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Perspectives

Medical research using governments' health claims databases: with or without patients' consent?

Feng-Jen Tsai[1,2], Valérie Junod[3,4]

[1]Master Program in Global Health and Development, College of Public Health, Taipei Medical University, 250 Wu-Hsing Street, Taipei City 110, Taiwan
[2]Graduate Institute of Health and Biotechnology Law, Taipei Medical University, Taipei, Taiwan
[3]Law School, University of Geneva, Geneva, Switzerland
[4]Faculty of Business and Economics, University of Lausanne, Lausanne, Switzerland
Address correspondence to Feng-Jen Tsai, E-mail: jeanfjtsai@tmu.edu.tw

ABSTRACT

Taking advantage of its single-payer, universal insurance system, Taiwan has leveraged its exhaustive database of health claims data for research purposes. Researchers can apply to receive access to pseudonymized (coded) medical data about insured patients, notably their diagnoses, health status and treatments. In view of the strict safeguards implemented, the Taiwanese government considers that this research use does not require patients' consent (either in the form of an opt-in or in the form of an opt-out). A group of non-governmental organizations has challenged this view in the Taiwanese Courts, but to no avail. The present article reviews the arguments both against and in favor of patients' consent for re-use of their data in research. It concludes that offering patients an opt-out would be appropriate as it would best balance the important interests at issue.

Keywords ethics, government and law, public health

Taiwan, as one of richest countries in Asia, successfully introduced universal health care coverage in March 1995. Currently, almost the entire population (99.9%) of nearly 24 million people is insured for a broad scope of health services: from dental care to obstetrics, from Western medicine to traditional Chinese medicine, and from preventive services to elderly home care.[1,2] Taiwan has implemented a model of single-payer insurance through its central public health care agency. Public insurance covers practically all medical services used by the population, with the exceptions of self-paid advanced health checkups, cosmetic treatments and private hospital beds. Insurance is mandatory. Cost-sharing by patients is minimal. So far the system has proven financially sustainable for public budgets. Public satisfaction remains high with 85.8% of the people reporting being satisfied with the system.[3] It is viewed as a possible model for other countries planning to introduce universal health care.[4]

Further leveraging this insurance system, Taiwan has been using the ample medical data generated by reimbursement claims to conduct medical research. The government has access to these data through patients' electronic card, which retains a record of visits to health care providers. Moreover, health providers send their data to the government to secure payment or reimbursement of health services. Since the government receives all data, it can maintain a complete dataset called the National Health Insurance Research Database (NHIRD). The NHIRD contains, *inter alia*, patients' demographic information, their precise diagnostic tests and results for all medical interventions, the drugs they were prescribed, the procedures they underwent and the corresponding costs. The breadth of information available allows conducting both simple and complex association studies. Most research projects seek to explain the factors correlated to a given disease or to identify the features linked with the use of a health service by patients.[5,6]

Moreover, NHIRD data can be cross-referenced and merged with data from several other databases (currently only medical-related databases) maintained by various services of the Taiwanese central government, such as the

Feng-Jen Tsai, Associate professor
Valérie Junod, Associate professor

cancer registry.[7–9] It allows conducting longitudinal studies over extended periods of time (more than 20 years since 1995), making the database uniquely valuable for medical research. Hence, NHIRD data enables a particularly broad scope of medical research. Indeed, a high number of retrospective research projects have drawn upon the NHIRD, leading to hundreds of publications in established medical journals.[10–15] Over a 12-year period (2003–15), over 3500 applications were approved.[16] In 2015, 517 applications were submitted, up from 142 in 2003 (Fig. 1).[17]

Nevertheless, use of the NHIRD and its medical claims data for further research purposes has been controversial in Taiwan.[18] In 2012, several human rights organizations launched a lawsuit to prohibit such use.[19] The procedure lasted for over 5 years; eventually in January 2017, the Supreme Administrative Court ruled that current practices regarding NHIRD use complied with the Taiwanese Constitution and the relevant statutes.[20,21] Despite this final ruling, one of the human rights organizations just recently (December 2017) applied to the Constitutional court, seeking an interpretation of Taiwan's Constitution (its articles 22 and 23).[22,23]

