

Case of the PONS study

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Poland is one of the most interesting countries in Central and Eastern Europe, where at the beginning of the 90's major amazing favourable health changes were observed after 30 years of increases in cardiovascular mortality between 1960-1990 among adults. In Poland (and neighboring countries), the cardiovascular transformation began with a 20-year delay in comparison to Western Europe. In Poland, cardiovascular morbidity and mortality continues to decline, as is the case in western European countries and in North America. The cause of this significant decline of CVD sustained over the last 20 years, seems to be strongly connected with changes in diet, especially rapid changes in vegetable fat consumption [1,2]. For this reason, but most importantly due to my long and very good collaboration with Polish cardiologists [3], when in 2005 I began developing study teams for the PURE study, I thought of Poland.

The PURE project idea came from the need to understand the underlying causes of global health changes – an observed for many decades increase in life expectancy, decline in infant and children mortality, and decrease of infectious diseases morbidity and mortality. During that time, an increase in morbidity and mortality from man-made diseases was observed: arteriosclerosis, hypertension, diabetes, obesity, and cardiovascular diseases; moreover, there exist globally significant differences in morbidity and mortality from these causes. Developing countries undergo a series of social transformations: economical and urbanization, which change lifestyle. It's expected that by 2020, over 85% of the global burden of CVD will be in developing countries. Therefore, there is an urgent need to understand how the social changes in countries with various levels of economical development influence the increase of the above-mentioned chronic diseases. The aim of the global PURE study is to analyse both macro-environmental changes (urbanization and other social factors) and individual factors (metabolic, genetic, connected with lifestyle) in 17 countries of the world with low, middle and high domestic income. The PURE project will allow an understanding of the 'causes of the causes' of changes in the health processes on world scale, and develop a strategy for reducing these unfavourable health phenomena [4].

In 2007, I invited Professor W. Zatoński to take part in the study, and Poland joined the project which has been implemented with great success. First, a country-specific food frequency questionnaire was developed for Poland. Currently, there began process of publishing the first results of the study; for instance, a paper published a few months ago in the *Lancet* [5].

The Polish PURE cohort consists of 2,100 participants and has currently entered the next stage of the study, which is a 10-year follow-up. At present, the 3 year follow-up is 100%.

When I heard about plans for another project in Poland, aimed at establishing a prospective cohort of over 10,000 participants – PONS – which is partly based on PURE, I decided to participate and assist. The PONS project study

components are compatible with the PURE project and allow for extending the Polish cohort. It will enable identifying risk factors and understanding changes in health in the Polish population, and in further perspective, developing effective methods of preventing and controlling epidemics of man-made diseases.

The PONS study is a landmark step forward, but it is important that this study not only contributes to furthering the concept of prevention and related knowledge in Poland, but also can be in a position to provide useful information that is general and is published in high quality international journals. In this regard, I would be happy to assist in developing focused protocols containing specific hypotheses that could be tested. By this I mean not simply descriptive data, but addressing specific objectives that lead to understanding as to why there is more diabetes, hypertension, and obesity, or why certain risk factors increase, or why the smoking rates decrease (causes of the causes). I would be happy if there can be adopted into the PONS study many of the ideas from PURE, as well as from the EPOCH component, that would build in the appropriate level of information gathering.

The second thing that is important is to ensure that whatever approach is used in such studies, one should have a sampling frame towards recruiting individuals so that the variation in results can be understood, as well as how the population was selected, and most importantly, to obtain an assessment regarding the degree to which the population is represented (see also commentary by Paolo Boffetta on external and internal validity). I realize that in a cohort study, internal validity is more important than external validity, but I expect that the PONS team will want to carry out a number of analyses based on the baseline data collection. Therefore, some mechanism of structure urban versus rural recruitment, and targeted recruitment in different parts of Poland that is relatively unbiased, should be considered. Thirdly, I think it is worth defining which outcomes are of interest and to identify them in advance. I would recommend that the PONS study should go beyond cardiovascular outcomes, and include injuries, depression, cancers, and other related conditions.

The hypotheses in the protocol are the key because they will help us to understand whether or not the right exposures are measured, and the right outcomes identified, and whether validated and tested tools are used.

In conclusion, I would like to congratulate the PONS team for this very important study and I wish to strengthen our collaborations in future.

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