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The devil is in the details. An analysis of patient rights in Swiss cancer registries.

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Abstract

Cancer registries are an important part of the public health infrastructure, since they allow to monitor the temporal trends of this illness as well as facilitate epidemiological research. In order to effectively set up such registries, it is necessary to create a system of data collection that permits to record health-related information from patients who are diagnosed with cancer. Given the sensitive nature of such data, it is debated whether their recording should be based on consent or whether alternative arrangements are possible (e.g. opt-out systems where information is automatically collected but patients can later withdraw). In the recent reform of the Swiss cancer registration legislation, the lawmaker set out to implement rules about the recording of data in cancer registries that would allegedly go beyond a consent-based model, in order to balance accurate registration and respect of patient rights. However, by analysing the operational norms of the new legislation and comparing them with those of other systems, it emerges that the Swiss rules *de facto* closely resemble a system of registration based on informed consent – in partial contradiction with the objective pursued by the lawmaker. In this paper we thus show how the details of a policy are crucial to determine its true nature and we highlight some critical elements – from an ethical standpoint – of the recently reformed Swiss policy on cancer registration.

Main text.

1. INTRODUCTION

Given the increased digitalisation in healthcare and biomedical research, privacy rules on how to safely process personal health data have become a topic of intense ethical and legal debate. In recent years such debate has been further fuelled by the reform the promulgation and implementation of the General Data Protection Regulation (GDPR), whose impact on the processing of health data – especially for research purposes[1] – is still being discussed. This has stimulated a heated discussion on which legitimate grounds could (or should) be used to process health data, which are generally considered as particularly sensitive.

The attention towards data protection aspects around the processing of medical information is also widespread in the cancer registry community.[2–5]. Indeed, cancer registration and data protection rules interact at different levels: from the question concerning the conditions to fulfil for data on cancer to be transmitted to the registry; to the question whether data from the cancer registry can be (re)used for retrospective registry-based research. The latter is particularly developed in the Nordic countries, where cancer registries have been existing for a long time and the data therein can - under defined conditions - be used for research without ethics approval and can be linked with other routinely collected data.[6]

Switzerland has recently passed a comprehensive reform of the cancer registration system at the federal level.[7,8] The new legislation came into force in between 2018 and 2020, and it regulates in a harmonised way the collection, recording and analysis of data in cancer registries all over the country.[9] Whereas population-based cancer registries already previously existed at a regional level, the new cancer registration obliges every canton[i] to develop a homogeneous system of cancer registration. Moreover, the new law also centrally established the variables that need to be collected and created a nation-wide institution in charge of the analysis of the data.[10] One of the main objectives of the reform was also to clearly define patients' rights with respect to the recording of their data in the new system of cancer registration. Indeed, the lawmaker determined that one of the weaknesses of the pre-reform situation was that rules on patients' rights were lacking and not uniform in different parts of the country.[11]

In this paper we analyse the rules on patient rights with respect to cancer registries in Switzerland and show that the current rules *operationally* resemble a *consent-based* model – despite the objective of the lawmaker to go beyond it. Moreover, we discuss some ethically problematic aspect of the current system. To do so, we first present the different models how cancer registrations can be classified from the perspective of patients' rights. Second, we illustrate the recently implemented Swiss solution to cancer registrations, which the lawmaker defined as a compromise between a *consent-based* and a 'Scandinavian' model. Thereafter, we examine more in detail how Swiss law concretely operates and argue that – rather than being truly a compromise – it is *de facto* very similar to a *consent-based* model.

[i] Switzerland is a confederation comprised of 26 states denominated *Cantons*.

From the start, we would like to underline that this paper concerns the modality how data is recorded in cancer registries. Whether such data – once recorded – should be reused for further research (and upon which conditions) falls outside the scope of the present article.

