

be “the difference in home systolic blood pressure between each active drug (spironolactone, doxazosin, bisoprolol) and placebo”. The function and obligation of the SAP was to specify how the primary hypothesis would be addressed, using the prespecified primary outcome measures, capturing the maximum amount of information that has been discovered by the trial. Hierarchical co-primary endpoints permit each endpoint in the hierarchy to be tested only if all previous tests are significant, so rendering it progressively harder for each hypothesis after the first to yield a positive outcome. Moreover, because the SAP prespecified use of all data without selection, averaging blood pressure responses for both the low-dose and high-dose periods, our primary analyses under-represent the true superiority of spironolactone at the end of each drug cycle. This finding is apparent in the figure, showing that the 50 mg dose of spironolactone reduced blood pressure almost twice as much as 25 mg, whereas there was little advantage from increasing the dose of bisoprolol or doxazosin.

The obstacles to performing all clinical trials these days are immense, with the power to control what is done for patients inversely related to evaluating patients’ real benefits and risks.

BW has received honoraria for lectures on hypertension from Novartis, Boehringer Ingelheim, Servier, Daiichi Sankyo, and Pfizer. TMM is chief investigator on two large investigator initiated, industry funded but university sponsored cardiovascular outcome studies (funded by Pfizer and Menarini/IPSEN/Teijin pharmaceuticals). His research unit also does industry funded studies by Novartis and Amgen, but none of these studies focus on blood pressure. TMM has also consulted or received honoraria from Novartis, Takeda, Daiichi Sankyo, Shire, and Astellus. TMM is the current president of the British Hypertension Society. MJB has received honoraria from Novartis. SVM declares no competing interests.

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- 1 Williams B, MacDonald TM, Morant S, et al. Spironolactone versus placebo, bisoprolol, and doxazosin to determine the optimal treatment for drug-resistant hypertension (PATHWAY-2): a randomised, double-blind, crossover trial. *Lancet* 2015; **386**: 2059–68.
- 2 British Hypertension Society, Pickering Lecture. Sept 23, 2014. <https://www.youtube.com/watch?v=wqLZD8cvT4o> (accessed March 9, 2016).
- 3 Farquharson CA, Struthers AD. Aldosterone induces acute endothelial dysfunction in vivo in humans: evidence for an aldosterone-induced vasculopathy. *Clin Sci (Lond)* 2002; **103**: 425–431
- 4 Williams B, MacDonald TM, Caulfield M, et al. Prevention And Treatment of Hypertension With Algorithm-based therapy (PATHWAY) number 2: protocol for a randomised crossover trial to determine optimal treatment for drug-resistant hypertension. *BMJ Open* 2015; **5**: e008951.

A step forward for data protection and biomedical research

To update previous correspondence to this journal,¹ we are pleased to report that, in large part through the efforts of the biomedical research community, a European General Data Protection Regulation that is favourable for research was agreed by Member States and Parliament in December, 2015.² Although the Regulation will probably not apply until mid-2018, now is an appropriate time to highlight the implications for biomedical research.

The Regulation deems health-related data and genetic data as so-called special categories of sensitive data, subject to increased restrictions. However, researchers can use these data without consent as long as it is permitted under EU or Member State law and appropriate safeguards are in place. The Regulation facilitates the reuse of data for research, even where the data were collected for another purpose.³ Where consent is used as the legal basis for processing personal data, it must be specific—but the Regulation indicates that broader forms of consent might be acceptable in scientific

research. In implementation, we hope the other legal bases afforded, such as legitimate interests, are clearly made applicable to research.

Several provisions that would otherwise apply under the Regulation will not apply to research, including data storage limitation periods and the duty to notify data subjects about processing when someone else collected the data. Member States might create further derogations from data subject rights. For the Regulation’s research provisions to apply, appropriate safeguards must be in place. Member States could determine these safeguards, but anonymised data must be used where possible. Pseudonymisation (key-coding) is suggested as another possible safeguard, if the research can be fulfilled without fully identifiable data. The Regulation suggests that data that have been pseudonymised should be considered personal data where they could be attributed to an identifiable person. Given the variation in Member State approaches to pseudonymisation, it will be interesting to see how this is interpreted in implementation, and guidance will be important to inform research practice.

After more than 4 years of negotiation and moments of serious alarm for research, the approved Regulation is a step forward. World-leading European research will continue to protect and promote privacy, improve health, and save countless lives. After formal agreement on the Regulation later this year, the research community and patient groups must continue to collaborate with policy makers to ensure that these new rules are implemented in a way that provides clarity and certainty for everyone.

We declare no competing interests.

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- 1 Dove ES, Townend D, Knoppers BM. Data protection and consent to biomedical research: a step forward? *Lancet* 2014; **384**: 855.
- 2 Council of the European Union. Proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). Dec 15, 2015. <http://www.statewatch.org/news/2015/dec/eu-council-dp-reg-draft-final-compromise-15039-15.pdf> (accessed Jan 10, 2016).
- 3 European Union. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Oct 24, 1995. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML> (accessed Jan 10, 2016).

