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Review

Data-driven sudden cardiac arrest research in Europe: Experts' perspectives on ethical challenges and governance strategies

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Abstract

Background: Observational studies using large-scale databases and biobanks help improve prevention and treatment of sudden cardiac arrest (SCA) but the lack of guidance on data protection issues in this setting may harm patients' rights and the research enterprise itself. This qualitative study explored the ethical aspects of observational SCA research, as well as solutions.

Methods: European experts in SCA research, medical ethics and health law reflected on this topic through semi-structured interviews ($N = 29$) and a virtual roundtable conference ($N = 18$). The ESCAPE-NET project served as a discussion case. Findings were coded and thematically analysed.

Results: The first theme concerned the potential benefits and harms (at individual and group level) of observational data-based SCA studies and included the following sub-themes: societal value, scientific validity, data privacy, disclosure of genetic findings, stigma and discrimination, and medicalisation of sudden death. The second theme involved governance through 'privacy by design', 'privacy by policy' and associated regulation and oversight. Sub-themes were: de-identification of data, informed consent (broad and deferred), ethics review, and harmonisation.

Conclusions: Researchers and scientific societies should be aware that ethico-legal issues may arise during data-driven studies in SCA and other emergencies. These can be mitigated by combining technical data protection safeguards with appropriate informed consent policies and proportional ethics oversight. To ensure responsible conduct of data research in emergency medicine, we recommend the establishment of 'codes of conduct' which should be developed in interdisciplinary groups and together with patient representatives.

Keywords: Research ethics, Data protection, Observational studies, Big data, Biobank, Genetics, Sudden cardiac arrest, Sudden cardiac death, Out-of-hospital cardiac arrest, ESCAPE-NET

Introduction

Sudden cardiac arrest (SCA) remains characterised by low survival rates across Europe.[1,2] Yet the increasing amounts of patient data and tissue combined with improved processing capabilities may facilitate observational studies providing breakthroughs in SCA prevention and treatment.[3,4] The ESCAPE-NET (European Sudden Cardiac Arrest network towards Prevention, Education, New Effective Treatment) consortium combines SCA datasets and biobanks from multiple countries. Such a large dataset is needed to unravel the multiplicity of causal factors; 'data-driven' studies provide advantages over randomized controlled trials in terms of both real-world applicability and ethicality, given their non-interventional nature. However, the linkage and use of sensitive data and biospecimens does give rise to privacy concerns.[5]

The emergency nature of SCA makes it in nearly almost impossible to obtain prior informed consent for data collection; acquiring consent after the SCA event is often problematic due to mental incapacitation immediately after the event and the low survival rates. Guidance is needed on the right balance between expected benefits and potential harms of observational studies with this vulnerable population.[6,7] In Europe, the General Data Protection Regulation (GDPR) provides the general data protection framework; specific regulations for using sensitive data for research are largely left to

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https://doi.org/10.1016/j.resplu.2023.100414

Member States.[8] Moreover, the GDPR does not apply to deceased persons, nor does it contain a provision for proxy consent of incapacitated subjects.[9] In those situations, guidance follows from national law and, if available, ethical guidelines. A lack of uniform European regulation applies even more in the context of tissue samples: biobanking research is mostly regulated through international 'soft law' instruments and – if present – national legal frameworks.[10]

With this study we aimed to explore the ethical aspects of (international) data-driven research in the context of SCA, and strategies to deal with these issues responsibly, using ESCAPE-NET as example. To this end, we conducted expert interviews and hosted a roundtable conference.

Methods

Study design

A qualitative design fits the exploratory nature of our study.[11] Data sources were semi-structured interviews with selected experts as "crystallization points" for knowledge,[12] and an online roundtable conference where open questions were discussed. The ESCAPE-NET project was used as discussion case (Box 1). ESCAPE-NET combines multiple European SCA study cohorts containing prehospital data from emergency medical services (EMS), electronic health records, and in some cases data from pharmacists and general practitioners.[13] In the Scandinavian countries, most data are gathered through linkage to national registers on medical treatment, cause of death, prescription medication, genealogy and socio-economic status.[14] A number of participating centres operate genetic biobanks of SCA patients and controls whose DNA is extracted from residual clinical biosamples, e.g. blood taken during hospitalisation, or endotracheal tubes placed by EMS.