2. TO BE OR NOT TO BE - BASED ON CONSENT? THE DIFFERENT MODELS HOW TO COLLECT PATIENTS' DATA IN CANCER REGISTRIES

One of the main points of discussion in the ethics of cancer registration is how to protect the confidentiality of the patient-doctor relationship and privacy of patients whose data is recorded.[12] Whilst this entails also the question of how to regulate access to cancer registries by third parties (e.g. researchers willing to conduct epidemiological studies), a crucial and preliminary element is to determine upon which conditions data routinely collected in the clinical context can be added to cancer registries in the first place. Recording of medical data in cancer registries can be classified from the perspective of healthcare personnel's duties or from the perspective of patients' rights. From the perspective of healthcare professionals, one can distinguish between voluntary and mandatory notification systems.[4,5] In the former, reporting by health professionals is not obligatory. In the latter, there is a clear duty for healthcare professionals to transmit data of their patients to the cancer registries, potentially enforceable through fines or other measures.

From the perspective of patients' rights, however, a slightly different classification can be outlined. On the one hand, a cancer registration system can be based on an (explicit) *consent-based* or *opt-in* model. In this case, patients are given the right to actively consent or dissent to their data being registered, thus giving them full control over their personal information. This was the case, for example, in a breast cancer registry in new Zealand until 2012.[13] This system is sometimes also called *opt-in* approach, in that patients must actively provide their consent in order for their data to be recorded, whereas the *default position* (i.e. what happens if patients do not express any preference) is that data is not collected. According to a recent study, the *consent-based* model is only present in a minority of European countries.[14] From an ethical standpoint, this system can be justified based on the idea that the informational self-determination – that is, "the ability of data subjects to shape how datafication and data-driven analytics affect their lives, to safeguard a personal sphere from others, and to weave informational ties with their environment"[15] – should be respected. Requiring people to actively consent before their data can be recorded gives them the possibility to negotiate their participation in the public sphere and its interference with the private sphere, which also lays at the core of the concept of informational self-determination.[16]

However, the *consent-based* model has generally been opposed on grounds that it undermines the mission of cancer registries to accurately monitor and improve the health of the population.[17] For example Coleman et al. claimed "the requirement that patients give written or verbal consent for data

about their cancer to be entered into a registry [produces] uncontrollable selection bias and distortion of incidence data which seriously detract from the usefulness of the data collected."[18] On a similar line Stiller argued that placing "on registries a duty to obtain permission from patients before registering them […] would be always impracticable and sometimes impossible - for example, if they have already died".[19] For these reasons, the recording of data in cancer registries is often justified not through consent, but through alternative legal bases provided by the law, such as article 8(3) of the old European data protection directive (95/46/EC)[ii] or article 9 §2 lit. h[iii] or article 9 §2 lit. i GDPR. This model is adopted – for example – by the Finnish Cancer registry, in which registration is not based on consent and thus patients do not have the right to withdraw it or to get their data out of it.[20] Or else, in the English system of cancer registration, it is the law (and not consent) that provides a justification for data to be recorded, and people are only given the right to opt-out from registration upon certain conditions.[21] One could argued that – as compared to *consent-based* model – in this case people have less control over their data at the individual level, since their ability to impede their data to enter the cancer registry is either curtailed (e.g. Finnish example) or limited (e.g. English example, data is recorded, but people can opt-out). The ethical justification of such a system can be found primarily in the objectives of cancer registries, which is that of promoting public health by allowing to monitor the impact of such disease on the population. Indeed, "[t]o be of value, data recorded must be accurate, reliable and as complete as possible",[22] something which can be hindered if the decision whether to include or not data on a certain case is left primarily to the single patient. A recent review of the literature also found that the papers reflecting on the ethics of *opt-out* systems of cancer registration (where consent is not needed, but patients have the right to withdraw their data at a later stage) mainly justify such system by appealing to its potential to guarantee that accurate and comprehensive data on cancer is recorded.[23]

In terms of data protection regulation, both models are technically possible. Data protection law generally requires that a legal basis is necessary to process data, and that, when *sensitive* data (such as health data) are processed, additional safeguards are to be met. At the EU level, for example, this is laid out in art. 6 and art. 9 GDPR. These clearly state that consent is but one of many of the potential legal bases whereupon data can be processed, [24] and they stress that – for sensitive data – such consent has to be explicit[25,26]. At the same time, an alternative legal basis for data processing can also be the existence of a relevant public interest (such as monitoring population health) and – if health data are processed for scientific purposes and according to member state law – consent is thus not necessarily required[27]. In respect to health research and to the processing of health data, the European Data Protection Board has explicitly outlined that "it is foreseeable and not incompatible (with ethical

