Where Public Health and Data Privacy Converge: The Case of PPTA Standards

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Recent changes in European data privacy law have created an opportunity for expansion of two PPTA standards—the National Donor Deferral Registry (NDDR) and the Cross Donation Check System (CDCS). In the past it was thought that implementation of these standards—both of which operate through the collection of information on individual plasma donors—would be impossible in Europe due to both strict data privacy requirements at the European level and widely varying rules at the Member State level. Passage of the General Data Protection Regulation (GDPR),[1] however, has brought additional clarity to the area of European data privacy law and now suggests a route forward.

PPTA'S VOLUNTARY STANDARDS

In order to fill gaps in regulation, as well as to encourage the implementation of "best practices," PPTA and its members have developed voluntary standards programs for the industry. The International Quality Plasma Program (IQPP) governs plasma collection center practices and encompasses standards on subject matter ranging from donor education to the cleanliness, safety, and appearance of a center. Although PPTA strives to maintain uniform and truly "international" standards, in some cases, exceptions are necessary to accommodate different legal and regulatory environments. This is the case with the two database-driven IQPP standards—NDDR and CDCS—which, due to European data privacy law, are currently implemented in only the U.S. and Canada.

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NATIONAL DONOR DEFERRAL REGISTRY

NDDR
National Donor Deferral Registry

Any plasma donor who **TESTS REACTIVE** for HIV, HBV, or HCV must be entered into a **NATIONAL DONOR DEFERRAL REGISTRY (NDDR)**. All donors are checked against the NDDR at each visit; those in the database are **UNABLE TO DONATE PLASMA.**

NDDR
National Donor Deferral Registry

NATIONAL DONOR DEFERRAL REGISTRY

The NDDR is a database of donor test results—specifically, results showing that a donor has tested positive for one of a handful of blood-borne viruses.[2] The purpose of the NDDR is to help ensure the safety of plasma protein therapies by preventing infected donors from donating, thereby preventing an infected donation from potentially reaching the plasma pool from which final products are manufactured. The quality of plasma-derived therapies is protected by three "pillars" of product safety—donor screening, testing, and viral inactivation. The primary role of the NDDR is to enhance and strengthen the donor screening pillar, though it also protects collection center staff and other donors.

Although the use of database technology is of relatively recent vintage, the NDDR concept is not new. In fact, the NDDR has been in operation, in one form or another, since 1993. During that 24 year period, there have been dramatic improvements in information technology, such that a donor's viral marker status—which used to be communicated by telephone and recorded manually—can now be recorded or confirmed by a collection center-NDDR interface that is direct and instantaneous. From the beginning, the program has been strongly supported by the U.S. Food and Drug Administration (FDA).[3] This likely explains, in large part, why all 600+ U.S. plasma collection centers have adopted the NDDR standard.

THE QUALITY OF PLASMA-DERIVED THERAPIES IS PROTECTED BY THREE "PILLARS" OF PRODUCT SAFETY—DONOR SCREENING, TESTING, AND VIRAL INACTIVATION.

Operation of the NDDR is relatively simple and straightforward. If a plasma donor tests positive for one of three viruses—HIV, Hepatitis B, or Hepatitis C—that individual's name, and a limited amount of additional data necessary to confirm the individual's identity, are entered into the database. On the screening side, whenever a new donor attempts to donate at a collection center, an NDDR check is run as part of the intake process. The result that comes back is either "match" or "not found." If the donor is in the database (i.e., if his or her information results in a "match") then, per the terms of the standard, that individual is permanently deferred and prevented from donating.

Source: Thomas R. Kreil, Ph.D. (PPTA Pathogen Safety Steering Committee, Chairman)

CROSS DONATION CHECK SYSTEM

The CDCS is a database of donation dates.[4] In contrast to the NDDR, which is intended to ensure the safety of the product, the purpose of the CDCS is to help ensure the safety of the donor. Both FDA and Member State health authorities in Europe limit the frequency of plasma donation for the simple reason that, while plasma is a renewable tissue, it takes time for the body to replace the donated volume. Although center personnel are required to educate donors regarding these frequency limits, there may still be situations in which individual donors attempt to donate too often. They may misunderstand how the frequency limits are applied or simply have forgotten about an earlier donation. Essentially, the CDCS is a means of ensuring that donors donate within the limits.