Participants

We conducted interviews ($N = 29$) with SCA researchers involved in ESCAPE-NET ($n = 16$) and with ethical and legal experts who are key opinion leaders on responsible data research ($n = 13$), meaning that they published academic papers on this topic and/or participated in relevant policy and oversight bodies. Interviewees were sought from the six EU countries where data for the ESCAPE-NET project is collected (The Netherlands, Italy, France, Denmark, Sweden, Czech Republic). Please see the online supplementary material for an anonymized list of experts, which specifies their working country and expertise (Table S1). Prior to the interview, respondents received information about ESCAPE-NET. For each discipline (medicine, ethics, law) at least one expert per participating country was interviewed. In the roundtable conference, 18 experts from the different fields participated; these had been previously interviewed ($n = 13$) or were newly invited ($n = 5$). The latter included SCA researchers from Germany and Norway who had much experience with the complexities of SCA data research but had no direct connection to ESCAPE-NET. The roundtable format was chosen to give all participants the possibility of equal input.[15]

Data collection and analysis

Interviews of between 60 and 120 min were conducted between 2018 and 2021. The interview topic guide was based on previous literature study[7] and pilot-tested within the research team. Interviews were audio recorded and transcribed following consent; ethics approval for this study was not required under Dutch law. Respondents were given the opportunity to receive the transcript and a summary to enable corrections. Interviews were thematically analysed using MAXQDA 2018 software and coding was done by two researchers (MARB and JCHV). Changes in coding structure were tracked to conclude that data saturation was achieved. The invitational roundtable conference was held in September 2020, and was transcribed and coded in the same manner. A document with conclusions was shared with conference participants to allow for corrections.

Results

Benefits and harms of SCA data research

Societal value

Respondents mentioned potential benefits and harms related to SCA registries and biobanks (see Table 1 for illustrative quotations). All experts acknowledged that observational SCA studies offer great potential for societal health benefits; an important precondition for any research that carries potential risks.[16] This societal value requirement reflects the medical-ethical duty of *beneficence* (i.e., relieving, lessening or preventing harm, and providing benefits) and is enshrined in ethical guidelines like the Helsinki Declaration and the Nuremberg Code. An example of ESCAPE-NET research with societal value is the discovery that the widely prescribed drug nifedipine, for high blood pressure and chest pain, is associated with increased SCA risk.[17]

Scientific validity

For studies to be valuable, it is an ethical prerequisite that they are also designed in a scientifically valid manner. The GDPR has 'accuracy' as one of its core principles regarding handling personal data. Interviewed SCA researchers made use of data management plans and/or standard operating procedures, and audit and quality control were regularly performed. Still, respondents noted that several issues may impact scientific validity of SCA research: low quality of data and inconsistencies in reporting, especially for linkage from various sources in the chain of care[18–21]; difficulties in international comparisons due to variations in health system characteristics and definitions[22,23]; and limited generalisability because of true differences across different regions and populations or due to selection biases when severely ill or deceased patients are excluded.[24–26]

Data privacy

Privacy risks are relevant in the context of researchers' duties of *non-maleficence* (i.e., avoiding the causation of harm) and respect for *autonomy* (i.e., supporting patients' self-determination). All researchers and some ethico-legal experts believed that the current data protection regime renders the possibility that a third party will illegitimately re-identify patients mostly theoretical because of the disproportionate effort needed. If a data breach would occur, privacy concerns for SCA patients were regarded as less worrisome compared to more sensitive conditions (examples mentioned were circumcision registries and studies of acute psychosis or sexually transmitted disease). For SCA victims who do not survive, most of the harm was thought to have disappeared; although experts acknowledged a risk of posthumous reputational harm and the fact that some types of data (e.g. genetic) may bring privacy concerns for relatives.[27] While researchers mostly focused on consequentialist harms to health, ethico-legal experts recognised that confidentiality is important out

Table 1 – Benefits and harms of SCA data research: illustrative quotations.