[ii] The use of this article as a legal basis to justify recording of data in cancer registry is indicated here for example in [5].
[iii]This article is basically equal to 8(3) of the previous data protection directive and it justifies the processing of sensitive data such as health data even without consent when the "processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services".

standards) that the other [as compared to "explicit consent"] legal grounds can be relied on for the processing health data for scientific research purposes".[28] Under these circumstances, it is evident that both an *opt-in* and an *opt-out* models are technically possible.

3. THE SWISS *HYBRID* MODEL AND ITS RATIONALE

The choice of how to regulate patient rights in relation to cancer registration was at the centre of a political debate in Switzerland, since the lawmaker has been drafting a comprehensive reform of cancer registries. Such reform led to the passing of federal law on cancer registration[7] together with an ordinance to help implement the law.[8] That the lawmaker was aware of the different models outlined above clearly emerges by looking at the accompanying documents that the Federal Council (the executive power at the Federal level who writes law-projects) publishes concerning the law-making process.[11,29] Specifically, it is explained that – in the discussion on how to regulate patients' rights with respect to the recording of their data – two models were considered. On the one hand, the lawmaker speaks of a *Scandinavian* model based on obligatory registration based on the law. Indeed, it is acknowledged that "the best way to guarantee a complete registration of cancer illnesses is to record the data without allowing patients the right to object".[11][iv] As an alternative, the lawmaker explains that also a *consent-based* model could be implemented, which would allow "the maximal expression of the protection of patients' rights" since the latter would have to "explicitly consent to the recording of their data".[11]

After considering these two possibilities, the Swiss lawmaker claims to reject both solutions. The *Scandinavian* model is considered "in contrast with the principle of informational self-determination"[11] of patients, and thus not in conformity with fundamental rights of privacy enshrined in Art. 13 of the Swiss Federal Constitution. The *consent-based* model, on the contrary, allegedly presents the problem that it "does not however allow to guarantee a complete cancer registration".[11] Based on these considerations, the lawmaker considered neither solution viable and selected an alleged compromise. The *hybrid* Swiss model is in fact based on a duty for healthcare professionals to report all cancer cases, coupled with a so-called "right to dissent"[v] and strong informative rights for patients. In brief, healthcare workers are now obliged to report every cancer case to the competent cantonal[vi] cancer registry. Patients' explicit consent is not needed, but at the same time "if she [the patient] objects to the recording of data by the registry, the patient can refuse that [registration] in any given moment".[11] Moreover, patients enjoy particularly strong informative rights, including the need to be individually informed about the planned transmission of data to the registry. Such information is given to the patient

[iv] The original texts are available in Italian, French or German, but we translated in English this and the following relevant passages.
[v] According to the official languages of Switzerland, the law text speaks of a "Widerspruchsrecht" in German, a "droit d'opposition" in French and a "diritto di oppositzione" in Italian.
[vi] The new law establishes that several cantonal (i.e. regional) cancer registries remain in operation, but the type of data collected and the procedures for collection are now harmonised at a nation-wide level.

individually by the treating physician who has the duty to communicate data to the cancer registry. To ensure that patients can reflect on cancer registration, for the first three months after they have received such information by the treating doctor, no data about their illness can be transmitted to the registry till such "time limit" (Art. 17)[8] expires. Such three-month "time limit" is present "to allow patients to whom it has just been communicated the information about cancer registration the time to decide whether to dissent to the registration of their data."[29] Indeed, the lawmaker explicitly says that "patients' rights are reinforced by the introduction of a time limit. […] in this way, the patient has an adequate time to reflect whether she wants to exercise her right to dissent. The register can proceed to record the data only after the time limit has expired in vain". The lawmaker claimed that by "giving patients a right to dissent it is possible to respect their informational self-determination"[11] and then speculated that "we can start from the assumption that the cases of dissent should remain very limited".

