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Research Predicting outcome after traumatic brain injury (*BMJ* 2008;336:425)

Intracranial pressure monitoring in severe traumatic brain injury

Should not be abandoned on the basis of recent evidence

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In a recent trial in the *New England Journal of Medicine*, Chesnut and colleagues attempted to provide class I evidence on the impact of intracranial pressure (ICP) monitoring on functional and neuropsychological outcomes after traumatic brain injury (TBI).[1] The authors concluded that there was no difference in the primary outcome—a composite of 21 equally weighted components—between the patients who had ICP monitoring and those who did not. This is a landmark study; undertaking such a trial has long been considered impossible because most experts consider ICP monitoring the primary basis for managing patients with severe TBI.[2] However, the findings require scrutiny before we can consider a fundamental change in managing these patients.

Since it was introduced more than 50 years ago, ICP monitoring has gradually become the standard of care in most centres that treat patients with severe TBI in most developed countries.[2] Firstly, increasing ICP indicates escalating mass effect (from haematomas, contusions, or diffuse brain swelling). If escalating mass effect is left untreated, brain herniation and death will follow. Secondly, ICP has a direct impact on cerebral perfusion pressure (the mean arterial blood pressure minus ICP). It is important to maintain cerebral perfusion pressure to avoid brain ischaemia.[2] ICP monitoring is used to guide the use of treatments for severe TBI, such as hyperventilation, osmotherapy, hypothermia, barbiturate coma, and decompressive craniectomy.

Numerous large cohort studies have shown that raised ICP (around 20-25 mm Hg) is independently associated with a higher risk of death after TBI.[3 4 5] However, a study published in 2012, a secondary analysis of data on 365 patients with severe TBI from a randomised trial, found no independent association between average ICP and neuropsychological functioning among survivors.[6] The only other study to question the usefulness of ICP monitoring was a retrospective cohort comparison study from the Netherlands, which showed that patients who received ICP monitoring were treated in the intensive care unit for longer than those whose ICP was not monitored, and their outcomes were no better [7] Nonetheless, because of abundant class II and III evidence, the Brain Trauma Foundation 2007 guidelines included a level II recommendation (moderate degree of clinical certainty) that ICP should be monitored in all salvageable patients with severe TBI.[2] In the UK, guidelines from the National Institute for Health and Clinical Excellence state that treatment in a neuroscience centre would benefit all patients with severe TBI, irrespective of the need for neurosurgical intervention.[8] Moreover, a large cohort study has shown that management of severe TBI in neuroscience centres is associated with reduced mortality.[9]

With such widespread acceptance of ICP monitoring, it would be difficult to recruit patients to a trial where one arm did not receive ICP monitoring. Chesnut and colleagues overcame this problem by identifying a group of intensivists in Bolivia and Ecuador who were unsure about its effectiveness and routinely managed their patients with severe TBI without ICP monitoring.[1]

The trial hypothesis was that a therapeutic protocol based on ICP monitoring would result in reduced mortality and improved neuropsychological and functional recovery compared with a therapeutic protocol based on imaging and clinical examination (control arm). Importantly, both arms received interventions aimed at lowering ICP, and significantly more patients in the control arm received osmotherapy and hyperventilation.[1] Furthermore, only 45% of participants were transported to the first hospital by ambulance. This should not affect the internal validity of the trial because baseline characteristics were similar in the two arms, analysis was intention to treat, and the follow-up was 92% in both arms. However, external validity is certainly limited because the prehospital management of severe TBI is more advanced in most developed countries, where most patients with severe TBI are transported to hospital by ambulance.[10]

Chesnut and colleagues found no significant difference between groups in the primary outcome, which was a composite of 21 equally weighted components. Because 12 of the 21 items are neuropsychological tests, neuropsychological performance is highly influential in the composite endpoint.[1] This is of concern if considered in light of existing literature.[2 6] A more conventional outcome measure, the extended Glasgow outcome scale, showed a non-significant 5% difference in both mortality and favourable outcome (favouring the ICP arm).[1] Moreover, as the authors acknowledge, the risk of a type II error was high: with 324 cases, the study had only 40% power to detect a 10% increase in favourable outcome on the Glasgow outcome scale.

Although the study investigators should be congratulated for recruiting patients to reach the intended target, the results must be interpreted with caution because of the high risk of a type II error. A move away from ICP monitoring in developed countries would be detrimental to the outcomes of patients with severe TBI. We also believe that a "normal" ICP should not be considered only in light of a particular cut-off value, because waveform analysis of the ICP is also important. ICP waveform analysis can provide information on cerebrovascular reactivity (PRx index) and can be used to estimate optimal cerebral perfusion pressure levels for individual patients.[11 12] Finally, with increasing recognition of the heterogeneity of TBI, further integration of multimodality signals (ICP, brain microdialysis, brain tissue oxygenation, electrocorticography) could enable clinicians to deliver individualised treatments to patients with severe TBI.