Societal value	"We are very much in a protection-paradigm, but what can be forgotten is that patients really like to participate and have their data used for good science." (23 – Ethico-legal expert)
Scientific validity	"We do not have the manpower to manage it for the whole country. We collect a huge variety of data, but only for a small area, which gives rise to questions about representativeness." (9 – SCA researcher)
	"In the UK they have do-not-resuscitate [DNR] orders, but not in Italy. The denominator changes if you remove all patients with DNR from the dataset." (8 – SCA researcher)
	"You would create an enormous selection bias, because deceased patients are the most ill patients of your cohort." (18 – Ethico-legal expert)
Data privacy	"It would be a breach of trust if personal data were available for a third party without the patient's knowledge." (5 – SCA researcher)
	"Before coming into the clinic, we'll tell them, do all your insurance before you meet me. Because once you're in my system and I have to write, 'I have seen an ECG with this and this', then the insurance company will get that information. But that is only when it goes from research to the clinical setting." (4 – SCA researcher)
	"It might be possible to wrong some patients by using their data, without actually harming them." (19 – Ethico-legal expert)
Disclosure of genetic findings	"It happened a few times that we looked at single genes and found stuff that could potentially save the lives of relatives. That's been difficult, not to inform them." (4 – SCA researcher).
	"Each case is specific and cannot be answered with a single question. When the information can save a life, it's different than when it's not life-threatening. The most important thing is to be clear about people's expectations" (25 – Ethico-legal expert).
	"Having this knowledge might increase stress which is in itself a risk factor. There should be exceptions only when a preventative measure can target that one mutation. But then it should be a screening program run by public health agencies." (28 – Ethico-legal expert)
Stigma and discrimination	"If your study finds that a minority group have a higher risk, then that group can be labelled as having these problems, while it might not apply to everyone." (6 – SCA researcher)
Medicalisation of sudden death	"The money you spend on one patient you don't spend on another. I think researchers should consider medical as well as social factors. (. . .) We always want to cure people and prevent sudden death. We think about having a good life, but we never think about having a good death. Sometimes I think that sudden death is a good death." (15 – SCA researcher)

of respect for participants' autonomy and to safeguard public trust in science.[28]

Disclosure of genetic findings

SCA biobanking research presents particular ethical questions. Firstly, some studies draw participants' blood for research purposes: this was seen as minimally invasive (in line with SCA survivors' views[29] but experts preferred residual blood leftover from care. Secondly, studies collecting DNA need to have a policy for the return of individual genetic findings. Different policies were present across ESCAPE-NET research groups. In two cases, patients could only participate if they agreed to be informed of actionable findings, following institutional policy. Some experts found this problematic because they recognised patients' autonomy in the form of the *right not to know*[30] without being excluded from participation. On the other hand, one researcher experienced moral distress from not being allowed by their institution to contact relatives of deceased patients with relevant findings. Whether researchers have a moral duty[31,32] to contact deceased patients' relatives with clinically actionable genetic findings is a complex ethical issue for which regulations differ per jurisdiction.[33] In the Netherlands, for instance, the physician's responsibility to medical confidentiality remains in place after a patient's death unless relatives are at major risk.[34]

Experts recommended that researchers create an incidental findings policy together with ethico-legal experts, detailing what counts as a serious and valid finding, and that a genetic findings committee is installed for large biobanking projects. Especially for low penetrance variants (i.e. causing a phenotype in only few carriers) disclosure should be done cautiously, preferably by genetic counsellors, so that people are not unnecessarily worried. One expert emphasized that the fading boundary between research and screening purposes might require upholding the Wilson and Junger screening criteria.[35] This notion is shared in the literature by Cho,[36] who states that "blurring the lines between clinical and research obligations should not be taken lightly. It is important to cross this line only with compelling reason, accurate information, and clear informed consent."