4. THE DEVIL IS IN THE DETAILS

As outlined in the previous section, a primary objective set out by the Swiss legislator with the cancer registration reform was to implement a system of data collection that could go beyond the limits of an *informed-consent* model based one. Indeed, it is claimed that "if registration depended on explicit patients' consent, there would be the risk of large gaps in the registration, and the aim of the new legislation would be totally called into question".[11] At the same time the legislator wanted to recognise substantial privacy rights of patients over their data. The solution developed might seem to combine the best of both worlds and thus represent a good example of the tendency to compromise, which "is deeply engrained in Swiss political culture".[30] But does the Swiss *hybrid* model truly represent a well-balanced compromise between the two extremes of a *consent-based* model and a 'Scandinavian' one[vii]?

By taking a closer look to how the Swiss *hybrid* model actually works, we argue that the answer to this question must be negative. Indeed, from the *operational* point of view, the Swiss *hybrid* model strongly resembles a *consent-based* model. To substantiate our claim, we compare the *operational* aspects of the Swiss model to a *consent-based* model, and also confront them with the solutions followed in England[21,31–33] and Finland[20,34,35] – both systems where the collection of data is NOT based on consent (see Table 1).

Table 1. Comparison of *consent-based*, Swiss, English and Finnish model.

[vii] By 'Scandinavian' model, we here refer to those systems where the recording of data in cancer registries is NOT based on consent, and where there are limited possibilities to opt-out for patients.

	Can the individual *preliminary* impede that data about his illness is recorded?	**Does the healthcare worker responsible for the registration have a clear *obligation* to talk with the patient about the registration before proceeding?**	**Does the interaction with the patient concerning cancer registration have to be documented?**	**What happens if the patient says nothing?**	**Can patients require the cancellation of their data from the cancer registry?**
***Consent-based* model**	Yes, by simply not providing consent.	Yes, in order to collect the informed consent.	Yes, since the informed consent has to be documented.	Data is NOT recorded, since consent is necessary	Yes, by withdrawing consent.
Swiss model	Yes, by exercising the right to opposition.	Yes	Yes.	Data is recorded.	Yes, by exercising the right to opposition.
English model	Potentially yes, depending how quick the opt-out right is exercised.	No.	N/A	Data is recorded.	Yes, by exercising the right to opt-out.
Finnish model	No	No	N/A	Data is recorded.	No.

Firstly, according to the Swiss model patients have the possibility to completely impede the recording of any of their health data in the cancer registry. Patients can do this by exercising their "right to dissent" when the illness is diagnosed and within the 3-month time limit from the moment they are informed by their own physician of the existence of cancer registration (see below). This situation is to some extent similar to the one encountered in a *consent-based* model, in which patients might avoid the recording of their data by simply not providing their consent. Clearly, a difference between the Swiss and the consent-based model is that in the former an *active* action is required (exercising dissent) to avoid recording of the data, whereas in the latter *abstaining* from an action (i.e. abstaining from providing consent) is sufficient. But the fact remains that – unlike in a system like the Finnish one – both models allow the *individual* (through action or abstention) to prevent data recording.

Secondly, in the Swiss model there needs to be a one-to-one encounter between the healthcare worker responsible for recording data for the cancer registry and the patient. In this encounter, the doctor has to inform patients on why/how their data will be transmitted to the cancer registry and on patients' rights, including the "right to dissent". The doctor also has the duty to document the date in which such interaction occurs (e.g. on the medical record of the patient).[29,36] From such date a three-month time limit must pass before any data is transmitted to the registry, in order to allow patients enough time to reflect whether they want to exercise their right to dissent. Even in this case, the situation is very similar to a *consent-based* model, where a one-to-one encounter between the patient and the healthcare worker in charge of cancer registration has to occur. Indeed, if we consider informed consent as a process, it

can conceptually be split in two phases: the *provision-of-information* phase; and the *decision-making* phase. Operatively, the *provision-of-information* phase of the Swiss model resembles exactly what would happen in a *consent-based* model. The treating doctor provides counselling to their patients, in order for them to make an informed decision concerning cancer registration. The only difference is that in a *consent-based* model, the *decision-making* phase consists in the patients choosing whether or not to provide consent. On the contrary, in the Swiss model the *decision-making* phase consists in choosing whether or not to exercise the right to dissent. Either way, the decision-making phase can end with patients refusing participation in the cancer registry: by not-providing consent in the consent-model, or by exercising the right to dissent in the Swiss model.