Competing interests: PJH, MC, and JDP are directors of Technicam (manufacturer of cranial access device for neuromonitoring); PJH chairs the British Neurotrauma Group (special interest group of the Society of British Neurological Surgeons) and is a vice president of the European Association of Neurosurgical Societies; AGK is a member of the academic committee of the Society of British Neurological Surgeons; MC is coauthor of brain monitoring software ICM+ (www.neurosurg.cam.ac.uk/icmplus) and has a financial interest in a part of the licensing fee through Cambridge Enterprise; DKM is a paid consultant or member of data monitoring committee for Solvay, GlaxoSmithKline, Brainscope, Ornim Medical, Shire Medical, and Neurovive; DKM co-chairs the European Brain Injury Consortium.

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Students in the United States have traditionally had a high level of exposure to drug industry sales representatives during their undergraduate medical education

Drug company gifts to medical students: the hidden curriculum

Policies to restrict promotional gifts to students seem to affect later prescribing behavior

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As relationships between healthcare professionals and the drug industry have come under increasing scrutiny in the United States, the industry's role in the education of medical trainees has emerged as a particularly contentious topic. A linked study by King and colleagues provides some empirical data to inform the debate.[1]

Students in the United States have traditionally had a high level of exposure to drug industry sales representatives during their undergraduate medical education.[2 3] For example, one survey at eight US medical schools published in 2005 found that, by their third year, 96.8% students reported attending a lunch sponsored by a drug company and 94.1% reported receiving a non-educational gift.[4] Students justified accepting meals and gifts by citing their lack of income and large debts, and educators pointed to the valuable support that industry could provide to didactic programs.[4] Data on the influence of promotional gifts on physicians' prescribing patterns were of questionable relevance, however, because students cannot write prescriptions or make decisions about patient care.

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Medical schools have recently started to re-examine their policies. Many have stopped representatives gaining access to patient care areas and the distribution of gifts, often at the suggestion of their own students.[5 6] These moves have been justified mainly for ethical reasons, appealing to professional and personal integrity.[7] They have been opposed by faculty members who worry about damaging collaborations between industry and academia, and by other students and educators who are skeptical that science based medical education could be corrupted by company sponsored textbooks, lunches, or educational conferences.[5]

Remarkably, little data exist on the effect of student-industry interactions, apart from a few small surveys showing that such interactions are associated with positive attitudes about industry marketing in general and scepticism about its negative consequences.[2] As a result, policies on industry interaction on medical school campuses around the US vary greatly.[8]

The current study adds an important new dimension to this debate.[1] King and colleagues examined the effect of restricting industry gifts to students on the prescription of three recently approved brand name drugs; prescription trends were measured at least four years after the policy was implemented, when all students had completed their residencies. Notably, the study drugs were members of pharmaceutical classes in which many other well validated alternatives, including generic drugs, were available, and the study drugs had no clear advantages. It was a clever choice because use of these drugs would be strongly related to physicians' susceptibility to the manufacturers' promotional tactics.

Using a difference-in-differences statistical model, the study found that attending a school with a gift restriction policy significantly decreased the odds of prescribing two of the three study drugs. Because none of the drugs were available when the study cohorts were in medical school, the gift restrictions could not have affected gifts directly related to the drugs. These restriction policies may have been accompanied by programs to educate students about the role promotional gifts can have on physicians' behavior, although such formal curriculums are rare. More likely, the results provide some insight into the "hidden curriculum" of medical education—the influence of the social environment, the daily routine of student life, and informal cues from mentors and peers on whom students model their professional development.[9]

According to this explanation, students in a school where industry promotion is regulated may be more likely to assimilate a healthy skepticism about pharmaceutical marketing into their professional development, with measurable downstream effects. Other research has shown that medical school experiences can predict future professional behavior,[10] so school level policy changes might also have this effect. The results are consistent with another recent study showing that limiting industry promotion to psychiatry residents was associated with more evidence based prescribing of antidepressants.[11]

An association between gift restriction policies and subsequent patterns of professional clinical practice provides empirical support to supplement the ethical arguments made by students and medical schools seeking to curtail industry promotion. If physicians who attended a medical school with a culture of receptiveness to industry gifts are more likely to prescribe heavily promoted brand name drugs that provide questionable therapeutic advantage, instituting restrictive industry interaction policies may be justified as a way of favoring evidence based medicine. This could also help reduce unnecessary expenditure at a time when healthcare spending continues to grow.

