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WHAT'S NEW IN INTENSIVE CARE

The challenge of local consent requirements for global critical care databases

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Health care systems around the world are increasingly using the large amount of routinely collected health data to understand health and disease processes better and to drive continuous improvement [1]. Critical care medicine has been at the forefront of these efforts, with several commercial and non-commercial ICU databases having been developed in a number of countries [2]. Such databases have the potential to be socially very valuable, supporting research, education, and quality improvement initiatives [3]. Linking databases across centres and countries can also increase their generalisability and accelerate knowledge discovery [2]. While activities that effectively utilise routine data to optimise and individualise care are urgently needed, efforts to create and link such databases can be undermined by concerns about data protection. These concerns are only likely to intensify as available data for research becomes more finely grained and more diverse (e.g. medical images, physiological waveforms etc.).

Patients have legitimate interests in controlling access to and use of their health data, and their informed consent will often be required for the use of their data for purposes other than they were collected. However, requiring individual informed consent for pseudonymised (de-identified) data to be used in healthcare databases and registers can lead to large increases in costs and create major selection biases that undermine the data representativeness [4]. Nevertheless, many jurisdictions allow for an ethics committee to waive the requirement for consent for such secondary uses of health data if specific conditions are met. For instance, one of us (L.A.C.) is involved in the well-known MIMIC (Medical Information Mart For Intensive Care) database, which contains clinical data acquired during the routine hospital care of patients admitted to critical care units at the Beth Israel Deaconess Medical Center in Boston [3]. MIMIC has had the requirement for individual patient consent waived by the local institutional review board for over 10 years because the project does not impact clinical care and the data are de-identified by removing all protected health information in accordance with the Health Insurance Portability and Accountability Act before being included [3]. However, numerous efforts with international collaborators to set up other critical databases (e.g. in Brazil, Belgium and Spain) or to link MIMIC with other established critical care databases (e.g. in the United Kingdom and France) have so far been thwarted by local ethics committees suggesting that individual patient consent may be required.

In an era of increasing global collaborative health research efforts, such variations in data consent requirements are problematic. There is a need for more

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Table 1 Key implications of the EU General Data Protection Regulation (*GDPR*) for global critical care databases

Summary of GDPR provision	Implication for global critical care databases
Extra-territorial applicability	
The GDPR applies to all data controllers and processors processing personal data of data subjects residing in the EU, regardless of whether the processing takes place in the EU or not	Global critical care databases that are based outside of the EU will need to comply with the GDPR if health data collected from patients residing in the EU are included in the database
Scope	
The GDPR applies to any personal data concerning an identified or identifiable natural person, but not to anonymous information.	As the GDPR does not distinguish between anonymised and anonymous data, critical care databases collecting identifiable data for research purposes will be excluded from the scope of the GDPR if the data are later rendered anonymised [9]
Pseudonymisation	
Pseudonymised data is now recognised as personal data if it could be attributed to a natural person by the use of additional information	Given pseudonymised health data is what critical care databases typically use, recognising pseudonymised data as personal data may result in more bureaucracy, particularly for those countries that currently consider pseudonymised data to fall outside the scope of personal data [9]
Special categories of personal data	
The processing of special categories of personal data ("sensitive personal data"), including genetic data, biometric data, and data concerning health, shall be prohibited unless certain conditions applies	Critical care databases using pseudonymised sensitive personal data will need to either obtain explicit consent from the data subject or for the data to be processed under the scientific research exemption set out in the GDPR, which could occur without consent if subject to appropriate technical and organisational safeguards [9]

consideration to be given to the correct equilibrium between protecting individual patients and the societal value of these activities, not only within countries but also between countries.

The risk of highly localised single-site ethical reviews undermining global biomedical data research has prompted some to propose the harmonisation of ethics review of specific types of data-driven research through the creation of multinational governance structures, arguing that "in a world of Big Research and Big Data, Big Ethics is needed" [5]. While we agree that there is a need for greater harmonisation of ethical reviews of global data research, we think local ethics committees will remain best placed to assess the values and norms of local communities. However, it appears that many ethics committees are currently uncertain how data research should be responsibly regulated, leading to growing concerns that ethics committees are overly concerned with risk and do not give sufficient consideration to the value of such research for population health [6]. It appears that a key factor driving such risk-adverse decisions is concerns about data protection regulation.