Thirdly, a further similarity between the Swiss model and the consent model occurs when examining the possibility that patients whose cancer data was recorded change their mind and want to withdraw from the cancer registry. In both models this is equally possible. In a consent based model the patient might simply withdraw consent; in the Swiss model patients may exercise their right to opposition, thus obliging the cancer registry to cancel all their personal data already recorded or to anonymise them.

All in all, the only substantial difference between a consent-based and the Swiss model seems to be that – if at the end of the one-to-one encounter the patient does not express any preference – in the Swiss model the data can be recorded (after the three-month time limit), whereas in the consent-based model this is not the case. This appears to be a relevant difference, since one of the most important features of consent in modern data protection law is its *explicit* nature, meaning that an affirmative action by the data-subject is required. For example, the GDPR has made it clear that consent "means any *freely given*, *specific*, *informed* and *unambiguous* indication of the data subject's wishes by which he or she, *by a statement or by a clear affirmative action*, signifies agreement to the processing of personal data relating to him or her" (art. 4 (11) GDPR, our emphasis) and that – when *health data* are processed based on consent – such consent has to be *explicit*, meaning that "the data subject must give an *express* statement of consent"(our emphasis).[25] In Swiss cancer registries, on the contrary, the processing of data can be performed also in absence of any *express* statement of consent by patients: as long as they do not exercise their right to dissent at the end of the one-to-one informative encounter or in the three months since the information-date, their clinical data may be officially recorded. However, from a practical perspective, one wonders how likely it is that – after a one-to-one encounter specifically aimed at informing about cancer registration – patients would not make up their mind about registration. If stimulated through individual interactions – which the lawmaker describes as crucial to allow "the patient to ask questions in case of doubts"[29] – one would expect that patients then actively decide what to do about their data, rather than remaining silent and not performing any affirmative action. Clearly, it could happen that people refuse to take an active decision at the end of the interaction, or that they decide to exercise their right to opposition, but then forget to actually send in the necessary documentation for enforcing their right in the three-month time limit which they are granted. If this happens, in the Swiss-model the data can nevertheless be transmitted to the cancer registry, whereas a *consent-based* model would not allow

it (since active/explicit consent would always be required). But 'relying' on patients' forgetfulness to exercise their rights does not seem coherent with the expressed objective of the Swiss legislator to respect informational self-determination in a meaningful way.

5. CONCLUDING REMARKS

In the previous sections we explained how patient rights with respect to cancer registration can be regulated. We have presented the new Swiss law on cancer registration and argued that the way Swiss rules actually operate practically defy the purpose of the lawmaker to go beyond a *consent-based* model. The objective of this paper is not to argue for one model of cancer registration over the other, but to show the importance to have *operational* rules that are coherent with the objective the lawmaker opts for – whatever that is. If the main objective of a policymaker with respect to cancer registration is to respect individual rights and make registration dependent on individual choice, then having a pure *consent-based* model might be more straightforward. If the priority is to maximise registration, then an obligatory model with very limited individual rights might be better. In the Swiss case, it may seem at first sight that the lawmaker refused the *consent-based* model and created a balanced compromise between these two solutions. On closer inspection, *operational* rules are significantly skewed towards a *consent-based* model.

