NHS
National Institute for Health Research

Clinical Research Network

NIHR Clinical Research Network urgent public health risk planning

Urgent public heath outbreaks can cause serious risk to human health. In the event of an urgent public health outbreak (eg a pandemic) the National Institute for Health Research (NIHR) Clinical Research Network must be able to rapidly set-up relevant research studies and ensure that these studies are successfully conducted so that their findings can inform the on-going care of patients during the outbreak.

This will require some changes to the usual processes undertaken by the Clinical Research Network, as well as the reprioritisation of both national and local resources in what may well be a challenging environment in terms of increased deman ds for patient care and falling staff numbers because of illness.

Consequently, the Clinical Research Network has an urgent public health plan in place to ensure that urgent public health studies can be set-up and delivered quickly and effectively.

Initiation of the urgent public health risk process summary

Initiation and identification of relevant studies

The Clinical Research Network's urgent public health risk process will be activated at the request of the Department of Health. It will begin with the identification of relevant studies. A number of studies have already been identified and granted the relevant research approvals in advance of an outbreak. (See table below).

Chief Investigator	Institution	Funder (& reference if applicable)	Project Title	UK CRN ID
Professor Steve Goodacre	University of Sheffield	NIHR- NETSCC (Ref 11/46/07)	The PAINTED study: PAndemic INfluenza Triage in the Emergency Department.	12725
Dr Marian Knight	University of Oxford	NIHR- NETSCC (Ref 11/46/12)	Maternal and perinatal outcomes of pandemic influenza in pregnancy.	14162
Dr MG (Calum) Semple	University of Liverpool	NIHR- NETSCC (Ref 11/46/22)	Real-time evaluation and refinement of tools and criteria used in primary care to aid hospital referral decisions for patients of all ages during an influenza pandemic.	12827
Professor Mervyn Singer	University College London	GSK	An open-label, multi-centre, single arm study to evaluate the safety, tolerability and pharmacokinetics of intravenous zanamivir in the treatment of hospitalised adult, adolescent and paediatric subjects with confirmed influenza infection	7444
Dr MG (Calum) Semple	University of Oxford	Wellcome Trust	ISARIC/WHO Severe Acute Respiratory Infection Biological Sampling Study	14152

Dr Wei Shen Lim	Nottingham University Hospitals	NIHR- NETSCC (Ref 11/46/14)	Double-blinded randomised controlled trial of early low dose steroids in patients admitted to hospital with influenza infection during a pandemic.	15318

Expediting study approvals and eligibility for Network support decisions

The Clinical Research Network will expedite the approvals through the CSP (Coordinated System for gaining NHS Permissions) process for those studies identified as relevant to the urgent public health risk. These studies will be given priority status and the relevant approvals will be granted within six working days. This includes rapid confirmation that the study is eligible for Clinical Research Network support.

Commercial studies approved and identified by the Department of Health as relevant to the urgent public health risk will also be given priority status by the Clinical Research Network and feasibility review will be completed within seven working days. Study set-up will be expedited and operationally managed by the Local Clinical Research Network (LCRN) teams. Oversight and coordination provided by the national Clinical Research Network Industry team.

Delivering urgent public health studies

The aim of the Clinical Research Network during an urgent public health outbreak will be to deliver identified research studies in an efficient and timely manner. This will involve both the national Clinical Research Network Coordinating Centre and the Local Clinical Research Networks. Studies identified as urgent public health will be excluded from the NIHR Clinical Research Network high level objective of first patient, first visit.

On-going reporting and monitoring arrangements

Daily* meetings of the Clinical Research Network Urgent Public Health Group will take place to monitor the progress and delivery of the identified research studies.

*or at a frequency determined by the severity of the situation