

1. Saatekirje

Tampereen alueen ihmistieteiden eettiselle toimikunnalle

Pyydän toimikunnan lausuntoa EU-rahoitteen SILNE-tutkimuksen WP5-osiota koskevasta koululaistutkimuksesta, jossa on mukana viisi eri maata (SILNE Tackling socioeconomic inequalities in smoking: learning from natural experiments by time trend analyses and cross-national comparisons).

Pyynnön peruste: Tutkimuksen rahoittaja edellyttää ennakoarviointia, joka on myös tutkimusrahoitusta haettaessa tutkimussuunnitelmassa esitetty. Myös kansainväliset alan tieteelliset julkaisut edellyttävät useimmiten arvioinnin toteuttamista.

Erityistä salassapitotarvetta ei ymmärtäksemme asialle ole, mutta kyselylomakkeita ei vielä tässä vaiheessa ole syytä laittaa julkisuuteen.

Tampereella 14.11.2012



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Introduction

General description of SILNE

For any strategy aimed to reduce socioeconomic inequities in health in Europe it is vital to tackle the large and widening inequalities in smoking. However, there is only limited evidence on effectiveness of tobacco control policies in terms of reducing inequalities. Especially lacking are evaluations of the effects of policies that have actually been implemented in different European countries. In addition, no studies have assessed the role of “strategic drivers” such as social welfare or educational policies.

The aim of the SILNE project is to analyse various “natural policy experiments” within Europe with the aim to generate new empirical evidence on the effectiveness of possible strategies to reduce inequalities in smoking. The project is divided into three main sections. First, time trends in various European countries will be analyzed with the aim to assess whether changes in national tobacco control policies have influenced inequalities in smoking cessation among adults. Second, comparisons between European countries will be made with the aim to assess whether cross-national differences in specific tobacco control policies were associated with inequalities in smoking initiation among adolescents. These cross-national comparisons will also assess whether different types of educational systems are associated with inequalities in smoking initiation. Third, the project will review the published results of intervention studies, and integrate these with our results. This innovative project will develop comparative research into a new strategy for the evaluation of natural experiments, combining methods from different disciplines.

General description of SILNE-WP5

SILNE -WP5 is part of second section of SILNE project. The overall objective of SILNE-WP5 is to assess how school-based social ties contribute to regular smoking socio-economic inequalities in smoking among adolescents within the different socioeconomic stratum and educational systems (general and vocational). A survey will be carried out in five European countries: Finland, Germany, Belgium, Italy and Portugal. These countries strongly differ on the index of educational differentiation (OECD and Duru-Bellat, 2005).

Table 1 presents a detailed working planned of SILNE-WP5.

Project SILNE - WP 5				
Milestones	Activity description	Deliverables		
		WP5 member responsible	Frame time	Date Requested
PHASE I - YEAR 2012				
Questionnaire design	Gathering comments and update version of questionnaires	WP5 project coordinator	January –August	August 20 th
	English version of questionnaires for the pilot			
Adapting and translating the questionnaires	Translation of the questionnaire into WP5 country languages	All partners: Belgium, Italy, Finland and Portugal	August	September 15
	Sending the translated version of questionnaires to coordinator project			
Platform of data entry	Design of web platform of data entry 1. Platform to name generator 2. Platform to school's and student's questionnaire	WP5 project coordinator	August-October	October 15
Ethics profile	National administrative process	All partners: Belgium, Italy, Finland and	August – October	
	Sending “ethic approval for conducting survey” to coordinator			November 1 st

	project (for example, a letter)	Portugal		
Piloting survey questionnaires	Invitation to school: letters, calls	All partners: Belgium, Italy, Finland and Portugal	September–Dec	
	Piloting the survey questionnaires		November–Dec	
	Data entry /cleaning		December	December 15
Recruitment of schools	Invitation to school: letters, calls	All partners: Belgium, Italy, Finland and Portugal	September- Dec	
	Sending list of participating schools (detailing size, type and proxy of socioeconomic status of the each school) to coordinator project.			December 15
Discussion of pilot results	Presentation of pilot results	WP5 project coordinator	January-2013	January 21 st - 24 th
	Discussion of the results : Special section at third consortium meeting in Brussels	All partners: Belgium, Italy, Finland and Portugal		
	Planning and timing of survey fieldwork			
PHASE II - YEAR 2013				
Conducting of survey	Administration of survey	All partners: Belgium, Italy, Finland and Portugal	February – April	Dates to confirm
	Data input and processing		April – June	
	Preliminary data analysis and reporting		July	
PHASE III - YEAR 2013 – YEAR 2014				
Exploratory data analysis	Analysis and reporting writing	All partners: Belgium, Italy, Finland and Portugal	August- December/ 2014	Dates to confirm
PHASE IV - YEAR 2013 – YEAR 2014				
Final analysis and reporting writing	Analysis and reporting writing	All partners: Belgium, Italy, Finland and Portugal	August- December/ 2014	Dates to confirm