Stigma and discrimination

Harms may occur at group-level too, affecting not only the data subjects but also the broader community.[37] To fulfil the aforementioned medical-ethical duties and the criterion of *justice* (i.e., fairly distributing benefits, risks and costs), SCA data research should be translated to practice in a responsible manner since "many of the privacy harms of big health data arise not merely in the collection of data, but in their eventual use".[38] One of the aims of ESCAPE-NET is to develop a risk prediction model to enable personalised prevention of SCA. Respondents noted that the use of such risks scores requires ethical reflection on how to communicate and use the information, especially given the small effect sizes expected in the general population. Another issue put forward was the fact that creating (genetic) risk scores for certain groups of patients can cause stigmatisation of these groups, such as ethnic minorities, if findings feed into social stereotypes (e.g. related to health behaviour).[39] Stigma is harmful in itself, but can also lead to group discrimination.[40]

Medicalisation of sudden death

Two interviewed researchers brought up a more meta-level concern about SCA research: they wondered whether SCA may be a 'good'

way to die for elderly people (who constitute the majority of SCA victims), and whether it might be more ethical to spend resources on research into other conditions, or at least on younger SCA patient groups only. This theme is reflected in discussions about the medicalisation of death and dignity in dying,[41] but is outside the scope of the current paper to discuss in any more detail. Whether researchers have a responsibility for those broader societal impacts, indirectly related to their work, was considered by the experts as a topic for further debate.

Responsible governance of SCA data research

To deal with ethical issues, experts discussed governance strategies that can be divided into three types.[42] Firstly, 'privacy by design' consists of technical and organizational measures built into the study design. Examples of measures operated by SCA researchers were data access logging, data separation, pseudonymization, and encryption. Secondly, for data that cannot be de-identified 'privacy by policy' measures are needed around data sharing and informed consent. Within ESCAPE-NET different policies were used, depending on national law and contextual ethical factors, such as the level of data sensitivity. For instance, consent was asked in all genetic studies, even though experts noted that re-identifying individual patients is also possible with clinical and demographic data. Thirdly, governance of SCA data research is steered by overarching (inter-) national regulations and oversight bodies. In what follows, we discuss the specific governance aspects most relevant for SCA research (illustrative quotes are presented in Table 2).

De-identification of data

Aggregating data into groups of multiple individuals or removing identifying information decreases the likelihood that specific individuals can be identified. The GDPR does not apply to completely anonymous data. To determine whether a natural person is identifiable, "account should be taken of all the means reasonably likely to be used" in terms of cost, time, and available technology (Recital 26). Instead of irreversibly anonymizing data, an alternative is *pseudonymization* which ascribes a code that is separately stored but can be linked back to the data subject.[43] This code may be kept by the treating physician or a Trusted Third Party (TTP) so that the data remain anonymous at least for the researcher.[44] Some respondents voiced concerns about the quality of pseudonymized data and one researcher had worked with old genetic samples where outdated codes in the lab and the database had to be re-matched manually. Still, experts preferred pseudonymization over anonymization as it allows addition of new data to a subject's profile, enables an audit trail to source documents, and permits patients access to their own data if desired. What is more, complete and irreversible anonymization is practically impossible because of the ability to cross-link with other datasets, especially in emergency research with many data sources along the 'chain of care'.[45,46]

Informed consent

Interviewed researchers experienced that most SCA survivors consent because they want to give back to society; in their ESCAPE-NET cohorts $\geq$ 90 % of patients consented to the use of their data. Some respondents felt that informed consent should not be required for non-genetic minimal risk research. This is similar to Porsdam Mann et al. who argue that data donation constitutes a *duty of easy rescue*: i.e. a moral obligation to help others when the cost to oneself is low.[47] Not requiring consent would prevent participation bias and lower the burden on researchers. Most jurisdictions contain exemptions to the consent requirement, for instance if obtaining consent would be reasonably impracticable or impossible, provided that the research serves a public interest and that privacy by design safeguards are in place.[48] Experts said this must be determined for every study separately: there should be no general exemption for observational emergency research. Legal experts explained that even if a consent waiver is justified, an accessible opt-out possibility should remain (e.g. with the help of a public information campaign). This was not the case in all ESCAPE-NET countries. For instance, in Denmark, there is no way to opt out of the use of clinical or socio-economic data for research, as a result of the country's history of data-driven epidemiology.[14]

