

women and their babies, especially at the time of birth, when lives are so vulnerable, particularly for those born premature. We need to focus attention on the critical period during labour, childbirth, and the days after birth, when the delivery of quality care, supported by the right drugs and the right supplies, makes such a difference. If there is anything that we can do to accelerate our progress to 2015 and beyond for maternal and child survival, then better care at the time of birth is essential. Birth is the world's golden moment for action.

Political leadership to help improve the fate of preterm babies is needed. Since World Prematurity Day last year, action has been taken on commitments, such as in Brazil and Uganda (table). In the UK, politicians came together this year to publish an across-party manifesto on the importance of the 1001 critical days from when a baby is conceived until the age of 2 years, signalling the importance of this issue to the UK.¹⁶ This year, let us dare to dream of further improvements for those born too soon, and then work to make them happen. Our health systems can be judged by how we care for newborn babies, especially preterm babies who can die, or be saved, by an effective health system. Is saving newborn lives not an important measurement and fitting indicator of universal health coverage in the post-2015 environment?

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Electronic cigarettes for smoking cessation

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In *The Lancet*, Christopher Bullen and colleagues¹ report the results of a study that is likely to have an important effect on the discussion of the role of electronic cigarettes (e-cigarettes) in tobacco control. Bullen and colleagues randomised 657 adult smokers wanting to quit to 16 mg nicotine e-cigarettes (as needed), 21 mg nicotine patches (one per day), or placebo e-cigarettes

(no nicotine, as needed) in a 4:4:1 ratio. Participants, who all lived in Auckland, New Zealand, could access the national Quitline (a telephone counselling service), but received no additional support. At 6 months, 21 of 289 (7.3%) participants in the nicotine e-cigarettes group had achieved biochemically verified abstinence, compared with 17 of 295 (5.8%) participants in the patches

group, and three of 73 participants (4.1%) in the placebo e-cigarettes group (risk difference for nicotine e-cigarette vs patches 1.51 [95% CI -2.49 to 5.51]; for nicotine e-cigarette vs placebo e-cigarette 3.16 [-2.29 to 8.61]). 57% of participants in the nicotine e-cigarette group had reduced tobacco cigarette consumption by at least half at 6 months, compared with 41% of those in the patches group ($p=0.0002$) and e-cigarettes received higher user endorsement than patches. Adverse events were generally not serious, and were much the same across groups.

The study provides valuable data, but it has limitations. The investigators measured sustained validated abstinence, which is the right outcome for this type of trial, but its power calculations used much higher unvalidated 7-day abstinence rates. This meant that the study was underpowered and so presents only tentative findings. There is also the issue of testing a new treatment in a suboptimum setting. The standard approach to assessment of new treatments includes careful supervision and monitoring of treatment adherence to increase the likelihood that treatments are used as intended. In this case, little effort was made to ensure that participants were using the e-cigarettes. The same was, of course, true for patch use, but more would have been learned from a comparison of two treatments used to their full potential.

Despite these caveats, which the investigators acknowledge, this was a pioneering study and it did generate new and useful information. The key message is that in the context of minimum support, e-cigarettes are at least as effective as nicotine patches. E-cigarettes are also more attractive than patches to many smokers, and can be accessed in most countries without the restrictions around medicines that apply to nicotine replacement therapy or the costly involvement of health professionals. These advantages suggest that e-cigarettes have the potential to increase rates of smoking cessation and reduce costs to quitters and to health services.

The main untapped potential of e-cigarettes, however, might not be in treatment of the minority of smokers seeking help with quitting, but rather as a safer consumer product for use by smokers in general. Such use could ultimately lead to the disappearance of combustible tobacco products and to the end of the epidemic of smoking-related disease and death. To rival cigarettes in providing what smokers want, e-cigarettes need to develop further, but under the pressure of

market competition, they are currently undergoing a fast evolution and are likely to keep improving.

Concerns have been expressed that rather than reducing or even replacing traditional smoking, e-cigarettes could increase smoking rates by attracting new recruits and reducing quit attempts. This situation is usually implied by the phrase “renormalising smoking”. Such an outcome seems counter-intuitive and contradicted by the present study¹ and by other data currently available,²⁻⁴ but it is theoretically possible. There is an obvious source of evidence as to whether use of e-cigarettes leads to an increase or reduction in tobacco smoking: the trajectories of sales of e-cigarettes and tobacco cigarettes. If growing sales of e-cigarettes coincide with increased sales of tobacco cigarettes, tobacco control activists arguing for restriction of e-cigarette availability would be vindicated. If traditional cigarette sales decline as e-cigarette sales increase, it would suggest that e-cigarettes are normalising non-smoking and that it is in the interest of public health to promote and support their development rather than try to restrict it. The European Union and UK are currently proposing to regulate e-cigarettes as medicinal devices, while leaving cigarettes available on general sale.^{5,6} If this regulation goes ahead, tobacco cigarettes will retain their market monopoly and we will never learn whether e-cigarettes would replace traditional cigarettes if allowed to continue evolving and competing with smoked tobacco on even terms.

