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Title: Addressing political, economic, administrative, regulatory, logistic, ethical and social (PEARLES) challenges to clinical research responses to (re-) emerging epidemics and pandemics: a systematic review

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Abstract: Background Epidemics are by nature unpredictable; they often occur in cycles and waves across geopolitical boundaries and disproportionately affect resource-poor settings. Clinical research generates critical evidence for improving clinical management and control of emerging epidemics. However, experiences from previous outbreaks have identified multiple challenges to conducting the necessary clinical research in a timely way. This systematic review aims to identify how political, economic, administrative, regulatory, logistic, ethical and societal (PEARLES) challenges can be overcome to advance clinical research preparedness and responses to emerging epidemics.

Methods A systematic review. Six databases were searched for English language peer-reviewed publications from 2008 until July 2018. Two reviewers screened records for inclusion, extracted and summarised data using a narrative approach. Publications reporting PEARLES challenges and solutions to conducting epidemic-relevant clinical research were included.

Results Of 2,678 articles screened for inclusion, 78 articles were included. Most articles presented clinical research experiences from the Ebola outbreak (2014-2016) and the H1N1 pandemic (2009). The publications presented a range of challenges to delivering clinical research. Some were universal, others depended on the context and nature of the outbreak. International agreed frameworks, research protocols and standards, including data sharing agreements, ethical publication standards and incentivised, primed, global clinical research networks were among the solutions recommended, together with national ownership, strengthening of country research capacity and community engagement from the outset. Despite the wide range of recommended solutions, none had been evaluated in real-time.

Discussion This systematic review highlights that to advance the field of outbreak science, solutions for rapid research deployment, delivery and dissemination must be developed and evaluated. Improvements are urgently needed to develop and strengthen collaborations, funding mechanisms, global and national research capacity and frameworks for various contexts and scenarios. Clinical research communities need to evaluate their activities and refine and rehearse outbreak research response plans in-between epidemics.

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