To truly implement a system based on a compromise between a *consent-based* model and one based on obligatory recording of data, other options could have been explored. For example, it would have been possible to renounce informing patients *individually* about their rights and instead promote far-reaching informative campaigns illustrating to the wider population (and not only to those already diagnosed with cancer) the scope of cancer registries and the possibility to exercise specific rights (including the right to dissent) with respect to their data. Indeed, Article 19 of the Swiss Cancer Registration Law actually establishes that "the national institute for cancer registration informs periodically the population […] in particular about: a. the nature, purpose and extent of data processing; b. patients' rights". Opting for population-based information campaigns has naturally the drawback that – if such campaigns are poorly implemented or if the public has little interest – it might be difficult to ensure that the population is genuinely informed. This risk could be mitigated by involving patient organisations (e.g. the Krebsliga in Switzerland) in setting up informative-events about the purposes, advantages and risks of the collection of data in cancer registries. Moreover, having public information campaigns would avoid individual influence by health care personnel, who – based on their own perceptions – might have a significant indirect influence on patients' choices whether to dissent or not to cancer registration. From a legal point of view, *individual* provision of information remains a pilaster of Swiss data protection law[viii], but it is generally possible to create exceptions to this principle when the collection and

[viii] See, for example art. 19 of the new Federal Data Protection law (available at https://www.fedlex.admin.ch/eli/fga/2020/1998/de).

subsequent processing of data is provided by a sector-specific law (like in the case of cancer registration legislation), is justified by a public interest and comply with the principle of proportionality (see also art. 36 Swiss Constitution on the conditions to be fulfilled to restrict fundamental rights).

From an ethical perspective, it must also be considered that the current Swiss model – which obliges doctors to have *individual* encounters with their patients to inform them about cancer registration and clearly document the date when such information was provided – might also unintentionally be the source of emotional harm. Indeed, it might be burdensome for patients to be *forced* (since their physicians have a duty to try and collect the data) to reflect on cancer registration in the difficult period when the illness is detected. Moreover, if the objective of the Swiss-model is also to have a high rate of data collected, the individual encounters between patients and doctors might turn into an ambiguous situation, which can also be perceived as deceptive. Indeed, doctors have to conduct a conversation about patients' informative rights and their right to dissent registration, in the *hope* (from the point of view of the lawmaker) that patients stay silent and do not exercise the right to dissent that they have just been made aware of, so that registration may proceed.

In legal analysis it is stressed how the real functioning of a policy is often determined by how rules established in the legislation are concretely operationalised, rather than by how they are dogmatically described by the lawmaker.[37] Our analysis of Swiss rules on cancer registration has shown that there might be a difference between what the legislator sets out to do and how the rules it creates concretely function. Clarity in how legal rules function is particularly important when it comes to data protection, given the interest of citizens to understand what happens with data related to them, especially when it comes to sensitive data like cancer-related information. For Switzerland, it is now important to closely monitor – as soon as reliable statistics are available, since the new Swiss model is active only since 2020 – the actual impact of the new rules on patient rights in cancer registration and on the collection of sufficiently complete and accurate cancer data, to see whether changes on the legislation are needed in the future. Some preliminary data suggests that our worries are well founded. Indeed, one cantonal cancer registry recently reported significant difficulties in the first year of implementation of the new law, stating that "in 70% of the cases, we did not receive the patient information-date [i.e. the date in which the treating doctor informs the patient that her data will flow in the cancer registry unless she dissents, and from which the three-month time limit to exercise the right to dissent begins], meaning that we could not record such cases. […] [This] leads to an under-recording of cancer illnesses: around 1500 tumours could not be registered due to the missing patient information-date" (our translation[ix]).[38] Similarly, the yearly report of another cancer registry responsible for different cantons highlighted that "we thankfully receive the clinical data from a lot of the people responsible for this, but in about 40% of these reports the patient information-date is missing, so that we cannot proceed with the recording of the available [clinical] data [in the register]"(our translation).[39] Other cantonal registries have

[ix] This and the following annual reports (references [38–42]) are originally in German.

mentioned similar challenges.[40,41] Moreover, one cantonal registry has underscored that "the provision of information to the patient [about the cancer registry] when the diagnoses is disclosed constitutes an interference in the medical work practices and it is hardly doable at this point in certain circumstances (e.g. in case of severe disease progression)"(our translation).[42] These difficulties might be related to the novelty of the system or to the challenges caused to the healthcare sector by the COVID epidemic in recent times. But they also indicate how the Swiss *hybrid* model might need some fine tuning to reach the objective of the legislator to combine patients' data protection rights and guarantee complete public health monitoring.

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