In the European context, the new General Data Protection Regulation (GDPR) is the key legal instrument in this domain and is directly enforceable in all EU member states. The GDPR entered into force in May 2016, but only applied from 25 May 2018. While early drafts of the GDPR raised concerns that the regulation may severely restrict data research [7], the final text adopted a more research-friendly approach and it is now thought the GDPR will make little impact on data research overall [8]. While the scientific research exemption set out in the GDPR will allow data to be included in databases without obtaining additional consent if specific conditions are met, the GDPR does introduce some important changes that global critical care databases will need to consider (see Table 1 for a summary of the key provisions of the GDPR).

Furthermore, there are concerns that the GDPR allows too much room for interpretation of the regulation by member states on key aspects of data protection, including sufficient methods of pseudonymisation (a means of de-identification); when data are considered fully non-identifiable; what further limitations should be set on processing sensitive data for research purposes; and sufficient safeguards and conditions for processing data under the research exemption [9]. While this may help recognise local values and norms, it risks undermining the goal of the GDPR to address the current heterogeneity of data protection within the EU. It has been suggested that negotiating sector-specific codes of conduct by professional bodies could help facilitate data harmonisation and integration [10]. Such a code of conduct could also help provide guidance to database operators, researchers, and ethics committees concerning necessary organisational and technical safeguards to protect patient's rights without unduly impeding important research.

With health systems increasingly leveraging routine clinical data, issues regarding consent for global critical care databases will likely only become more prominent and they need to be proactively addressed. This presents an excellent opportunity for the European Society

of Intensive Care Medicine to play an important role in this area. The Society should consider forming a committee tasked with consulting the national societies of intensive care in the EU and key partners across the world to canvass the initiatives, challenges, lessons and best practices of societies in relation to this issue, with the goal of developing a code of conduct in relation to critical care databases.

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Compliance with ethical standards

Conflicts of interest

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References

1. Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL (2013) An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep 43:S16–S27 (**Special report**)
2. Celi LA, Mark RG, Stone DJ, Montgomery RA (2013) "Big data" in the intensive care unit. Closing the data loop. Am J Respir Crit Care Med 187(11):1157–1160
3. Johnson AE, Pollard TJ, Shen L, Lehman LW, Feng M, Ghassemi M, Moody B, Szolovits P, Celi LA, Mark RG (2016) MIMIC-III, a freely accessible critical care database. Sci Data 3:160035
4. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, Kapral MK (2004) Investigators in the registry of the Canadian stroke network. Impracticability of informed consent in the registry of the Canadian stroke network. N Engl J Med 350(14):1414–1421
5. Dove ES, Bartha M, Knoppers BM, Zawati MH (2014) Towards an ethics safe harbor for global biomedical research. J Law Biosci 1(1):3–51
6. Spector T, Prainsack B (2018) Ethics for healthcare data is obsessed with risk—not public benefits. The conversation 2018. Available online at: https://theconversation.com/ethics-for-healthcare-data-is-obsessed-with-risk-not-public-benefits-89575. Accessed 16 Mar 2018
7. Nyrén O, Stenbeck M, Grönberg H (2014) The European Parliament proposal for the new EU General Data Protection Regulation may severely restrict European epidemiological research. Eur J Epidemiol 29:227–230
8. Rumbold JMM, Pierscionek B (2017) The effect of the General Data Protection Regulation on medical research. J Med Internet Res 19(2):e47
9. Shabani M, Borry P (2018) Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation. Eur J Hum Genet 26:149–156
10. BBMRI-ERIC (2015) Position paper on General Data Protection Regulation 2015. Available online at: http://www.bbmri-eric.eu/wpcontent/uploads/BBMRI-ERIC-Position-Paper-General-Data-Protection-Regulation-October-2015_rev1_title.pdf. Accessed 16 Mar 2018