The end of the legal dispute before Taiwan's administrative courts does not entirely put to rest the objections raised against the use of this database for research purposes. The main criticism relates to the lack of patient consent. As mandatory health insurance, information of insured individuals is automatically recorded to ensure payment to health providers. Under this arrangement, patients in Taiwan are not asked to consent to the collection and (re)use of their data. Moreover, they cannot opt out should they be aware of the research use and not want to participate. The government has argued against the need for opt-in or opt-out consent on the grounds that data are duly anonymized (actually coded or pseudonymized) before transmission to researchers and that additional safeguards have been implemented, notably the requirement to obtain prior approval from a research ethics committee.[24]

Additional precautionary measures entered into force in June 2016—partly in reaction to the legal dispute. Presently, the database is released by the National Health Administration, no longer by the authorized research-oriented institution—National Health Research Institute (NHRI). The governing framework for release was also updated: the former guideline entitled 'National Health Insurance Research Database Value Added Service Application Principles' was replaced in June by an administrative rule which now governs access to the NHIRD.[25] Information on the application process is available online on a website operated by the National Health Administration. Aiming to reinforce privacy, researchers can now only consult the data in pre-agreed locations, having to conduct all queries on-site.[26] They must agree in writing that they will not attempt to re-identify patients whose data are included in the dataset.[27] Finally, researchers no longer receive access to the entire database (i.e. containing all patients in Taiwan), rather to a smaller subset of ~1 million individuals.

The situation in Taiwan raises general issues that many other countries are also facing. The key question is: Should research on public insurance medical data be allowed without patients' consent, if the datasets at issue are anonymous from the recipient's perspective? The matter is all the more important given that all UN Member States have committed to achieving universal health coverage by 2030, one of the United Nations Sustainable Development Goals.[28] The current trend in favor of Big Data and broad data sharing among researchers also underscores the significance of the issue.

There are of course good reasons both for and against such practice. Let us start with reasons supporting this use:

- Research performed using the NHIRD is typically public health research intended to further the interests of the Taiwanese population. Use of the NHIRD is best suited for concrete issues that concern large groups of patients.[29] Of course, such research may not be as reliable as a randomized placebo-controlled clinical trial. However, its results can promptly provide helpful inputs regarding the performance of health care delivery,[30] thus benefiting many patients.[31] Taking part in socially valuable research may be seen as a moral duty, since each individual is likely, at some point in life, to derive an individual benefit from medical advances.[32]
- By and large, research using the NHIRD is conducted by academic researchers, public hospital officers or public health agencies. Most of the results are published.[33] The publications are of increasingly high quality.[16,34] Under current regulations, commercial companies (e.g. pharmaceutical companies) cannot use the NHIRD directly, being obliged to partner with public-sector researchers. Therefore, there is little risk that the NHIRD could be used for projects that do not increase public knowledge[35] or that are unduly 'privatized'.
- As previously mentioned, the NHIRD is particularly valuable because of its comprehensiveness (i.e. nearly all health data from the entire Taiwan population are available for query). If an opt-in were required or if an opt-out were available, the data analyzed for research would be less complete, making the results less reliable.
- The cost of removing data related to non-consenting patients from the database should also be considered. Introducing a consent procedure (either an opt-in or an

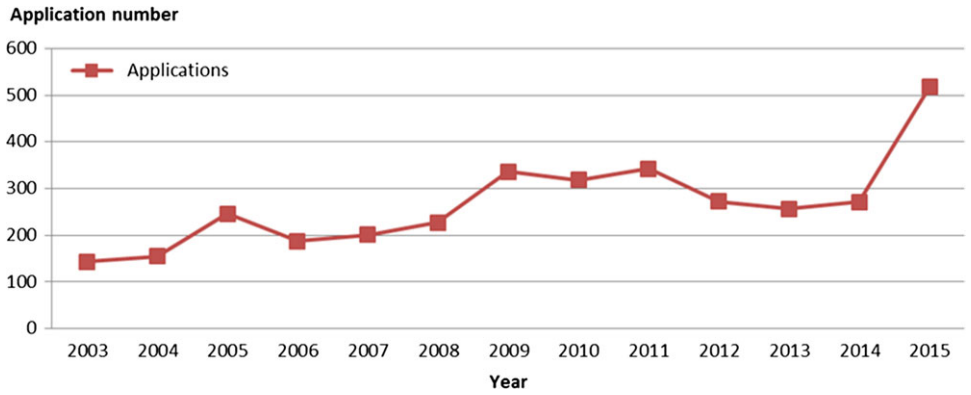

Fig. 1 Application number for NHIRD by year.

opt-out) should not be done without first assessing the likely administrative expenses.

