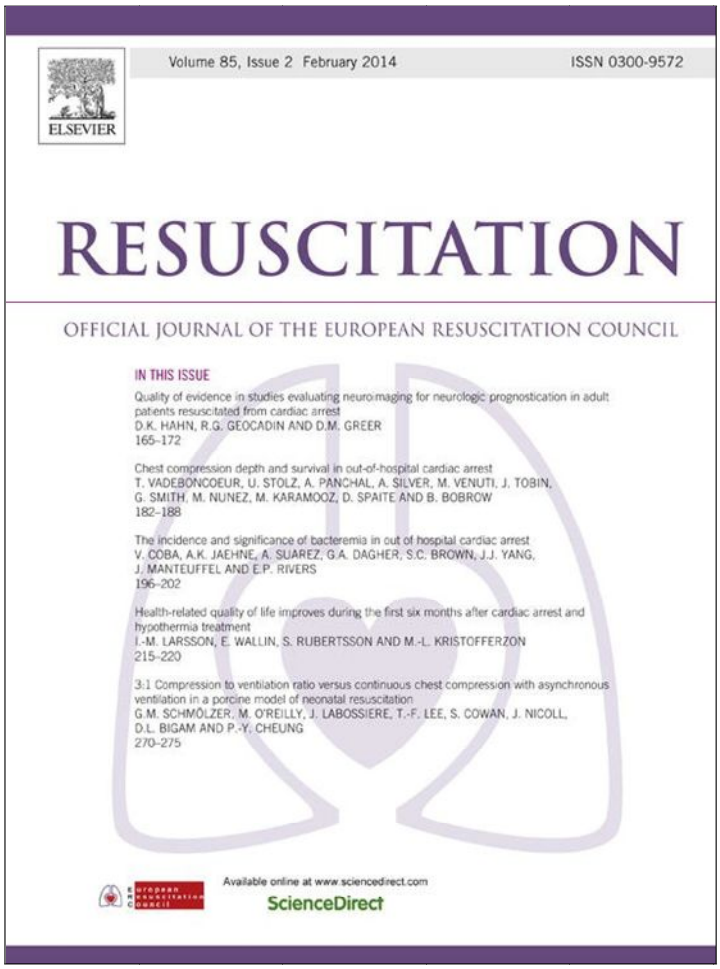

Resuscitation 85 (2014) e27

Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Letter to the Editor

Current policies on informed consent in Japan constitute a formidable barrier to emergency research

Sir,

Emergency medicine research is mired in an ethical dilemma: Do researchers discontinue valuable research when unable to obtain informed consent or include patients in clinical trials without their informed consent?[1] During emergency treatments (e.g., resuscitative care), patients are unable to sign informed consent forms when admitted. The United States has had guidelines since 1996 concerning the steps researchers can take when prior informed consent cannot be obtained in clinical trials.[2] Furthermore, the European Commission introduced rules regarding clinical research for European countries in 2001, although consensus was not reached then on how researchers should act when prior informed consent cannot be obtained[3]; in 2010, however, new regulations were established, and it was hoped that these would stimulate clinical research in emergency medicine across Europe.[4]

In Japan, no reported emergency clinical studies with interventions have been conducted without first obtaining informed consent. This may be because ethical guidelines regarding clinical studies in Japan differ from those in Europe and the United States, where clinical studies are reviewed by institutional review boards (IRBs) in accordance with internationally accepted good clinical practice (GCP) guidelines. In Japan, clinical studies can be broadly classified into "clinical trials" and "clinical studies."

Clinical trials are conducted to gain regulatory approval to manufacture and sell new medicines, or to expand indications and additional or altered dosages or amounts of established medicines. Clinical trials are reviewed by the Ministry of Health, Labour and Welfare (MHLW), and are conducted in accordance with GCP guidelines.

Conversely, clinical studies involve prospective research and interventions, and are conducted to improve diagnoses and treatments by using confirmed diagnostic techniques or medicines. Additionally, clinical studies are conducted in accordance with governmental ethical guidelines and do not follow GCP guidelines, thus differing from clinical trials. Clinical studies can further be classified into two types: with and without interventions. Confusion has arisen in researchers because of the subtle differences in the ethical guidelines between study types. In addition, despite having ethics committees in relevant institutions, there is still a lack of legal regulation and government monitoring of clinical studies. Thus, in the future, it is anticipated that all clinical studies in Japan will be subject to the GCP guidelines and be reviewed by IRBs, just as in Europe and the United States.

Nevertheless, it is currently impossible in Japan to conduct clinical trials and clinical studies with interventions in emergency medicine when informed consent cannot be obtained; researchers may only proceed with trials by obtaining consent from a legal representative of the patient. The Japanese Association for Acute Medicine proposed revision of these ethical guidelines to the MHLW on 12 December 2012; discussions regarding these revisions are currently underway.

If these guidelines are revised, it would be particularly important to gain the trust of the general public so that clinical studies in emergency medicine can be conducted even when informed consent cannot be obtained.[5] Accordingly, it would be necessary to conduct information sessions and awareness campaigns for the general public regarding their participation in clinical studies.

Conflict of interest statement

The authors declare no conflicts of interest.

Funding

This work was supported by a Grant-in-Aid for Young Scientists (C) (127100000424), and a Health Labour Sciences Research Grant to SN, NY, and HS.

References

1. Largent EA, Wendler D, Emanuel E, Miller FG. Is emergency research without initial consent justified: the consent substitute model. Arch Intern Med 2010;170:668–74.
2. Cone DC, O'Connor RE. Are US informed consent requirements driving resuscitation research overseas. Resuscitation 2005;66:141–8.
3. Druml C, Singer E. Consent in emergency care research. Lancet 2011;378:26–7.
4. Sheehan M. New European Union regulation of clinical trials is not conflicting on deferred consent in emergency situations. BMJ 2013;346:f1163.
5. Biros MH, Sargent C, Miller K. Community attitudes towards emergency research and exception from informed consent. Resuscitation 2009;80:1382–7.

Ryota Inokuchi*
Susumu Nakajima
Naoki Yahagi
Department of Emergency and Critical Care Medicine, The University of Tokyo Hospital, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan

Hajime Sato
Department of Health Policy and Technology Assessment, National Institute of Public Health, 2-3-6 Minami, Wako, Saitama 351-0197, Japan

* Corresponding author. Fax: +81 3 3814 6446.
E-mail addresses: inokuchir-icu@h.u-tokyo.ac.jp (R. Inokuchi), nakajimas-ort@h.u-tokyo.ac.jp (S. Nakajima), yahagin-eme@h.u-tokyo.ac.jp (N. Yahagi), hsato-tky@umin.ac.jp (H. Sato).

5 September 2013

0300-9572/$ – see front matter
http://dx.doi.org/10.1016/j.resuscitation.2013.09.026