B.4. Ethical Issues

4.1. General issues

The project has very limited ethical implications. It involves no work with genetically modified or dangerous organisms or human tissue and no animal experimentation.

The project has no foreseeable harmful effect on the environment or abnormal safety aspects.

The proposed project will not be harmful to humans or the environment.

The project partners will make use of existing databases that contain aggregate data or otherwise anonymous data that cannot be associated with particular individuals. We confirm that the existing data have been approved for secondary use in this study.

4.2. Rules regarding the survey among 16-17 years old students

Personal data will be collected in the interview surveys of adolescents (WP5). Among volunteering and consenting 16-17 year olds, data will be collected on smoking behaviour, socioeconomic status, social networks, and a few life style related factors. All interviewers conducting the surveys will be trained to respect all students and their opinions. We will prevent issues such as stigmatisation that may be related, in specific settings, to sensitive issues such obesity, social isolation, low education marks, or poverty.

Before administering the interview surveys, we ask for the consent of persons to whom the information relates, and also ask parents' consent. All students will be fully informed about the contents and the aims of the study. More specifically, we confirm that participating students will have the right:

1. To know that participation is voluntary
2. To ask questions and receive understandable answers before making a decision
3. To know the degree of risk and burden involved in participation
4. To know who will benefit from participation
5. To know the procedures that will be implemented in the case of incidental findings
6. To receive assurances that appropriate insurance cover is in place
7. To withdraw themselves, their data from the project at any time
8. To know how their data will be collected, protected during the project and destroyed at the end
9. To know of any potential commercial exploitation of the survey.

Complete confidentiality of data will apply, and the data collection will conform to requirements of national and European legislation on data protection. The handling of personal data will comply with the Personal Data Protection Act in each country. Only data relevant for the conduct and analysis of the SILNE project will be collected. All data obtained will be anonymised and protected from unauthorised access. Data will be transferred into password-protected computer systems exclusively by members of the research team designated for the particular tasks.

Review and approval of the survey design will be requested at all participating countries sites from the respective ethics committees. We confirm that copies of ethical approvals by the competent local/national Ethics Committees will be submitted to the European Commission prior to the commencement of the survey. When applying for ethical approval from the competent local/national Ethics Committees, detailed information will be provided on:

1. the procedures that will be used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc) and the nature of the material that will be collected (e.g. sensitive or personal data etc).

2. the informed consent procedures that will be implemented. Copies of examples of Informed Consent Forms and Information Sheets will be included. These will be in language and terms understandable to the participants.
3. privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.

An external independent Ethics Advisor will be appointed to oversee the ethical concerns involved in this research. A report by the Ethics Advisor will be submitted to the European Commission with the Periodic Reports.

ETHICAL ISSUES TABLE

(Note: Research involving activities marked with an asterisk * in the left column in the table below will be referred automatically to Ethical Review)

Research on Human Embryo/ Foetus		YES	Page
*	Does the proposed research involve human Embryos?		
*	Does the proposed research involve human Foetal Tissues/ Cells?		
*	Does the proposed research involve human Embryonic Stem Cells (hESCs)?		
*	Does the proposed research on human Embryonic Stem Cells involve cells in culture?		
*	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			X

Research on Humans		YES	Page
*	Does the proposed research involve children?	x	See above
*	Does the proposed research involve patients?		
*	Does the proposed research involve persons not able to give consent?		
*	Does the proposed research involve adult healthy volunteers?		
	Does the proposed research involve Human genetic material?		
	Does the proposed research involve Human biological samples?		
	Does the proposed research involve Human data collection?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			

Privacy		YES	Page
	Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	X	see page above
	Does the proposed research involve tracking the location or observation of people?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			

Research on Animals		YES	Page
	Does the proposed research involve research on animals?		
	Are those animals transgenic small laboratory animals?		
	Are those animals transgenic farm animals?		
*	Are those animals non-human primates?		
	Are those animals cloned farm animals?		