Health equity for LGBTQ people through education

We applaud *The Lancet* Editors (Jan 9, p 95)¹ for drawing attention to new initiatives to improve the health and wellbeing of lesbian, gay, bisexual, transgender, and queer (LGBTQ) people worldwide. Many challenges remain, but the US Department of Health and Human Services report presents a strategy for change that could inform the efforts of other nations. However, one important aspect is missing from the worldwide conversation on addressing the health needs of LGBTQ—educating ourselves.

Barriers to equitable health care for LGBTQ populations include discrimination, transphobia, and homophobia in health-care settings. There is a need to instil cultural competency when engaging with LGBTQ communities, because LGBTQ people can face intrusive and inappropriate language and questions, hostility, and verbal abuse from health practitioners.

Some patients report having to educate medical professionals about their identity.² Research findings show that increased contact with LGBTQ patients and specific teaching on LGBTQ health improves student knowledge

of, engagement with, and attitudes towards LGBTQ people.³⁻⁵ Results from studies in the USA and Canada suggest that not enough teaching is done on LGBTQ health in medical training,⁶ and similar studies are underway in Australia and New Zealand.

Although these are encouraging developments and innovations in medical education to bring about health equity for LGBTQ people, as raised in *The Lancet* Editorial, more work needs to be done. We encourage our fellow physicians and educators to initiate meaningful change in their workplaces and classrooms, by educating a generation of health professionals who are able to provide appropriate care for LGBTQ patients and advocate their wellbeing.

We declare no competing interests.

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- 1 The Lancet. Meeting the unique health-care needs of LGBTQ people. *Lancet* 2016; **387**: 95.
- 2 Riggs DW, Due C. Gender identity Australia: the healthcare experiences of people whose gender identity differs from that of their natal assigned sex. Adelaide, SA: Flinders University, 2013. https://www.humanrights.gov.au/sites/default/files/21_Pub_Sub_Melody%20Moore_Transhealth_Flinders_University_Gender_Identity_Australia_Report.pdf (accessed Feb 11, 2016).
- 3 Kelley L, Chou CL, Dibble SL, Robertson PA. A critical intervention in lesbian, gay, bisexual and transgender health: knowledge and attitude outcomes among second-year medical students. *Teach Learn Med* 2008; **20**: 248–53.
- 4 Sanchez NF, Rabatin J, Sanchez JP, Hubbard S, Kalet A. Medical students' ability to care for lesbian, gay, bisexual and transgendered patients. *Fam Med* 2006; **38**: 21–27.
- 5 Wallick MM, Cambre KM, Townsend MH. Influence of a freshman-year panel presentation on medical students' attitudes toward homosexuality. *Acad Med* 1995; **70**: 839–41.
- 6 Obedin-Maliver J, Goldsmith ES, Stewart L, et al. Lesbian, gay, bisexual, and transgender-related content in undergraduate medical education. *JAMA* 2011; **306**: 971–77.

Tobacco control in China: still a long way to go

On Dec 28, 2015, the Chinese Center for Disease Control and Prevention

released the 2015 Chinese Adults Tobacco Survey Report.¹ According to this report, in 2015, about 27.7% of Chinese adults (defined as age ≥ 15 years; 52.1% of men and 2.7% of women), corresponding to more than 316 million people, were current smokers, and average daily consumption was 15.2 cigarettes. In 2010, the Global Adult Tobacco Survey² reported that 28.1% of Chinese adults (52.9% of men and 2.4% of women) were current smokers, with an average daily consumption of about 14.2 cigarettes. Prevalence of smoking in China has not changed in the past 5 years. If the present status persists, tobacco use will cause 2 million deaths per year in China by 2050.³

In 2003, the Chinese Government signed the WHO Framework Convention on Tobacco Control (FCTC). Despite some efforts being made in tobacco control, major gaps still exist compared with FCTC requirements. First, a WHO report in 2014 pointed out that China failed to implement standard packaging of cigarettes; warnings covered only 30% of the bottom of the front and back of cigarette packs, compared with at least 50% as per regulations in Article 11 of FCTC.⁴ Second, in China, taxes on tobacco products are not levied substantially (40–46% of retail price vs FCTC's requirement of 75%).⁵ One of the most important barriers impeding the progress of radical tobacco control is the conflict of interest between the tobacco industry and tobacco control policies, since the China National Tobacco Corporation is a state-owned enterprise.⁵

To control cigarette smoking, the Chinese Government should establish strict state-level legislations on tobacco control. Besides, the government should increase tobacco taxation, print eye-catching warnings on cigarette packs, reduce the rate of smoking initiation, increase support for smoking cessation, legislate the prohibition of tobacco advertising, and implement smoking bans in public areas. Most importantly, the government should establish a new



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