  - To the extent that datasets are correctly coded, the odds of an individual included herein being (re)identified are very low. Accordingly, the transmission and use of such a dataset does not threaten actual harm to individuals. Further, individuals run no risk of discrimination. Lack of actual or potential harm calls into question whether there is a legitimate individual interest to object to the use of the data.

- The security of the NHIRD and of the datasets transmitted to researchers has been well maintained. There has been no report of abuses nor cases of leaks or breaches.[36]
- The use of the NHIRD without consent is analogous to other government use of population data to inform government action or to generate statistics (e.g. statistics describing the population of children attending public schools, the population paying the most taxes or the population using public transport). The government's traditional authority to produce statistics is not questioned, even though individuals' consent is almost never sought for this 'ordinary-type' of research.
- Similarly, current use of NHIRD for research can be compared to the use of medical data for quality controls or quality audits. Such controls or audits are commonly conducted within medical institutions. Patient consent (whether as an opt-out or as an opt-in) is never sought. Quality control is integral to medical care, as it is meant to reduce medical errors and to improve medical procedures within the institution. Yet, the objectives assigned to quality controls are not very different from those ascribed to medical research in general.
- In contrast to research using genetic information or biological samples, NHIRD data is unlikely to uncover information that the patient does not already have. Whereas biobank research might reveal that a patient carries a gene for a condition of which she was not aware, this can hardly happen with purely retrospective research using the NHIRD.[37] Only data already at hand is (re)analyzed through the NHIRD. Hence, the possible adverse implications of NHIRD research on patients' wellbeing are limited.
- When surveyed, a large majority of the Taiwanese population states its strong support for public health research; a large majority would give consent for research using their coded medical information.[38] One can thus contend that leveraging claims data for public health research actually matches the ultimate preferences of most patients in Taiwan.
- Despite these valid grounds, other reasons plead against further use of medical claim data without consent.
- Past hacking-related scandals have made everyone aware that even reputed companies active in sensitive sectors (e.g. financial sector and health sector) can fall victim to breaches.[39,40] If there remains any risk that databases can be hacked and that patients' identifiable data falls in the hands of unauthorized third parties, then patients should have their say in how their data are further processed.
- Increased use of electronic patient records is regarded as valuable because these records can facilitate medical treatment and decrease medical errors. However, these electronic medical files are also generating fears among patients because these records are believed to be more prone to abuses. Research in Taiwan has shown that patients express substantial privacy concerns.[41] Using data without consent is likely to amplify these existing concerns, thus hindering the broad use of these new electronic tools.
- De-identification is not as straightforward as it may seem.[42,43] How datasets are coded before transfer is generally not known to patients and sometimes not even to

the medical and research community. Thus, a patient cannot be sure who had access to the datasets prior to anonymization. Even if anonymization is executed without breaching privacy, the absence of transparency may foster distrust among patients.[44–46]

- Coding (pseudonymization) works to prevent those who analyze the dataset from inferring the identities of the various patients in the datasets. However, it works considerably less well when one operates in the reverse direction; that is, when one is looking for a specific known patient in a dataset (also called singling out).[47,48] For example, an ill-intentioned researcher with access to a comprehensive dataset could feasibly locate the medical files of, say, a well-known politician who lives in a certain geographical area, who has had three children, and who has suffered from a rare disease during a certain year. Using the publicly available information about this politician, one can pinpoint the handful of files that correspond to the said profile. Hence, anonymization of datasets does not offer strong protection, at least not for those patients about whom substantial information is already in the public domain.[49]
- Patients reveal data about their health status and submit themselves to tests and examinations with the expectation that the corresponding data will only be used by those who participate in their medical care. Whenever services are paid through insurance, they expect that the insurance will access the data only to the extent necessary to institute reimbursement. Unless they have been specifically informed, they do not expect their data to be further exploited for research purposes. This is even more true when medical data can be linked with non-medical information contained in other government databases.[50] Re-using health data with neither information nor consent contravenes the expectations of patients. As a result, it weakens trust in doctors, in governments and in researchers—i.e. all parties involved in the exploitation of data.[51]
- Some patients believe that the information they provide and the data that their body produces belong to them; therefore, they should be the ones deciding what is done with them. When data are further exploited for research purposes with neither prior information nor prior consent, these patients feel a violation of their perceived ownership rights. And once again, such sentiment of violation weakens the trust in government, in medicine and in research.[52]
- When surveyed, most patients—whether in Taiwan or in other countries—are strongly supportive of medical research, but nonetheless expect to be informed and asked for permission before access and re-use are undertaken. In other words, patients are by and large ready to offer their consent, but still insist on being asked for it.[53–56]

