is replaced with fat-mimicking, insoluble MilaCel apple fibre paste.
- Possible mediators, barriers and facilitator to children's acceptance of adapted school lunch desserts.

Pennotec will share the data collected from the evaluation with Imperial in a fully anonymised way. Imperial will analyse the data to assess:

- school cooks' feedback on the use of the reduced-calorie dessert recipes
- students' acceptance of adapted school menu desserts
- students' consumption behaviour on the adapted desserts by exploring possible mediators, barriers and facilitators to students' acceptance of adapted school lunch desserts

SWEET App:
The evaluation of the SWEET App project aims to evaluate the effectiveness of the SWEET App in increasing children's physical activities and improving their dietary quality. Old Library Trust in North Ireland developed the SWEET App, and will independently conduct the SWEET App evaluation, including a quantitative evaluation (a SWEET App trial) and a qualitative evaluation (a semi-structured interview via telephone). With participants' consent, Old Library Trust will fully anonymize the data including the data collected using online questionnaires during the SWEET App trial and the transcriptions from the audio-recorded telephone interviews and then share the fully anonymised data with Imperial College London subject to a pre-signed data agreement.

ICL's study will only involve analysing the fully anonymised data to anonymised secondary data collected from the evaluation of the SWEET App project pilot by the Old Library Trust in North Ireland. ICL's project aims to produce scientific evidence to support the fight against childhood obesity, evaluating the effectiveness of the SWEET App in increasing children's physical activities and improving their dietary quality.

SHIFT:
The SHIFT pilot project aims to generate evidence to show that the SHIFT cold-delivered meals are healthier, appealing and affordable alternatives to existing unhealthy meals like take-aways. SHIFT developed their meals and set up a localised distribution network to increase the availability and accessibility of healthy food in local communities. SHIFT undertook a number of activities in 2021 to pilot SHIFT meals, including an Easter Holiday Programme, a Summer Holiday Provision, school pilots, and cafe pilots. SHIFT sold a large number of meals and got overall positive feedback from consumers and organizations during these activities. SHIFT found that their meals were healthier alternatives to high street takeaway and contract caterers, and sometimes to supermarket and home cooking.

ICL's study has not gathered new data (due to the fact that the SHIFT project was not sustainable and therefore could not support an external evaluation). Instead, they will perform a descriptive

analysis followed by a cluster analysis of the data. The ICL evaluation will only use anonymised secondary data gathered by SHIFT, and consent was obtained by SHIFT from participants to do so.

Ethics approvals were carried out as necessary for each pilot project evaluation. Details on all ethical approval obtained for the evaluations is as follows:

FlavorID
- Imperial College Research Ethics Committee (Ref: 22IC7747). Obtained 06/09/2022

MilaCel
- Imperial College Research Ethics Committee (Ref: 22IC7785). Obtained 17/06/2022

SWEET App
- Imperial College Research Ethics Committee (Ref: 21IC7295). Obtained 13/12/2021

SHIFT
- The permission of the Ethics Committee was not required as only anonymised secondary data was analysed and consent was obtained by participants to do so.

I have noted in my previous reports the potential for real, perceived, or potential conflict of interest when involving industry partners in policy projects such as this one, and the need to ensure that this risk is effectively managed throughout the Project. This being said, no ethical concerns have been brought to my attention. I note that regular monitoring of progress has taken place through monthly catch ups with all four project teams and that regular communication has also been maintained with the project teams through:
- monthly catch up calls;
- periodic reporting at M6, M12 and M18 which detail the work carried out in the given period, deviations, deliverables, impact and risk management. The completion of an acceptable report is linked to the interim payment. Any information deemed concerning by the management team would be followed up with a meeting to provide clarity; and
- presentations at STOP project consortium roundtables, which offers a forum for questions and answers by partners to the project teams.

4.5 WP8 – Health Care

The first and second ethics reports detailed the work completed in WP8 Health Care regarding the randomised control trial on an obesity intervention in Spain, Sweden and Romania.