Consent is not a panacea, as there can be data privacy concerns for people other than the one consenting, such as blood relatives, or non-participants subjected to the created risk prediction models.[49] Still, various respondents thought 'opt-in' consent should be the default as *"it can give people a good feeling that they were able to give their data for science"* (11 – SCA Researcher) or *"in light of respect for patients' autonomy"* (8 – SCA researcher). Asking for consent shows respect and promotes public trust.[69,70] One researcher found it most important to inform patients about what will *not* be done with the data, e.g. sharing with commercial parties, which various experts thought should only be done after explicit consent. No SCA researchers shared identifiable data with commercial third parties; some shared pseudonymised data with defibrillator manufacturers or data mining companies. One respondent noted that an increasing amount of valuable research is conducted by public–private partnerships, but was worried participants would not understand this. Indeed, people do not always understand or recount what they consented to[50,51]; so the value of consent lies in the promotion of autonomy and the fact that people can refuse when they do not trust the researchers.

In Europe, there is an ongoing policy and scholarly debate about the question how *specific* consent forms should be in order to be legitimate.[52] After consent has been obtained, data may be used for the purposes described in the consent form ('purpose limitation'). Respondents agreed these purposes can be as broad as 'SCA research' and some thought they extend to all health-related research. In previous research, this *broad consent* was also found acceptable by SCA survivors as they prefer to make the main choice themselves but wish to leave specifics to researchers.[53] Asking specific consent for each sub-study might be burdensome and one expert advocated for *dynamic consent*, where an online communication system is used to inform patients of changes in data use, and where participants can easily choose to opt-in or opt-out of specific uses, and decide with whom data may be shared.[54] In this system, participants may also provide preferences regarding (re)contact and whether they want to be informed of findings, similar to *meta consent* where preferences for the type of consent are recorded.[55] Such approaches may enhance autonomy, trust and social engagement, but depend on funding for the required communication infrastructure.

Specific for the emergency setting is that many data need to be collected during or shortly after the SCA event, e.g. ambulance ECGs would otherwise be overwritten. Consent for research with such data is necessarily 'deferred' until the patient is conscious, either in the hospital or at home after a few months. Experts generally preferred the latter. There was agreement that data should be placed on hold until consent is obtained and that the timing of contact

Table 2 – Responsible governance of SCA data research: illustrative quotations.

De-identification	"Right now there is broad consensus that double-coded data is not anonymous. Somewhere in the chain, personal data will be processed." (17 – Ethico-legal expert)
	"With the chain of care it's impossible to collect anonymised data. Later on, while analysing, you can anonymise. But if you do genetic analyses and need to report to the patient or the patient's family, you need to be able to get back to the patient." (2 – SCA researcher)
	"If you seriously hamper data quality, pseudonymization is not in the interest of the patient." (1 – SCA researcher)
Informed consent	"If you do not ask consent, you should provide a lot of information about the research, to create openness and transparency. For example, a website containing study results and information about the researchers and affiliated institutes." (20 – Ethico-legal expert)
	"In the end consent is about trust in doctors, which is more crucial than any kind of information about the research." (2 – SCA researcher)
Timing of consent	"As a researcher I prefer opt-out, also because people often do not understand what they sign for anyway. If you do ask consent, it should be after a few months. In the ICU, the person is in a dependency position and I don't think that is right." (13 – SCA researcher)
	"I usually say, "You can think about it and I'll come back later" or "I will call you later". Because sometimes it's so confusing what's going on, so I would contact them later when they were at a coronary care unit or at home. I look at the situation and the people and make a decision based on that." (12 – SCA researcher)
Consent for post-mortem data use	"There may be purposes that I couldn't have known about while I was alive, that I would not have consented to when my data are used after death." (22 – Ethico-legal expert)
	"It might rip open some scars if you have a husband or wife who has died and you get a letter that they have been included in a study. I don't know if that can be informed consent in any way because it's a stressful situation." (5 – SCA researcher)
Ethics review of observational studies	"Not only because of the difficulty of consent, but also because data could be reused, it is really important to have oversight from a specific committee." (27 – Ethico-legal expert)
	"Most researchers here are only asking ethics committees for approval because of different journals requesting that, not because it's required by law." (16 – SCA researcher)
Harmonisation of governance requirements	"The most important would be harmonising all decisions at a national level. There are now 40 ethics committees in this country, which is still a big number." (10 – SCA researcher)
	"I think it is also a waste to jeopardise this whole registry system in order to harmonise everything. It is too heterogeneous to harmonise." (2 – SCA researcher)
	"Striving to European harmonisation is a great plea, but it's far away still. Even in our own country it is difficult to get all hospitals on the same review policies. The GDPR leaves room to national regulations, so we stay in our own cultures. (. . .) Adjusting the GDPR or national law is a formal and difficult process, while a code of conduct would be a living document able to withstand the ticking of time." (21 – Ethico-legal expert)

