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Legal Preparedness and Ebola Vaccines

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later in life, geriatric medicine is not synonymous with palliative medicine, and curative (but also preventive) actions are often possible.[4] Non-frail individuals make up a substantial proportion of people aged 70 years or older and their treatment results for diseases such as cardiovascular diseases and cancer do not differ from those who are younger. In pre-frail and frail individuals, good results are often obtainable with individualised treatment, but this is clearly an area where more research is needed.

If preventive actions at young ages are increasingly successful, we will also have healthier elderly people in the future than we do now; this notion is important for the extrapolation of Goal 3.4. In the meantime, we need geriatric medicine for the increasing number of people aged 70 years or older who have chronic disorders. The proper treatment of these elderly people is a human rights issue, but geriatric medicine is also effective to promote functionality and wellbeing, giving more life to years lived.

We declare no competing interests.

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For **members of EUGMS** see appendix

1 United Nations. Sustainable Development Goals for 2030. https://sustainabledevelopment.un.org/sdgsproposal.html (accessed June 17, 2015).
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3 Lloyd-Sherlock P, Ebrahim S, McKee M, et al. A premature mortality target for the SDG for health is ageist. *Lancet* 2015; **385:** 2147–48.
4 Cruz-Jentoft AJ, Franco A, Sommer P, et al. Silver Paper: the future of health promotion and preventive actions, basic research, and clinical aspects of age-related disease—a report of the European Summit on Age-Related Disease. *Aging Clin Exp Res* 2009; **21:** 376–85.

See Online for appendix

Is crowdfunding a viable source of clinical trial research funding?

As public research grants for randomised controlled trials (RCTs) have diminished and become increasingly competitive, researchers have to search for alternative funding sources. Crowdfunding, in which projects are funded directly from the public through the internet, might represent a potential source of RCT funding.[1] However, whether or not crowdfunding campaigns for clinical RCTs are successful is unclear.

To explore the success of research crowdfunding campaigns, we assessed the top online (based on site volume) English crowdfunding websites: Gofundme, Indiegogo, Kickstarter, Teespring, Patreon, YouCaring, CrowdRise, DonorsChoose, Kiva, and Giveforward. Additionally, we examined medical research crowdfunding websites: Experiment, Consano, Petridish, and Cancer Research UK. We (AS and JK) independently searched these crowdfunding websites using the following search terms: "clinical study", "randomized clinical trial", and "research". We also independently established whether a campaign met our eligibility criteria of funding for a clinical RCT that was led by an academic or research institution. A consensus process to resolve disagreements was established.

20 campaigns met our eligibility criteria (Cohen's κ=0·88; appendix). Eight (62%) of 13 completed campaigns achieved their fundraising goals. Unsuccessful campaigns raised 1–6% of the funding sought. Five (63%) of eight campaigns that reached their funding goals were for pilot or phase 1 studies. 19 (95%) of 20 campaigns used a flexible model (ie, researchers kept all the funds raised) compared with a fixed model (ie, researchers kept the money only if the target was met). The maximum funds raised were US$3 113 000 (£2 000 000) for the Oncolytic Virus for Patients with Neuroendocrine Tumours study. Although details were restricted, most research projects seemed to have had some funding from other sources.

Our research suggests that most crowdfunding campaign funding targets are achieved. Crowdfunding might represent an effective option to rapidly raise research funds to do RCTs. Even unsuccessful campaigns were able to raise some funds, albeit a small percentage of their target goal. This strategy might be especially useful for pilot or phase 1 studies because funding from national public agencies is insufficient. Further research with crowdfunding is needed to establish strategies that maximise the likelihood of success.

PJD has used crowdfunding (Indiegogo) to support clinical research. AS and JK declare no competing interests.

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1 Chakradhar S. In new crowdfunding trend, donors decide fate of clinical trials. *Nat Med* 2015; **21:** 101–02.

Legal preparedness and Ebola vaccines

On Dec 9, 2014, US Secretary of Health and Human Services Sylvia Burwell issued a declaration[1] under the US Public Readiness and Emergency Preparedness Act to provide immunity from legal claims in the USA related to manufacturing, testing, development, distribution, and administration of three candidate Ebola vaccines except in instances of wilful misconduct. Although progress in combating Ebola in west Africa has shifted public attention away from vaccine

development and deployment, we should not forget that the management of legal liabilities related to vaccines has been an important subject of discussion between national governments, international organisations, vaccine manufacturers, and other parties who have been engaged in the worldwide response to the Ebola outbreak during the past year.

