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Nordfalk, Francisca; Hoeyer, Klaus

Published in:
Scandinavian Journal of Public Health

DOI:
10.1177/1403494817745189

Publication date:
2020

Document version
Publisher's PDF, also known as Version of record

Scandinavian Journal of Public Health, 1–5

ORIGINAL ARTICLE

The rise and fall of an opt-out system

FRANCISCA NORDFALK & KLAUS HOEYER

Center for Medical Science and Technology Studies, Section for Health Services Research, Department of Public Health, University of Copenhagen, Denmark

Abstract

Introduction: In Denmark, citizens participate in register-based research without the possibility of opting out. However, in 1995 it was made possible for Danish citizens to register an opt-out called 'researcher protection' [*forskerbeskyttelse*], which implied that researchers could not contact people to invite them to participate in research projects, such as clinical trials or questionnaries, based on their registrations in national registers. Data already registered could still be used for research. In 2014, this possibility of opt-out was revoked by law. *Aims:* The aims of this paper are to understand how the Danish researcher protection system came about, why it was terminated and what we can we learn from this example. *Methods:* We conducted a descriptive analysis of a copy of the former researcher protection register along with policies and media debate surrounding the rise and revocation of the researcher protection system. *Results:* Our results show how both the inception and the abolishment of researcher protection appear to be ad hoc and without specified criteria of success. An examination of the recorded entries in the researcher protection registry could have led to changes in its administration as an alternative to its total abolition. ***Conclusions:*** **In future opt-out systems, there should be focus on monitoring register practices and the purpose and criteria for evaluation must be defined prior to implementation.**

Key Words: *Opt-out, opt-out systems, register-based research, research participation, consent, medical ethics, Denmark*

Introduction

When recruiting participants for research, it is important to ensure high response rates from an unbiased population [1]. One way of recruiting is to actively inform potential participants about the study and ask if they are willing to consent to participate – also known as 'opt-in'. Another way to recruit is to presume consent. This approach can be combined with an opt-out system in which those who genuinely do not wish to participate must actively decline. As a consequence, opt-out systems typically imply transferring the obligation to act onto those who wish to abstain from participation. Opt-out systems often generate higher participation rates and a more representative population than opt-in systems and are therefore preferred by many researchers [1–3]. In the literature, when studies of public opinion find opposition to presumed consent, adding an opt-out option tends to be presented as a solution [4,5].

We describe the rise and fall of a particular Danish opt-out system. To understand the nature of this system, it is important to comprehend the Danish register structure. All citizens in Denmark are assigned a unique 10-digit civil registration (CPR) number and this number is recorded in the Central Person Register (CPR). The CPR contains information about name, address, gender, marital status, birth, citizenship, kinship, membership of the Danish church, possible legal incapacity and whether or not this information is accessible to others. The individual CPR number is used in practically all contacts with public (and many private) services and, by making all the data traceable for each individual person, the CPR number facilitates

Correspondence: Francisca Nordfalk, Centre for Medical Sciences and Technologies, Section for Health Services Research, Department of Public Health, University of Copenhagen, Øster Farimagsgade 5A, Øster Farimagsgade 5A, Copenhagen K, 1014, Denmark. E-mail: nordfalk@sund.ku.dk

Date received 10 April 2017; reviewed 21 September 2017; accepted 24 October 2017

DOI: 10.1177/1403494817745189
journals.sagepub.com/home/sjp
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combinations of all other registers covering health, education, employment and income. Data from health encounters are routinely transferred to national registers using the individual's CPR number [6,7]. This pervasive registration of citizens has made some consider the entire country of Denmark a cohort study [8]. As other Scandinavian countries share many features of the Danish register structure [9], it is particularly relevant for Scandinavian researchers to learn from this Danish case of a register-based opt-out system. Opt-out systems are increasingly discussed and recommended internationally [10,11].

In Denmark, researchers can conduct register-based studies on the Danish population using the CPR number without the consent of the participants and without it being possible for people to opt out. However, from 1995 to 2014, it was possible for Danish citizens to register a version of opt-out called 'researcher protection' [*forskerbeskyttelse*] in relation to their CPR number. Researcher protection meant that researchers, who would otherwise have used the CPR to identify participants for research, could not contact them. It thereby mainly affected the recruitment of research participants and hindered surveys based on CPR numbers. It also affected people recruited for research in other ways – for example, in the course of clinical care, because if someone was under researcher protection, then researchers could not combine register-based information with their clinical participation, irrespectively of their clinically given consent [12]. However, researcher protection did not affect the continual registering of data on citizens and it was still possible for researchers to include people under researcher protection in purely register-based studies without consent.

We know very little about how opt-out systems operate in practice. Most studies of register-based opt-out systems have been conducted either as comparative trials between opt-out and opt-in systems in relation to specific medical data or electronic health journals, or as studies of attitudes towards opt-out systems [1–3,13]. Case studies of long-term operational opt-out systems embedded in healthcare systems are limited. We present a brief analysis of the rise and fall of a Danish opt-out system to illustrate some central caveats worth considering before other healthcare systems embark on the introduction of opt-out systems for research.