should be based on the patient's recovery. Experts believed that consent given by a patient before mental capacities are sufficiently restored after a SCA, cannot be regarded legally and morally valid. To assess individual decision-competency, the Appelbaum criteria can be used.[56] Some respondents suggested that the appropriate timing should be approved in advance by a research ethics committee. In most countries, consent from next-of-kin may be asked if the patient remains incapacitated.

We also discussed with experts whether consent would be required for the inclusion of deceased patients' data, an important question in research on acute and life-threatening illness. In most ESCAPE-NET studies there is no role for next-of-kin in deciding about (non-genetic) data uses, as there is no legal basis and it may be an emotional burden on them. Experts agreed it would be best to inform people during their lifetime about the post-mortem use of data. Regarding genetic studies, experts noted that there is an ethical responsibility, albeit not a full legal duty in most countries, to disclose clinically actionable genetic findings that indicate serious risk to relatives of the deceased.[33] A number of respondents said that if a study may potentially give rise to such findings, it is useful to notify relatives as soon as possible about the research taking place.

Ethics review of observational studies

Given the limitations of consent and anonymization, especially in the SCA setting, what is needed is a "shift from personal data protection to data protection tout court."[57] Even when data are anonymized, experts believed that observational studies should be subject to ethical oversight. This is currently not the situation in many European countries where studies with existing and pseudonymised data or tissue are exempt from ('full') ethics review, but there is no clear international guidance on the criteria for exemptions.[58] Ethics review was found to be important because of the potential impact on individuals and society, and because it provides the opportunity to give advice about ethical and legal aspects to SCA researchers, who expressed a desire for more guidance. For instance, RECs or data protection authorities evaluating observational studies should determine whether consent is needed, but should also assess study aims and methodology, just like for randomised controlled trials, in order to gauge whether the public interest is served. Experts thought assessment needs to be proportional to the kinds of data (and tissue) used and the proposed uses.

Harmonisation of governance requirements

Respondents experienced regional and (inter-)national differences in ethics committees' requirements for observational studies, which complicated cooperation and affected study validity, thus unnecessarily impeding progress in science.[59–63] Creating a European ethics approval process would be practically difficult but at a minimum, review procedures should be harmonised at a national level. Experts also noted the differences in interpretation of privacy laws. In addition to the GDPR and its implementation laws in EU Member States, other legal regimes and national *lex specialis* may regulate data protection for health research. It is not always clear how these laws should be applied to the SCA setting, which complicates the conduct of research and the proper protection of patients' rights. Therefore, experts mentioned the idea of an ethical *code of conduct* specifically for observational research in emergency medicine, but in the conference they agreed that there should not be too many different codes. Instead, when general codes of conduct for observational studies are created or updated, these should contain a provision on research in the emergency setting, and SCA researchers may need to lobby for this. In line with our findings, the European Data Protection Supervisor has recognised the need for further harmonisation and is advocating for a general, international code of conduct for processing personal data in the health sector.[64]

Discussion

We have provided an overview of expert perspectives on responsible data-driven SCA research. When privacy measures are deployed correctly, and combined with ethics oversight, the risks of observational SCA research are kept to a minimum. Still, researchers should recognise that adhering to ethical and legal requirements is more than mere administrative necessity, given the potential for individual and societal harms. Our findings also have significance for the broader field of health data research and more specifically for other emergency settings, such as trauma, stroke, or COVID-19. Namely, in those settings similar questions arise around the difficulties of obtaining prior informed consent or the responsible use of deceased patients' data. In this paper, we addressed the governance options relevant for SCA and other acute and critical illness research, but due to the variety of themes our descriptions are necessarily limited in detail and not linked to specific jurisdictions.