I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	X
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Research Involving Developing Countries		YES	Page
	Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?		
	Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc)?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		X

Dual Use		YES	Page
	Research having direct military use		
	Research having the potential for terrorist abuse		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		X

**TAMPEREEN YLIOPISTO
TAMPEREEN ALUEEN IHMISTIETEIDEN
EETTINEN TOIMIKUNTA**

Lausuntopyyntö 10/2012: "SILNE Tackling socioeconomic inequalities in smoking: learning from natural experiments by time trend analyses and cross-national comparisons" (professori Arja Rimpelä, Terveystieteiden yksikkö, kansanterveys).

Päätös: Toimikunta antaa puoltavan lausunnon. Ei varsinaisesti eettisiä ongelmia. Toimikunta haluaa kuitenkin todeta seuraavat asiat, jotka pyydetään huomiomaan ja muuttamaan tiedotteessa/tutkimussuunnitelmassa.

Toimikunta toteaa, että tiedotteen kuvaus tutkimuksesta ei vastaa riittävän tarkasti tutkimussuunnitelmassa esitettyjä tavoitteita. Tiedotteessa mainitaan, että tutkimuksella on tarkoitus selvittää, kuinka 14-16-vuotiaiden sosiaaliset suhteet vaikuttavat tupakointiin ja muuhun terveystiettyymiseen. Kyselylomakkeessa on monia kysymyksiä, jotka koskevat nuoren kotia ja perheen toimeentuloa, mm. nuoren käsitystä perheen taloudellisesta asemasta suhteessa muihin perheisiin. Vaikka tutkimussuunnitelma painottaa sosioekonomisia tarkasteluja, tiedote ei näitä tuo esiin. Maininta näistä tulisi liittää tiedotteeseen.

Toimikunnan mielestä tutkimuksen tiedotteessa tulee tuoda selkeästi esiin se, että ennen kyselylomakkeen täyttöä varmistetaan se, että tutkittavat ymmärtävät vastaamisen olevan vapaaehtoista. Tiedotteessa tulisi myös mainita se, että mikäli tutkimuksessa ilmenee tutkittavien kannalta arkaluonteisia tietoja, kyseiset tiedot ovat luottamuksellisia.

Tutkimussuunnitelmaan/lausuntopyyntöön ei ollut liitetty rekisteriselostetta. Tämä on ongelmallinen aineiston säilytyksen ja vastuiden kannalta. Koska henkilötietolain 3 §:n mukaan henkilötiedolla tarkoitetaan kaikenlaisia luonnollista henkilöä taikka hänen ominaisuuksiaan tai elinolosuhteitaan kuvaavia merkintöjä, jotka *voidaan* tunnistaa häntä tai hänen perhettään tai hänen kanssaan yhteisessä taloudessa eläviä koskevaksi. Tietosuojaryhmä on

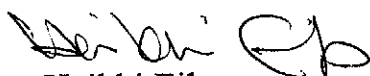
antamassaan lausunnossa 4/2007 todennut välillisen tunnistettavuuden osalta, että tietoja saattaa olla tunnistettavissa, koska tieto yhdistettynä muihin tietoihin (joiden ei välttämättä tarvitse olla rekisterinpitäjän hallussa) mahdollistaa henkilön erottamisen muista. Rekisteriseloste on myös tässä tutkimuksessa laadittava ja lähetettävä toimikunnalle. Tähän liittyy myös kysymys siitä, mitä suostumuslomakkeille tehdään, kun ne on saatu lasten vanhemmilta.

Lisäksi toimikunta keskusteli tutkimuksen aikana kertyvien vakavien ja arkaluonteisten tietojen käsittelystä. Vaikka kyse on luottamuksellisista tiedoista, miten tutkijat toimivat, jos esiin tulee hyvin vakavia, vaikkapa huumeiden käyttöön liittyviä tietoja?

Tutkimussuunnitelmaa ei edellä mainittujen muutosten jälkeen ja tämän lausunnon jälkeen tarvitse enää lähettää toimikunnan arvioitavaksi. **Rekisteriseloste pyydetään lähettämään toimikunnan sihteerille.**

Tampereella 27.11. 2012

Merk.
Professori Markku Ojanen
Puheenjohtaja



Heikki Eilo
Sihteeri

PDF: Luvut 20121130120337

MY DOCUMENTS