Another implication of the effect of the hidden curriculum on medical students' subsequent behavior is that the way industry interaction policies are implemented is as important as the policies themselves. King and colleagues evaluated graduates of schools that were the earliest to adopt these policies and probably had relatively solid support for them. As policies emerge on more divided campuses they may contain loopholes—such as restricting on-campus interactions but supporting them off campus—or be undermined by dismissive comments from educators. Such a counterproductive environment may, paradoxically, contribute to worse outcomes. Thus, advocates for gift restrictions and other industry interaction policies should seek campus consensus about the measures, soliciting input from all affected parties and focusing on practical interventions that make compliance straightforward and not overly onerous. Although such consultations require an investment of institutional resources, they should reinforce the impact of these policies on medical trainees' professional development and future prescribing habits.

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Aviation and public health

Are we forgetting to consult on the health implications of airport development?

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The United Kingdom's Department for Transport recently drafted an Aviation Policy Framework for the UK to achieve a balance between the economic importance of aviation and promoting good health and quality of life in the community.[1] The framework stressed transparency in decision making, and it has been sent for consultation to the Department for Environment, Farming and Rural Affairs; the Treasury; the Department of Energy and Climate Change; and the Department for Business, Innovation, and Skills but disappointingly not to the Department of Health.

A commission chaired by Howard Davies was launched in 2012 to make recommendations on airport expansion in the UK,[2] and, most recently, a public consultation on London's airport expansion opened with the promise of "the fairest possible evaluation" of the available options.[3] Evidence from the public consultation will be submitted to the commission.

Safeguarding public health in the face of industrial development should be one of a government's main priorities. The World Health Organization 1999 Charter on Transport, the Environment and Health[4]—still extant and adopted by the UK government—recommended that community well-being be put first in transport and infrastructure policies. It emphasised coordination between transport, environment, and health policies.

The major direct adverse effects of aviation on health are noise, pollution, and the spread of communicable diseases. Indirect effects are an increasing challenge, as growth in air travel makes the aviation industry a major driver of climate change.

Adverse health effects from noise are well established, particularly poor performance at work from interrupted sleep and impaired cognitive development in primary school children who live near airports.[5] A narrative review commissioned and funded by the US Federal Aviation Administration Office of Environment and Energy and published in 2010 concluded that there was a likely association between repeated exposure to night-time aircraft noise and hypertension and ischaemic heart disease in adults.[6] A 2007 study commissioned by the Department for Transport recommended the use of lower thresholds for noise metrics in dose-response research,[7] and action is well overdue.


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Noise from both aircraft and road transport affects health, but aircraft noise has the greatest effect

Noise from both aircraft and road transport affects health, but aircraft noise has the greatest effect. Although modern aircraft are less noisy, numbers of flights are increasing. Airports are served by road, rail, and air transport, and people living nearby are subjected to noise from all these sources, with attendant potentially serious health outcomes. Efforts are being made to reduce air pollution from industrial and domestic sources, but less effort is directed at noise from aircraft.

Pollution associated with the aviation industry is also a health hazard. Because of radiative forcing, the impact of emissions from jet aircraft is about twice that from land based sources. Particulate and other emissions result from aircraft and road traffic in the vicinity of airports, and are associated with cardiorespiratory morbidity and mortality.[8] Landing and take-off emissions have received most attention, but recently cruise emissions have been shown to affect human health; about 8000 premature deaths annually worldwide may be attributable to this source.[9] Regardless of whether technological advances in aircraft design and performance will reduce noise and air pollution, aircraft flying now may continue to be airworthy for many years.

As for climate change, its health impacts are not confined to national boundaries. Although the developing world may be bearing the major brunt,[10] the UK's resilience may diminish as climate shocks become more severe and frequent. This has to be reconciled with the aspiration not only of the UK, but of countries such as India and China,[11 12] to facilitate growth in business, trade, and tourism by expanding civil aviation.

Unlike Environmental Impact Assessments, Health Impact Assessments (HIAs) are not obligatory, but should be conducted before policy decisions are made on major developments, to ensure that commercial interests are not placed before health.[13] The government's record on airports is disappointing. For the major London airports only developments at Stansted had HIAs. However, the assessments were conducted by BAA (British Airports Authority), scarcely a transparent arrangement, because BAA, acting as the regulator and enabler, also had a major obligation to its shareholders.

The 2007 report of the Royal Commission on Environmental Pollution recommended that HIAs should be mandatory, incorporated explicitly in sustainability appraisals, and subject to independent review.[14] No action has been taken. It also emphasised that restriction of further airport development was crucial.[15] Expert committees may occasionally produce inconvenient truths; the commission has been disbanded and not replaced.

In the UK the Civil Aviation Authority will be responsible for regulating aviation and airport planning. It is essential that health is considered when airport developments are planned. The Department of Health and the newly designated Public Health England must make their voice heard in the debate on the future of aviation policy. So far they have not.