In its current form, the CDCS has only been in operation for two years but, like the NDDR, it was preceded by lower tech efforts. Prior to implementation of the CDCS database, centers located in close proximity to one another would exchange information by fax and would track donation frequency manually, using paper records. Consequently, moving to an electronic approach has not only improved reliability, but has substantially reduced the amount of center staff time required to manage the system. Like the NDDR, the CDCS is strongly supported by FDA and all U.S. centers are currently participating.

From an operational perspective, the CDCS is slightly more complex than the NDDR for the simple reason that the regulations governing donation frequency are more complex. The CDCS is currently configured pursuant to FDA's donation frequency rules. Essentially, plasma donor is prohibited from donating more than once in a single day and more than twice in any 7-day period. A CDCS check, which takes place at the time of each donation, records the date of the current donation and examines the donor's recent donation history. If the current donation would exceed the frequency limits, then the donor is prevented from donating. Notably, the CDCS maintains only a rolling 7 days' worth of donation date information, as this is all that is required to ensure compliance with the frequency limits.

THE GENERAL DATA PROTECTION REGULATION

Data privacy in Europe is currently governed by the Data Protection Directive.[5] However, in less than a year—on May 25, 2018—the Directive will be replaced by the GDPR in all Member States. Because it is a regulation rather than a directive, the GDPR should ensure a greater degree of uniformity in data privacy regulation across the EU. This is due to the fact that a regulation, as opposed to a directive, takes automatic effect and need not be implemented by national law. In the case of a regulation, opportunities for individual Member States to impose additional requirements as also more limited (though not completely non-existent).

The GDPR limits the ways in which "personal data" (i.e., any information relating to an identified or identifiable person) can be collected and used. Indeed, the GDPR specifies that processing of certain categories of "sensitive" personal data, including health data, is prohibited, subject to a few important exceptions. The GDPR applies to all data processors—regardless of whether based inside or outside Europe—that offer goods or services in the EU and/or monitor data subjects' behavior in the EU. Awareness of these requirements should be a top-level compliance priority, as failure to adhere to the GDPR can result in substantial penalties, including fines of up to €20 million ($21.46 million) or four percent of annual worldwide turnover.

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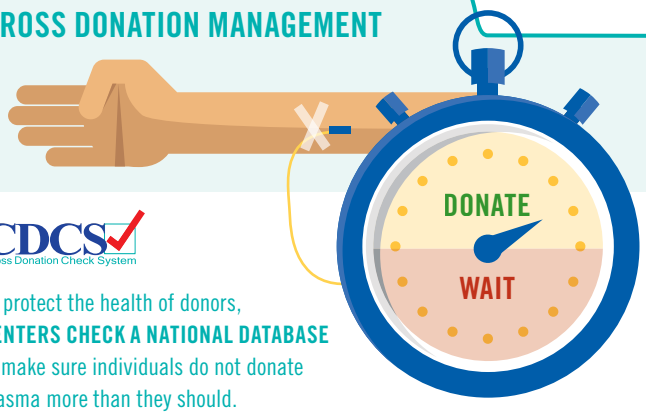
CROSS DONATION MANAGEMENT



CDCS Cross Donation Check System

To protect the health of donors, **CENTERS CHECK A NATIONAL DATABASE** to make sure individuals do not donate plasma more than they should.

