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Intercontinental Elicitation of Informed Consent for Enrollment in Stroke Research

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Physician-elicited explicit informed consent via cell phone is a method of prehospital enrollment into clinical trials which maximizes the autonomy of research subjects [1, 2]. Commercialized Voice over Internet Protocol (VoIP) phone simultaneous ring systems [3], internet-based faxing systems and internet-based enrollment tools allow for safe enrollment of prehospital acute stroke patients into the NIH-funded Field Administration of Stroke Therapy – Magnesium (FAST-MAG) clinical trial from remote locations [4, 5].

Case Report

In May 2009, a FAST-MAG physician-investigator was traveling in the Republic of Estonia prior to attending the European Stroke Conference and responded promptly to an enrolling line call from the Los Angeles City Fire Department firefighter-paramedics at 11:02 in Los Angeles (20:02 in Estonia) (fig. 1). Paramedics had screened an 88-year-old woman with dysarthria and left-sided weakness, blood pressure of 176/100, and irregular pulse of 112 for the FAST-MAG study using a positive Los Angeles Prehospital Stroke Screen and symptom onset less than 2 h (30 min in this case). The patient told the physician-investigator by cell phone that she was functionally independent in activities of daily living prior to stroke symptom start, and confirmed the recent onset of slurred speech and weakness.

The patient reviewed a copy of the informed consent form specific to the destination community hospital along with the physician, who answered all questions and confirmed patient decision-making competency prior to her signing the study consent in parallel to routine paramedic evaluation, preparation, and transport procedures. At 11:13, 41 min from onset of symptoms, the paramedics initiated the field loading dose of the study agent (either 4 g magnesium or placebo-normal saline).

The physician-investigator next connected to the internet, identified the phone number of the destination hospital, called by cell phone, and informed the emergency department attending physician of the enrollment and briefly reviewed the study protocol. The paramedics arrived at the hospital at 11:25 with maintenance study agent infusion (16 g magnesium sulfate or placebo over 24 h) initiated at 11:35. The consent form was faxed to the investigator in Estonia using a web-based faxing system, electronically cosigned, and internet-faxed back to the emergency department for placement in the patient chart. In addition to the study agent infusion, after initial CT scan demonstrated no hemorrhage, the patient received intravenous tissue plasminogen activator and was admitted for evaluation and care.

Discussion

This case demonstrates that technology can bridge geographic barriers to research enrollments in clinical trials, just as it can for clinical encounters. The cell phone enrollment process in the FAST-MAG trial was developed to connect patients in the field with enrolling physicians, but once in place actually enables instantaneous research discussions across long distances and across continents. In the present case, a patient experiencing acute stroke in the Western United States was enrolled in a trial by a physician in Eastern Europe over a distance of 5,650 miles (9,090 km). By having a select group of central enrolling investigators who are very familiar with enrollment procedures and establishing a means of immediate cell phone communication with paramedics on-site, the FAST-MAG trial has been able to successfully enroll over 1,000 subjects to date [4].

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Fig. 1. FAST-MAG enrollment procedure: paramedics use their dedicated field cell phone (step A) with preprogrammed fast-dial to connect to the local FAST-MAG line which forwards immediately to multiple field-enrolling investigators. The responding field-enrolling investigator discusses the trial and elicits informed consent from the patient. Paramedics initiate the FM study field dose (step B) on the way to the destination hospital (step C). The field-enrolling investigator calls the local hospital emergency de-

partment to speak with the local receiving hospital investigator and site coordinator to inform them of the enrollment. The informed consent form, signed by the patient (or legally authorized representative), is faxed to a virtual internet electronic fax number (step D), where it is emailed to the investigator. The investigator then signs the consent form using the mouse pad to generate an original signature and returns the form via internet fax (step E).

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