On the basis of previous experience with other vaccines,[2] it is reasonable to expect that administration of Ebola vaccines (or similar medical countermeasures responding to other public health emergencies in the future) will almost certainly result in at least some adverse events that will give rise to legal liabilities, for which it is not clear what the legal and financial process for claims against manufacturers, distributors, or providers might be. Individuals experiencing such adverse events, manufacturers, governments receiving vaccines (eg, Guinea, Liberia, and Sierra Leone in the context of Ebola in west Africa), governments supporting vaccine distribution outside of their borders (eg, the USA, the UK, and France in the case of Ebola), and populations benefiting from widespread vaccination all have a shared interest in recognising, understanding, and managing potential liability as effectively as possible within the framework of a global public health response.

Legal immunities for innovators and manufacturers of vaccines, such as the Public Readiness and Emergency Preparedness declaration made by Secretary Burwell, can be part of the solution. However, the cost of injuries attributable to vaccines should not simply fall on target populations. To allow such a result to occur risks feeding the same doubts that have thwarted some vaccination efforts in low-income and middle-income countries across the world. Several options are available to the global public health community to address potential legal liabilities in various public health emergency scenarios, including situations such as the Ebola outbreak. Unlike many contingencies associated with future pandemics or similar global public health crises that are difficult—if not impossible—to predict, creating an improved framework for management of legal liabilities is a preparation that all interested stakeholders can make before the next global health emergency occurs.

We declare no competing interests.

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1 US Department of Health and Human Services. Secretary Burwell issues declaration under PREP Act to support development of Ebola vaccines. http://www.hhs.gov/news/press/2014pres/12/20141209a.html (accessed July 6, 2015).
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Another step change for tobacco control in China?

In their Editorial about tobacco control in China (May 30, p 2122),[1] the Editors of *The Lancet* discussed the steps that the Chinese Government is taking to control tobacco, which includes the adjustment of China's consumption tax on the wholesale price of cigarettes. Is increasing tobacco taxation really another step change for tobacco control in China?

China is the world's largest tobacco producer and manufacturer, and is also home to more than 300 million smokers who consume over one-third of the world's cigarettes and another 740 million people who are exposed to passive smoking. Tobacco use in China is causing a substantial rise in health hazards and economic burden, therefore comprehensive tobacco control is clearly needed. International experience and results of studies consistently show that raising taxes on tobacco is one of the most cost-effective ways to reduce tobacco use.[2] Hence, the WHO and relevant experts have repeatedly suggested that the Chinese Government should control tobacco use by sharply increasing tobacco taxes. However, for a long time, the government has been hesitating to use such strategies in its bid to reduce tobacco use for some well known reasons.[3]

The excise taxes on cigarettes in China have always been very low: in 2011, taxes levied on the retail price of cigarettes were still far from reaching the 70% suggested by WHO. A tobacco consumption tax was introduced in 1994, and the tax rate increased slightly in 1998, 2001, and 2009. Furthermore, every time the tobacco tax rate increased, China's tobacco industry subsequently increased their subsidies to cigarette manufacturers to offset the negative effect. As a result, tobacco excise taxes could not be fully passed on to retail prices, and the retail prices barely changed.

On May 7, 2015, the Chinese Ministry of Finance announced an increment in the consumption tax on wholesale cigarettes from 5% to 11% and each cigarette would also be taxed ¥0·005.[4] The next day, the State Tobacco Monopoly Administration announced a 6% increase in wholesale cigarette prices and recommended a 10% increase in the retail price of each pack of cigarettes.[5] Unlike previous tobacco tax adjustments, this increase in tobacco taxes is passed on to retail prices, which was considered impossible when taking into account the unique relation between the tobacco industry and the Chinese Government. After May 10, 2015, we observed that cigarette prices had increased by about 10% in many tobacco stores.


Associated Press

For the **Global Adults Tobacco Survey China 2010** see http://www.who.int/tobacco/surveillance/survey/gats/en_gats_china_report.pdf?ua=1

Most people who care about tobacco control welcome tobacco tax adjustment and regard it as another step for tobacco control in China after the announcement of a