Methods

We conducted a descriptive analysis of the accessible data on researcher protection – primarily, a copy of the former researcher protection register, acquired through Statistics Denmark, where a copy was retained according to legal statutes aimed at ensuring historical documentation. Because of the CPR, we were able to link the registrations of researcher protection to demographic information on the population, including sex, age, socioeconomic status and municipality. We were interested in how many people were under researcher protection, characterized by their demographic variables, and how registrations to researcher protection developed throughout the period. The data were analysed using the SPSS version 22 software available at Statistics Denmark. We also analysed all political documents concerning the inception and the abolishment of researcher protection available on the website of the Danish Parliament [14,15] and looked into any media debate covering researcher protection using an online media monitoring system [16]. Both the political documents and the media debate were analysed using Madden's thematic coding principles [17], thereby allowing us to focus on the arguments in both the inception and the later abolishment of researcher protection. Our aims were to answer the following questions: how did this Danish opt-out system arise, why was it terminated and what can we learn from this piece of history?

Results

The researcher protection register was created in 1995 through an addition to the law regulating the CPR [18]. The only documented reason for the creation of researcher protection is that it came about in response to requests from three citizens who had expressed concerns about being identified by researchers through records using their CPR number [19]. The legal note states how citizens who have 'name and address protection' (a one-year protection of their name and address from disclosure to private individuals) would also automatically get researcher protection. The purpose of the opt-out system was not stated and, without a clear purpose, there was no basis for evaluation.

In spring 2014, the Danish Parliament revoked the part of the law that referred to the researcher protection register, effectively withdrawing the register from use. With this revocation, all Danish citizens could therefore again be contacted by researchers after being identified through the CPR register. At the point of revocation, about 900,000 citizens were registered under researcher protection. Even though, in principle, it affected many citizens, the revocation of the law and the consequent withdrawal of the register never caused any substantial political or public debate.

The register on researcher protection was somewhat disorganized and it had clearly not been

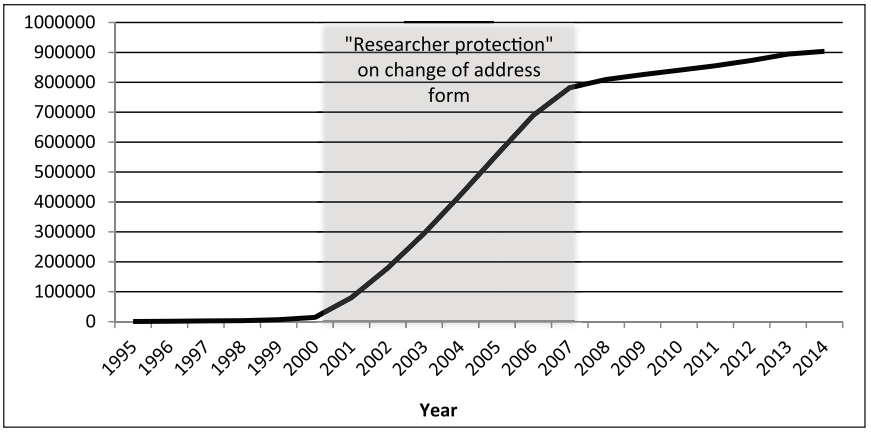

Figure 1. Number of citizens under researcher protection.

scrutinized either during or after its operational period. We were informed that we were the first researchers to look into it. Consequently, the number of citizens who had opted out by registering under researcher protection cannot be determined with absolute certainty, but our calculations suggest that it consisted of 903,779 citizens when the register was abolished from use in 2014, about 16% of the Danish population.

From 1995 to 2014, the register thus increased significantly. However, it was not a linear increase throughout this period (see Figure 1). The increase coincided with a change in the practice of administrating the registrations. In 2000, the administrative responsibility for maintaining the researcher protection register shifted from the state to the municipalities. As the municipalities already administered the aforementioned name and address protection, the municipalities decided to administer the researcher protection in the same way. In May 2000, it was added as a separate 'tick-off' option on a paper form, which was mandatory for citizens to fill in whenever changing address. With this new administrative practice, many Danish citizens now incidentally encountered the researcher protection option. In addition, the person filling in the paper form could simultaneously register other members of their household, effectively opting out on their behalf. If citizens had name and address protection, then they would automatically be granted researcher protection, but whereas name and address protection was operational for only one year, researcher protection was for life. From 1995 to mid-2000, the majority of registrations for researcher protection were a consequence of name and address protection. However, from mid-2000, when researcher protection was added to the paper form for changing address, only about 10% of the registrations to researcher protection were due to name and address protection.

In 2007, a group of scientists drew attention to the growing researcher protection register and it was decided to remove researcher protection from the paper form [20]. The registrations to researcher protection continued, but not at the same rate. However, as Figure 1 shows, the register was already approaching 800,000 citizens by 2007. The high number of registrations posed a threat to the possibility of conducting CPR-based research recruitment. Consequently, responding to requests from researchers, the Danish Parliament in 2014 passed an Act abolishing the researcher protection register from use. The argument for this abolition was 'in consideration of the possibility of completing representative research' [21].