Having summarized the arguments for and against retrospective research using health claim databases, we reach the conclusion that offering an opt-out is ultimately the best solution to balance the opposing interests. Offering an opt-out allows those who presume ownership in their data to defend their perceived right;[57] it helps protect those who are more at risk of being singled out using information in the public domain;[49] it creates an opportunity for a public discussion about what the government does, how it does and why it does it.[58] Those who do not agree with current practices are given a chance to weigh in and, with their collective refusal, even influence and improve the entire process.[59] Finally, a form of consent is always more respectful of the patient's right of autonomy.[37] Even though autonomy is mainly considered a way to prevent harm and to minimize risks to patients, it is also an 'absolute' value in the sense that allowing individuals to make choices strengthens individuals' sense of self and upholds their sense of dignity.[60,61] Autonomy is therefore valuable even in situations where there are no risks to patients' physical and mental wellbeing. The ample literature on autonomy sustains this viewpoint: Autonomy and informed consent are consubstantial with respect for human dignity and serve to acknowledge that each of us is a different individual entitled to uphold his or her values, opinions and preferences.[62] In that sense, autonomy is a fundamental international human right, which can only be limited by the State under strict conditions. Restrictions may occur, but primarily in case of public health emergencies (e.g. epidemics), provided that the interference with patients' autonomy and privacy is deemed truly necessary (application of the proportionality principle).

Furthermore, past experiences with various forms of medical research on data, including potentially risk-prone projects, such as genetic biobank research, show that opt-out or refusal rates are usually low, provided that patients receive comprehensive information that details both the benefits of the research and the implemented safeguards.[63,64] With low opt-out or refusal rates, the risk of jeopardizing the reliability of the research findings is also low. Researchers would retain confidence in the consistency of their measured outcomes, while patients would retain faith in the trustworthiness of the medical and research ecosystem.

Contrary to fears sometimes voiced by researchers, an opt-out is not so difficult to implement. Patients are typically asked to fill out administrative forms at doctors' or clinics' welcoming desk. Adding an opt-out form to the documents

already provided is feasible. The opt-out information provided could be summarized on a one-page document, while the oral explanation should last no more than 5 min. Creating a website that repeats and expands upon this information would be straightforward; the website should also highlight the medical achievements made possible thanks to research on medical claim data. The website should also enable revocation of consent through a simple process. From time to time (e.g. every 5 years), patients should be asked if their declaration on file still matches their current wishes. Finally, appointing one ombudsperson to answer queries, guide patients, receive consent withdrawals and mediate possible disputes would constitute an efficient use of public funds in view of the expected benefits for all parties. These various measures should be delineated in a statute adopted by Parliament, so that it carries the legitimacy that follows a public debate among the population or at least among its political representatives. Finally, this should be viewed as an ongoing process accompanied by regular impact assessments and proper assessment of the likely costs.

Ethical texts on medical research insist that the interest of the individual must prevail over the interest of society in research and its associated benefits—even though the rule is not as absolute as the lay reader might suppose (think for example about phase I clinical trials on healthy volunteers).[65,66] However, in the case of medical research using governments' health claim databases, we conclude that the interests of society in increasing knowledge and in developing new treatments and the interest of the individual in preserving his or her private sphere could be reconciled through an opt-out right. This would achieve a fair compromise between the interests of all parties involved. Preserving trust in the research community is simply too valuable to be short-changed.

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Conflicts of interest

The authors state they have no conflict of interest.

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