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No national government has yet implemented a statutory health in all policies process such as that proposed by the Welsh government

Working towards "health in all policies" at a national level

Wales as a world leader?

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The World Health Organization has challenged governments to adopt the principle of "health in all policies" to tackle the social determinants of health and health inequalities.[1] However, policy making is complex, especially across multiple government departments, which makes implementing such an approach challenging. The Welsh government is consulting on whether and how to introduce this principle, asking if there is a "need for a public health bill to place statutory duties on bodies to consider public health issues."[2]

The strategy proposed in the Welsh green paper echoes Geoffrey Rose's famous conclusion that to improve the health of a nation the "only acceptable answer, is the mass strategy, whose aim is to shift the whole population's distribution of the risk variable."[3] The mass strategy proposed is healthier public policy in multiple areas, including education, social care, housing, transport, and urban planning. With life expectancy in Wales lower than in England and health inequalities within Wales increasing, this offers the possibility that Wales's first public health bill will rise to WHO's radical challenge for a health in all policies approach to tackling social determinants of health.

If Wales establishes a statutory duty on non-health policy makers to improve health at a national level it will lead the way in the United Kingdom and internationally. The Welsh government could look towards South Australia, where the state government introduced a model of health in all policies in 2007.[4] High level political commitment, dedicated resources, and expert advice provided the impetus, and a socioecological "health lens" tool was developed that is now applied to all state policies to ensure that population level health is promoted strategically alongside economic growth.[4] Although some countries have adopted cross government health targets, no national government has yet implemented a statutory health in all policies process such as that proposed by the Welsh government.

The health lens approach is a five stage collaborative process, whereby public health staff support other government departments and agencies to develop healthier policies through engagement with stakeholders, evidence gathering to assess health impacts, generation of joint policy recommendations, "navigation" through the policy making process, and evaluation.[5] In South Australia this has complemented prevention activities that focus on children and young people, whose lives are shaped by multiple non-health policies.[4] If adopted nationally in Wales, this approach would ensure that all future education policies support health and wellbeing—for example, by preventing reforms that allow playing fields to be sold off. More broadly, the use of the socioecological health lens would ensure that policy makers consider how secondary schools may inadvertently increase psychological health problems during adolescence.[6]

Geoff Mulgan, who advised former UK Prime Minister Tony Blair on public policy and joined up government, recommends cross cutting budgets and policy teams underpinned by strong networks to ensure "systems thinking and, hopefully, a reduction of unintended consequences [without] excessive bureaucracy and transaction costs."[7] The South Australian model provides a template for a public health policy team to work across Welsh government to "health proof" all future policies from an early stage in their development and according to the best available evidence. This would mean all policies would be subjected to a rigorous prospective health impact assessment, rather than retrospective assessments that have limited scope for national level health improvement or policy reform.

According to Mulgan, new training programmes and professional roles are also likely to be key to putting the principle of health in all policies into action across the policy making agenda.[7] The Welsh government's Public Policy Institute, which is being launched in 2013, aims to facilitate training and new partnerships, including those between policy makers and public health professionals. Appointing health improvement advisers in all seven Welsh government directorates could help to ensure that health is fully integrated across government and that policy initiatives with harmful effects on health are avoided.[8]

Public policy making across sectors in this context would still be a challenging prospect, even with more joined up government, because it requires all departments and agencies to be explicitly health centred for the first time. To use the example of education policy again, schools' core business is to promote students' learning (not health) and recent education policies that focus on promoting attainment though targets and greater inspection have probably limited schools' capacity and motivation to promote health.[9] However, one major strength of the health lens process is that, by engaging stakeholders at the start of the process,[5] public health policy teams can work collaboratively with the education sector and "sell" them the wider benefits that promoting student health will have on behaviour and learning in schools.

Evaluating the results is another challenge, although innovative "policy trials" have already been used by the Welsh government to examine the health effects of the national exercise referral scheme and free breakfasts in primary schools.[10 11] These could be replicated in other policy areas, such as secondary and higher education, housing, and transport, to study and optimise new national policies and examine their impact on health. Wales is also strongly placed in terms of national level data linkage facilities, which are needed to support effective horizontal health governance.[7] The new Centre for Improving Population Health through E-Health Research (CIPHer), based in Swansea, could also monitor and evaluate the impact of policies on health.

Of course, complementary multi-level behavioural interventions will continue to be relevant alongside greater policy level action, especially for vulnerable populations who may benefit least from some healthy public policy reforms.[12] A statutory health in all policies approach in Wales would also not tackle income inequality directly, but it might mitigate some of the societal harms arising from it. As such, the Welsh green paper opens the door to a far more radical approach than the "nudge" inspired English public health strategy.[13] Doing nothing is still an option at this stage, but the Welsh government should ask itself not whether it can afford to take health concerns into account across all policy areas, but rather whether it can afford not to.

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