APPLICATION OF THE GPDR TO PPTA'S STANDARDS—PROBLEMS AND SOLUTIONS

With this background in mind, it is fair to say that, while expansion of NDDR and CDCS to Europe would need to be managed with the requirements of the GDPR in mind, those requirements do not appear to be an absolute bar. With respect to the technical security requirements, for example, the versions of these programs in place in the U.S. already incorporate firewalls and strong encryption. Likewise, the GDPR's requirements of anonymization and "data minimization" (i.e., collecting and processing only as much data as necessary) are built into both programs. For example, only the last four digits of the donor's national identification number (in the U.S., typically the Social Security number) are retained, and data minimization is incorporated by design. The NDDR is not an all-purpose storehouse of donor health information. Rather, it contains records on the three blood-borne viruses of greatest concern. Similarly, the CDCS is not a historical log of every single donation. Rather, it is a limited record of donation dates needed to ensure compliance with frequency limits that is regularly purged.

The fact that the GDPR, as a default rule, prohibits the processing of health information is a more significant, though not insurmountable, obstacle. The GDPR provides a number of specific legal bases for processing personal data, one of which is the performance of a task carried out in the public interest. Focusing on the core objectives of the standards thus appears to provide a clear route forward. Both NDDR and CDCS are designed to perform tasks in the interest of public health—NDDR by contributing to product safety and CDCS by protecting donor safety. The strong support of FDA and, it is expected, European health authorities as well, is a testament to this fact.

Even if this strong public health rationale were not present, there is another option. Collection and use of an individual's personal data is permitted when the individual provides consent. Because informed consent is already a part of the plasma donation process—the donor consents to venipuncture, acknowledges potential complications from the donation process, etc.—an additional consent regarding the collection and processing of personal health information would appear to suffice. The GDPR provides a number of specific requirements to ensure that the consent is "informed"—such as disclosure of what data will be collected, how it will be used, and how long it will be retained—but complying with these requirements should be, if not routine, at least an easy adjustment for collection centers that already value and prioritize donor education.

The one requirement that merits additional mention, and suggests that industry should not rely on the donor's consent alone as the legal basis for data processing, is the right of erasure/right to be forgotten. As part of the informed consent, a collection center would also be required to disclose the donor's rights with respect to the collected data, including the right to *withdraw* consent. If consent is the only legal basis for collection, this would require the data processor to purge the data in question. This would potentially create issues for the CDCS because, in some Member States, donation frequency is defined in terms of a yearly cap. This would prevent implementation of the rolling 7-day data purge in place in the U.S. system.

In contrast, the problem is potentially more difficult with the NDDR, both because of the duration of retention (essentially indefinite) and the sensitivity of the data. It is certainly conceivable that some donors, when informed of a reactive test result, would withdraw consent to retention of information on their status as HIV, HBV, or HCV positive. If a substantial number did so, it would severely undermine the NDDR's donor screening function. It is not at all clear that such withdrawals of consent would be widespread, but the potential consequences of the right of erasure should be carefully evaluated. Right of erasure concerns also suggest that the primary public health function of both standards should be a point of emphasis with the data privacy authorities.

MOVING FORWARD

A more comprehensive legal review will likely be needed to ensure GDPR compliance. In addition to the issues outlined above, the fundamental question of how, and under what conditions, the two databases could be hosted outside the EU will need to be addressed. Because individual Member States are granted more flexibility with respect to health data, it will also be necessary to determine whether the data privacy laws of Germany, Austria, Hungary, and Czech Republic—where most source plasma collection centers are located—impose any additional requirements. Nevertheless, this initial analysis provides cause for optimism, and suggests that the prospects for expansion of NDDR and CDCS to Europe are strong. •

References

1. Regulation (EU) 2016/679.
2. PPTA, National Donor Deferral Registry Standard (2008), at http://www.pptaglobal.org/images/ IQPP_NDDR_V3_0.pdf.
3. Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 80 Fed. Reg. 29842, 29854 (May 22, 2015) ("We recognize that the NDDR is a voluntary, self-regulating initiative by the Source Plasma Collection industry that is operated by a third party administrator. We agree it is an important industry practice to ensure the safety of plasma-derived therapies.")
4. PPTA, Cross Donation Management Standard (2016), at http://www.pptaglobal.org/images/ IQPP/Standards_Revisions/2016/QPPS16025a_CDMS_Final.pdf.
5. Directive 95/46/EC.