There hardly exists a commentary that would not recommend more research, and this one is no exception. More data are needed on the efficacy of e-cigarettes in smoking cessation and in harm reduction (when used under different conditions and compared with different comparators); on their long-term safety, both in comparison with cigarettes (whereby e-cigarettes can be expected to be orders of magnitude safer⁷) and in absolute terms (whereby some health risks might yet emerge⁸); and most importantly, on the effect that increasing e-cigarette sales are having on sales of tobacco cigarettes. In terms of practical implications of the results of the study by Bullen and colleagues, stop-smoking services which distribute nicotine replacement therapy with minimum support now have a cheaper alternative to consider, and health professionals will now hopefully feel easier about recommending e-cigarettes to smokers, or at least condoning their use.



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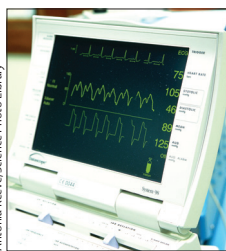
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I have received research funding from, and provided consultancy to, manufacturers of smoking cessation medication. I have no connections with any manufacturers of electronic cigarettes.

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Is the intra-aortic balloon pump leaking?



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Combined invasive and pharmacological treatment strategies have improved outcomes in acute myocardial infarction (MI) substantially. However, mortality in cardiogenic shock, which occurs in about 7% of patients admitted with acute MI, continues to be associated with high mortality (40–50%).¹ Yet trials in the emergency setting of acute MI complicated by cardiogenic shock are exceptionally difficult to conduct. Therefore, Holger Thiele and colleagues should be commended for the rigorous IABP-SHOCK II trial, which is the largest trial in this setting to date. In *The Lancet*, Thiele and colleagues report the 12 month follow-up.²

The underlying mechanism in cardiogenic shock is depression of myocardial contractility due to extensive MI, leading to a vicious cycle of reduced cardiac output, low blood pressure, reduced coronary blood flow, and ongoing reduction in contractility and cardiac output.³ Despite compensatory mechanisms such as peripheral vasoconstriction and redistribution of circulation to the vital organs, this leads to multiple organ failure. The principal concept behind mechanical cardiac assistance in cardiogenic shock is to support the compromised circulation. The intra-aortic balloon pump (IABP) has long been the most accessible and frequently used mechanical cardiac assist device in the catheterisation laboratory. The IABP is a catheter-mounted balloon positioned in the descending aorta, usually through a percutaneous femoral approach. Counterpulsation is achieved by rapid inflation (diastole) and deflation (systole) of the balloon synchronised to the cardiac

cycle. It augments diastolic coronary and systemic blood flow, and reduces systolic afterload, peak left ventricular wall stress, and myocardial oxygen consumption. Only a small increase of cardiac output is reported (0.5 L/min).

In 2012, Thiele and colleagues⁴ reported the 30 day outcomes of IABP-SHOCK II, a randomised, open-label, multicentre trial that randomly assigned 600 patients with acute MI complicated by cardiogenic shock and treated with early revascularisation (percutaneous coronary intervention [96%] and coronary artery bypass graft [4%]) to either IABP therapy or no IABP therapy. All other intensive care unit treatment was standardised according to guidelines. There were no differences in the primary efficacy endpoint of 30 day mortality (IABP group 40%, no IABP group 41%; relative risk [RR] 0.96, 95% CI 0.79–1.17) or safety endpoints. Moreover there were no differences in lactate concentrations, dose and duration of catecholamine therapy, and renal function.

The newly published 12 month results² extend and strengthen the short-term findings. Mortality was mainly determined in the acute phase, but mortality thereafter was still substantial. 12 month mortality did not differ between groups (IABP group 52%, no IABP group 51%; RR 1.01, 95% CI 0.86–1.18) and there were no meaningful differences in the subgroup analyses. Importantly, no divergence in the mortality curves was observed, as was seen with the long-term results of the earlier trials SHOCK and BCIS-1.^{5,6} Furthermore, there were no significant differences between groups in the frequency of reinfarction, stroke, functional class, or quality of life

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