Harmonisation preserves research resources

In their Comment, the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) clinical characterisation group outline how harmonisation of clinical characterisation studies is achieved through their collaborative resource-sharing and data-sharing platform.1 We fully agree with both the importance of international harmonisation and the authors’ approach. Yet, in our opinion, they could have expressed more clearly how important harmonisation is to use resources in research responsibly and efficiently.

ISARIC contributors in Germany face the dilemma of having multiple national and international clinical registers for patients with COVID-19. For example, in addition to ISARIC, the University Hospital Düsseldorf enters patient information into the Lean European Open Survey on SARS-CoV-2 Infected Patients (LEOSS) register,2 which as of July 8, 2020, contains data from 3048 patients (most are from Germany, but the aim is for international contributions), and national registers of German academic societies (German Society for Pediatric Infectious Diseases [DGPI])3 and German Interdisciplinary Association for Intensive Care and Emergency Medicine, where daily data contribution to the latter has become mandatory. Consequently, time needed for data capture and entry by clinical and research staff is multiplied and records are entered with substantial delay. Although negotiations on harmonisation started internally at the hospital in early February, and were extended to some register providers, different emphases of the registers and concerns about feasibility of some aspects of ISARIC data provision resulted in the current situation. Importantly, LEOSS providers were concerned about pseudonymised collection of data, which might have necessitated individual informed consent from patients,2 and the DGPI register providers expected ISARIC forms to be too extensive to facilitate widespread participation by clinicians. Ultimately, under strict conditions, some German ethics committees waived the need for individual consent for collection of pseudonymised clinical data, and the time needed for completion of ISARIC core forms and data entry is less than 30 min per case.

Another European example shows that early communication and cooperation between study leads can produce a more efficient setup. Facilitated through the Penta ID Network of paediatric infectious diseases researchers, in the first week of February, ISARIC shared their data specification with the Spanish paediatric register for COVID-19 patients (EPICO),3 which then integrated several items into its case report forms. Currently, EPICO is continuing to harmonise its register with further data capture tools from WHO and other cohorts. In this way, data from several registers can be combined at any point in time and physicians do not waste time with multiple data entries. We feel this is an important learning point: harmonisation can best be achieved by reaching out to scientific societies and eminent researchers at the earliest time possible, and by open sharing of resources without claiming ownership of the generated results.

We declare no competing interests.

*Malte Kohns Vasconcelos, Cristina Epalza, Hanna Renk, Alfredo Tagarro, Julia A Bielicki
malte.kohnsvasconcelos@med.uni-duesseldorf.de

Paediatric Infectious Diseases Research Group, Institute for Infection and Immunity, St George’s University of London, London, UK (MKV, JAB); Institute for Medical Microbiology and Hospital Hygiene, Heinrich Heine University Düsseldorf, 40225 Düsseldorf, Germany (MKV); Paediatric Infectious Diseases Unit, Department of Paediatrics, Hospital Universitario 12 de Octubre, Madrid, Spain (CE); Paediatric Research and Clinical Trials Unit, Instituto de Investigación Sanitaria Hospital 12 de Octubre and Translational Research Network in Paediatric Infectious Diseases, Fundación para la Investigación Biomédica del Hospital 12 de Octubre, Madrid, Spain (AT); Department of Paediatric Cardiology, Pulmonology and Intensive Care Medicine, University Children’s Hospital Tübingen, Tübingen, Germany (HR); Paediatrics Department, Hospital Universitario Infanta Sofía, Paediatrics Research Group, Universidad Europea de Madrid, Madrid, Spain (AT); Department of Infectious Diseases and Vaccinology, University of Basel Children’s Hospital, Basel, Switzerland (JAB); and Fondazione Penta Onlus, Padova, Italy (JAB)