We believe that technical measures such as pseudonymization should always be in place, also for deceased patients, as long as this does not disproportionately limit the conduct of research. While some respondents thought that informed consent is only necessary when anonymization is impossible, we feel that their standpoint disregards the limitations of anonymization and the fact that control may still be important even if data are anonymized. Ignoring participants' expectations may also harm trust in the research enterprise. Experts agreed that exemptions from consent should be reviewed by a research ethics committee on a case-by-case basis. If consent is asked, a model based on 'deferred' and broad consent (albeit with limits to this breadth, e.g. limited to sudden cardiac arrest research and not other disease areas) was found acceptable, which is in line with patients' views and the recently updated European Resuscitation Council (ERC) guidelines.[65] Our study adds that consent from SCA survivors is most valuable when deferred until the patient has fully regained cognitive capacities. This may be some months after the SCA event.[53]

Further study is needed regarding innovative governance solutions to facilitate data sharing and improve data subjects' control.[66] For instance, digital consent tools would allow SCA survivors to easily register (broad) consent preferences, including on when they can be approached for consent. Research aimed at improving communication about complex aspects of studies (e.g. involving commercial parties, genetic risk scores, or uses after death) would help avoid patients opting out due to lack of understanding. SCA research may also benefit from population-based democratic governance tools such as data cooperatives,[67] as these enable potential SCA victims to register privacy preferences in advance. Another valuable avenue would be to create government-appointed national SCA registries across Europe, which would help centralise ethical governance and remove some legal uncertainty, while allowing for larger and more representative cohort studies.[8,19,68] Specific research registries and biobanks will continue to be needed, however, for in-depth studies.

Our study highlights the interdisciplinary nature of this topic which calls for societal dialogue about data research in emergency medicine between medical, epidemiological, humanities, legal, policy, and ICT experts as well as lay people. Scientific societies such as the ERC should position themselves and endorse an active, structured dealing with the topic. We advocate the development of an up-to-date code of conduct for SCA data research, or addition of a section about emergency medicine to a more general code (e.g.[64,69,70]). This might be a joint effort with societies in intensive care medicine facing the same issues.[63] The development of such a code will help to clarify to what rules observational SCA research has to oblige and will also stimulate collaboration and harmonisation on the EU-level. The latter becomes even more urgent given the rise of artificial intelligence that exacerbates ethical concerns around data-driven research.[70]

Funding

This study was part of the ethics work package of the ESCAPE-NET project, which is funded by the European Union's Horizon 2020 Research and Innovation programme under Grant Agreement No 733381. MARB, HLT, MTB and DLW also received funding from the - COST Action PARQ (grant agreement No CA19137) supported by COST (European Cooperation in Science and Technology).

Author contributions

MARB wrote the manuscript draft. MARB and JCHV conducted the expert interviews and JCHV's master's internship report provided input for the manuscript. MTB, HLT, MCP and DLW participated in the design of the study and the organisation of the interviews and roundtable conference. Discussions with DD provided important input for the paper and DD helped with the organisation and content of the conference. All authors reviewed the manuscript and revised it for important intellectual content, and they have all read and approved of the final manuscript.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing inter-

ests: All authors except JCHV, DD, and MCP are part of the ESCAPE-NET project (Horizon 2020 grant agreement No 733381) which was the case discussed during the interviews. DD was a part-time employee at Resuscitec GmbH, Freiburg, Germany in R&D, until 6/2020, which was before the invitational conference.

Acknowledgements

The authors wish to thank all interview and roundtable participants for their time and input. We also wish to thank Xanthe de Voogd as independent researcher for coding a number of interview transcripts for validation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resplu.2023.100414.

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