Letter to the Editor

Italian Ministry of Health and the Istituto Superiore Di Sanita: from vigilance to ownership?

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Who owns disease surveillance data? If data are gathered via a research plan granted to a public research institute is this institute or those who finance the research the sole responsible party for data usage and implementation? Is the ‘sensitivity’ of some surveillance data an argument for depriving the investigators of the freedom to publish? Is an agreement awarding the sole granters the faculty of free use of those data scientifically and ethically acceptable? Finally, can the necessary, if not mandatory collaboration between two public health institutions confound their distinct responsibilities?

The questions above are some major ones which arise from a recent agreement (Accordo di collaborazione, 2014, hereafter referred to as the ‘Accordo’) between the Italian Ministry of Health (MoH), namely its National Center for Disease Prevention and Control (the CCM) and the Istituto Superiore di Sanità (ISS), the scientific and technical body of the Italian Health Service. Through this agreement, the CCM, which has managerial and no research or technical personnel, grants to the ISS for the fiscal year 2015 more than 2.5 million Euros to perform disease surveillance activity in the national territory, in some fields also bound to international obligations. By statute, the ISS is a public research Institute under MoH vigilance. It was last year declared by the Italian Government to be in receivership and under budgetary controls. Despite this, the ISS retains full technical and scientific autonomy. Its independence is a good thing since it avoids political interferences on its statutory activities, while assuring provision of quality data and evidence-based support to MoH itself and other public health policy makers. The resources that CCM annually allocate to ISS applicants support research activities upon which MoH policies, regarding such critical health issues as human disease prevalence and risk factors, antibiotic-resistance trends, vaccination schedules, certification of technical devices, food safety, to quote only some of them, are implemented. Although qualified as ‘routine surveillance’, these projects are not simple gathering of numbers and documents but are true research activities with rigorous study design and methods of data collection, assessment and reporting. Arguably, these criteria are used when the CCM, through its reviewer panels, allocates resources to some proposals and not to others.

Unfortunately, reading through the pages of the ‘Accordo’, it does appear that the ISS investigators are simple executors of ministerial ideas, not proponents of their own research plans. Bitterly enough, one of the articles of the Accordo (N° 4) states that everything generated in the research, including the Authors’ reports and potentially patentable materials, is the “exclusive” property of CCM, meaning they do not belong to, or are not even shared with, those who really proposed and performed the studies. Still more, the CCM reserves to itself the right of publishing the data, or even ‘selling’ (?) them, without previous consent by the ISS researchers, with only ‘the indication’ of those who did the job. Clearly, acknowledgement is not enough for CCM! Without doubt, the words used in the above paragraphs of the ‘Accordo’ are not those of a scientific agreement between institutions collaborating on a peer basis to the benefit of public health. Rather, they sound akin to those typical of a Material Transfer Agreement, whereby, for instance, an industry allows a researcher to use a proprietary reagent or drug, under restricted conditions. Is this really what the ISS investigators deserve, not even sharing with CCM the responsibility and property of the data they produce?

Italy remains a country with remarkably low infrastructural investments in, and dramatic shortage of money allocated to, research. Public Health research
is suffering, as other research fields are. In this scenario, it is understandable that to amass some money a commissioned, yet solid research institute such as the ISS, honored in the past by two Nobel Prize winners, may think acceptable an agreement that makes the funder, not the investigator or the ISS itself, the true owner of the data coming from disease surveillance activities. Nonetheless, it remains scientifically unsound and potentially dangerous. Is a shift from vigilance to ownership, which creates a loss of scientific autonomy of the ISS, the project that the MoH really pursues?

Reference

Comments on Dr Cassone’s letter to the editor

Ranieri Guerra
Director General for Health Prevention, Italian Ministry of Health

Dear Sir,
I have read with interest the letter that Dr Cassone, a previous scientist at Istituto Superiore di Sanità (ISS), wrote on the recent agreement signed by the Ministry of Health (MoH) and ISS on the collection, consolidation and analysis of surveillance data, among other issues. While Dr Cassone’s opinions are respectable, they are based on the wrong assumption that the MoH assigned the related funds to ISS according to a call for research proposals. This has never been the case, as the National Center for Disease, Prevention and Control (CCM) is not a research-funding programme, nor is the said budget delivered to ISS according to a competitive procedure.