Due to the COVID-19 pandemic, adjustments were made to the RCT in light of social distancing restrictions. The intervention originally entailed 10-weekly face-to-face group sessions which utilised evidence-based parenting practices, followed by the use of a mobile app for six months to support healthy eating and physical activity. The pandemic made face-to-face group sessions impossible, so a decision was made to deliver the intervention online.

- For Romania, a revised ethics approval document was submitted and approved in 2020 for this change.
- For Sweden, the ethics amendment was approved in January 2021, until then physical groups had still been possible.

- For Spain, no revision to the ethics application was required as the original agreement was broad enough to include any contingencies, as long as the objective and the ethics of the project were maintained.

4.6 WP10 – Multi-Stakeholder Action

The objective of WP10 is to contribute to the improvement of obesogenic environments by structuring stakeholders mobilisation and participatory involvement, sharing knowledge, using a whole-of-society approach, promoting shared understanding of 'health in all policies' drivers, challenges and solutions of the obesogenic environment in which children live.

The first stakeholder survey was drafted around the time GDPR was applied. WP10 partners chose to interpret GDPR in its strictest form, omitting the plan to work with identified stakeholders. Instead, stakeholders were anonymised and were identified only though the welfare triangle and field of work. GDPR was used throughout the project duration in WP10 while addressing stakeholders.

5 Data Storage, Sharing and Transfer

Data continues to be stored on the restricted cloud storage software, BOX, which ensures encryption in transit using AES 256-bit security.

Access to data is only granted to teams working directly on the analysis and processing of the data.

Subject to GDPR and other relevant legislation, datasets were made openly accessible and downloadable. No sensitive or personal data was placed in the public domain.

For WPs that collected primary data, appropriate data sharing agreements were put in place with the other partners involved to allow access.

Data transfer agreements currently exist in WP2, WP3, and WP8 between the following Project partners:

WP2:

- Sciensano and the Federal Public Service of Health (Brussels) and Imperial College London

WP3:

- Imperial College London and University of Zagreb
- Imperial College London and University of Crete
- Imperial College London and CItta della Salute d della Scienza di Torino
- Imperial College London and University of Ljubljana
- Imperial College London and Barcelona Institute for Global Health (IS GLOBAL)
- Imperial College London and University of Timisoara
- Imperial College London and University College London
- Imperial College London and Children of the 90s (ALSPAC) University of Bristol
- Imperial College London and Swansea University
- Imperial College London and University of Porto
- Imperial College London and Universiteit Hasselt
- University of Torino and University of Helsinki

WP8:

- Imperial College London, Consorcio Centro de Investigación Biomédica en Red MP (CIBER), Karolinska Institute (KI), and Universitatea de Medicină și Farmacie Victor Babeș Timisoar (UMFT)

These data transfer agreements can be submitted to the European Commission on request, as per the project's ethics deliverable D12.3 POPD – requirement no. 3.

6 The UK and the EU

The UK left the EU on 31 January 2020 (with a transition period to 31 December 2020). Imperial College London is the only UK partner in the project and has ensured that appropriate measures are in place to guarantee the ability to continue to share data with STOP's European partners without violating any data protection laws.

There are a limited number of personal data shared between partners in the project. Most data have been anonymised in such a manner that the data subject is no longer identifiable. In the case of personal data transfer, Imperial College has data sharing agreements in place (as listed in the above section). Now that the UK is a 'third country' under the EU GDPR in terms of personal data transfers, Imperial College has ensured Standard Contractual Clause agreements are in place between the partners it shares data with (and vice versa).

Data transfers from the UK to the EEA (and other countries deemed to have effective data protection regulations by the EU) continue unaffected. The UK has adopted all of the existing European Commission adequacy decisions. In addition, the UK has declared that the EEA is a 'safe place' to transfer personal data, and therefore no other gateway mechanism is required for UK to EEA transfers. This is reflected in a UK-specific version of the GDPR (known as the "UK GDPR") which took effect on 1 January 2021. The UK GDPR provides a replica regime for transfers of personal data outside the UK, similar to the rules in the EU GDPR for ex-EEA transfers.

Even though we can only regret the UK's withdrawal from the European Union, we are confident that all necessary measures have been taken to limit its impact on the Project.