Discussion

The unfortunate Danish experience with an opt-out system that became so prevalent that it needed to be abolished contains several lessons worth considering before endorsing opt-out as the preferred measure in pursuit of high participation rates in research. The researcher protection register, in many ways, grew because it was easy to register, but this ease of registration was probably in conflict with ensuring the genuineness of the wishes of those registering. Most importantly, however, the inception in 1995, as well as the 2014 abolition, appear to be quick-fix solutions without adequate contemplation either of the purpose or of the criteria of success for the researcher protection register as an opt-out system. If the purpose were to ensure public legitimacy, the sudden abolition must be said to be unfortunate. Likewise, if the purpose of researcher protection was to respect the autonomy of individual citizens, then it can be considered as a triple failure: those entering the register might not have been aware of the implications of registration; some were unknowingly registered by

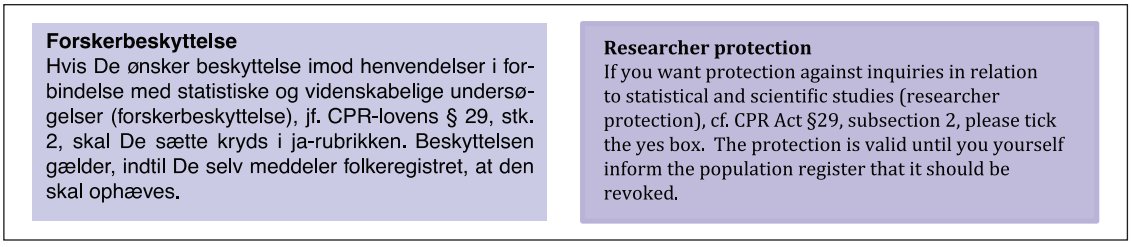

Figure 2. Information on researcher protection on the change of address form in Danish and English (authors' translation).

others; and the abolition of the register constituted a new way of overruling the recorded wishes of those who were aware of these implications. We support this claim with four main arguments.

First, name and address protection was responsible for a share of the registrations to researcher protection. Therefore some citizens under researcher protection had not actively applied for it and would not have known that they were registered with a lifelong opposition to being contacted by researchers as a consequence of a one-year registration for name and address protection.

Second, about 25% of the people registered under researcher protection were under the age of 18 years, which is the age of majority in Denmark. This indicates that some people came under lifelong researcher protection when their parents registered whole families on the change of address form. As a consequence, the proportion of people over 18 years of age who were under researcher protection not caused by name and address protection was only 10% before researcher protection was on the change of address form, 70% from 2001 to 2008 and around 40% from 2008 to 2014.

Third, throughout the period, the available information on what researcher protection entailed was limited. On the change of address form, researcher protection was explained with just 35 words placed in a small box on the back of the form (a separate page from where box should be filled in) (Figure 2). This short text can be interpreted in multiple ways and, had it been a part of a consent process, it would not have been considered adequate information according to standards set by the Helsinki Declaration [22].

Fourth, this opt-out system did not prevent the use of health data in other forms of register-based research. In this way, it did not allow citizens to opt out of research participation completely, it only deprived citizens of an opportunity to opt in to further research. As such, it was a false label all the way through.

Before the researcher protection register was abolished in 2014, the details and opportunities of the register were never looked into; close scrutiny of the recorded entries to the register could have led to a consideration of changes in its administration as an alternative to its total abolition.

Conclusions

In many ways, the fate of this Danish opt-out system illustrates some of the potential pitfalls when implementing opt-out in a system for research recruitment otherwise depending on presumed consent. From its inception, during its administration and as it was revoked, this opt-out system was marked by ad hoc solutions without any clear purpose and a lack of criteria for, and processes of, evaluation. To make matters worse, the register was abolished and therefore effectively deleted without being scrutinized and without informing the people registered or providing them with alternatives.

What might we learn from these mistakes? For a start, a clear purpose for the system and a process for monitoring and evaluating it would have been useful. If the pupose of the policy was to enhance autonomy, other improvements could have included better information prior to registration, and limits to registrations so that only competent individuals could register themselves. The practice of lifelong registration rests on the idea that a person retains the same attitude(s) towards research participation throughout their whole life. This might be unfounded. A person might think opt-out sounds appealing at the age of 20 and feel differently when confronted with cancer at the age of 55. Should opt-out be aimed at respecting autonomy, it might be valuable for future systems to implement invitations to reconsider at certain intervals. In short, when other healthcare systems consider implementing opt-out systems, we recommend that they first consider the fallacies of this Danish experience.

Acknowledgements

We thank Claus Thorn Ekstroem, Lea Larsen Skovgaard and Ezio Di Nucci for helpful comments on earlier versions of the paper.

Declaration of conflicting interests

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work has received funding from the European Research Council under the European Union's Horizon 2020 research and innovation programme (grant agreement number 682110), as well as the Global Genes, Local Concerns project funded by the University of Copenhagen's 2016 Excellence Program for Interdisciplinary Research.

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