What Dr Cassone seems to surprisingly ignore, is that CCM enters into contractual agreements with its executive partners, whether these are regional authorities, central administrations or qualified institutes, like ISS. The list of eligible entities that can enter into such agreements is public and subject to law. This sounds even more surprising as everything related to CCM is published on the relevant website (http://www.ccm-network.it/) for the sake of transparent administration that the MoH has adopted.

Dr Cassone may confound the (published) rules on the competitive section of CCM and its top-down section, managed by means of negotiated procedures, also well described in the CCM regulations. Unfortunately, he seems to neglect that all procedures, programmes, proposals or requests for funding addressed to CCM are reviewed in detail by the written and certified procedures of two committees, whose membership includes regional authorities and other central and peripheral stakeholders. Needless to say, all relevant decisions are also published in the named website, along with reports, technical papers, reviews, data and all materials generated with CCM financial support. The principle is that whatever is worked out with public money has to be made available to the public, once consolidated.

The MoH needs to guarantee, as the main regulator in this area, that materials generated are of acceptable quality and are not biased by possible sectorial vested interests of any kind.

Disease surveillance represents an atypical case study in the CCM portfolio. It covers several diseases and conditions and stays in the basic responsibility of the MoH, through an articulated information flow that includes local health authorities, contracted sentinel practitioners, hospitals and other clinical sites, regional authorities and finally the national (and sometimes supernational) level. Based on cost and opportunity analysis, the MoH decides whether funding and management of surveillance is operated in-house, or contracted out to qualified public entities. In any case, the end results are carefully designed systems capable to generate validated, updated and usable information supporting policymaking decisions at all levels, supplying the fundamental information needed by the national health service. A recent bill prescribes that any such entity should maintain its databases and registries with its own financial resources.

This may obviously contribute a final answer to Dr Cassone’s questions and doubts. In fact, the ISS went bankrupt for two consecutive years and was eventually put under compulsory administration by the MoH for that reason. Therefore, it seems unlikely that ISS will have the required financial resources to meet the surveillance needs from its own budget, even if the MoH
would decide to grant that responsibility to a technical and research oriented institution.

As a consequence, the MoH decided to reshape the national health information system, which it maintains in-house in collaboration with regional and local authorities, in order to enable direct data capturing and quick, transparent, detailed analysis, and is investing substantial resources to that end.

This means that in the next couple of years the possible ambiguity in the interpretation of roles, so far based on the fair relationship between a commissioning body (the MoH) and an executing body (ISS), will be re-established. It is also clear that ISS will be able to continue pursuing its scientific interests, by means of project proposals and applications that will be considered, for instance, in the competitive modality set forth by the National Research Programme, and not by CCM.

In terms of data property and utilization, once again it seems that Dr Cassone ignores the fact that rules and regulations are extremely clear for all the commissioned parties in CCM. Contracts are binding documents that both signing parties must comply with, especially when generated assets are of public interest. The identification of ISS as a preferred MoH partner (in a highly populated scenario of excellent competitors) does not mean that the MoH owns the ISS, but rather stands in recognition of the ISS’s technical capacity and valuable skills.

The MoH (the commissioning party) has always acknowledged ISS’s role as an excellent executing partner agency within the CCM domain. It would sound rather bizarre that the executing party manages analytical data, reports formally on its own, publishes papers based on data, which are not its property, changing the contractual relationship by simply acknowledging financial support. May I invite everybody, including Dr Cassone to browse the CCM website for all related information and clarifications.

Antonio Cassone’s reply to the letter by Dr Guerra

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The letter by the CCM Director is appreciated, but unfortunately, it confirms that the MoH, through the CCM, is the contractual owner of the surveillance data generated by the ISS scientists. The CCM assurance that ISS scientists will continue to enjoy the CCM high estimation is also highly appreciated but I notice that estimation does not even reach the extent of at least sharing between ISS and CCM the intellectual property of the data ISS scientists plan, gather, assess and report to CCM (see the article 4 of the Accordo). Dr Guerra’s frank qualification of ISS as ‘an excellent executing partner agency within the CCM domain...’ is self-explanatory: no other words could better define the loss of ISS scientific and technical autonomy in their surveillance activities.