EDITORIALS

Editorials are usually commissioned. We are, however, happy to consider and peer review unsolicited editorials
See http://resources.bmj.com/bmj/authors/types-of-article/editorials for more details

thebmj.com
News: Psychologists' firm was paid $81m to implement CIA's "enhanced interrogation" program (*BMJ* 2014;349:g7639)
Obituary: Helen Bamber (*BMJ* 2014;349:g5924)
Editorial: Medical professionalism and abuse of detainees in the war on terror (*BMJ* 2014;348:g2947)

Torture and doctors' dual obligation

Health professionals need support to put the wellbeing of detainees first

Julian Sheather deputy head of ethics, BMA
Rhian Beynon communications manager, Freedom from Torture, London, UK
Tom Davies Stop Torture campaign manager, Amnesty International UK, London, UK
Kamran Abbasi international editor, *The BMJ*, kabbasi@bmj.com

People held in detention are vulnerable. Complex physical and psychological health needs are compounded by loss of freedom that constrains detainees' ability to assert their interests. The purpose of custodial institutions and environments is not therapeutic. Health professionals who look after detainees find themselves torn by divided loyalties: their primary obligation to patient wellbeing conflicts with their obligations to institutions and employers.[1]

Involvement of health professionals in torture is indisputable. A recent report by the US Senate Intelligence Select Committee confirmed that the line between medical care and interrogation was breached by the Central Intelligence Agency (CIA) during the "war on terror."[2] Health professionals supervised waterboarding sessions and cleared detainees for enhanced interrogation. Medical staff were involved in rectal feeding and hydration, which the CIA considered useful in overcoming detainees' refusal of food and fluids despite no evidence of its benefit. Meanwhile in Saudi Arabia, a panel of medical experts has assessed whether blogger Raif Badawi is fit enough to be flogged.[3]

Figures from Amnesty International's Stop Torture campaign show that torture was reported in 141 countries over the past five years.[4] Torture has a central role in policing and public security operations across the globe. Perpetrators act with impunity, and medical professionals see many victims of torture in relation to their detention. This is despite international prohibitions regarding any non-therapeutic participation, or any use of medical skills and knowledge, by medical professionals in torture or interrogation.[5]

Documentation is important

Properly resourced and supported, independent health professionals can have an important role in preventing torture and holding those who torture to account. They can identify and support victims of torture, provide vital forensic evidence, and assist in reporting torture and other forms of abuse to the relevant authorities. Unfortunately, health professionals in these settings struggle to maintain their clinical and ethical independence when faced with coercive institutions.

Don't swallow this

Assessment and documentation of torture requires specialist forensic expertise; without this the claims of torture victims cannot be corroborated and appropriate care may not be delivered. But resource constraints or a lack of political will mean that such expertise is seldom available. Although documentation of torture can be traumatic for a survivor, a comprehensive medicolegal report on the physical and psychological effects of torture can provide important evidence towards a claim for political asylum. An inadequate medicolegal report makes an asylum claim hard to substantiate and may place victims at risk of further torture if they are sent home.

> Health professionals in these settings struggle to maintain their clinical and ethical independence

Up to 8000 torture victims pass through the UK immigration detention system each year.[6] Detainees in immigration removal centres receive health checks because UK policy dictates that if there is independent evidence of torture people should be detained in these centres only in "very exceptional circumstances." This safeguard is ineffective: a government audit reported that only 9% of medical reports of torture resulted in the detainee being released.[7]

Health professionals face a critical challenge. Moral disorientation generated by the competing demands of dual obligations contributes to the abuse of detainees. Hence, health professionals must be able to exercise independent clinical judgment. Dual obligations are hard to escape, but if they are properly understood and disclosed their effects can be diminished.

New approaches are therefore required to support health professionals confronted with violation of detainees. An international professional network can help overcome isolation, emotional fatigue, and institutional neglect. Training to identify and document torture, in line with international standards, should be compulsory for all health professionals who work with detainees who are at risk of, or who have survived, torture.[8] Medical schools and universities also have an important role in establishing clear ethical standards, compliant with international law, that adequately prepare health professionals.[9] Unless difficult systemic changes are made, states will continue to use torture with impunity.

Torture remains widely used despite evidence of its inability to gather reliable information. It is a complex, politically driven phenomenon that is used to terrify, punish, and intimidate. Health professionals cannot expect to eradicate torture themselves but can be independent witnesses, documenters, reporters, and healers to prevent violations of the fundamental human right to health of vulnerable people.

Cite this as: *BMJ* 2015;350:h589

thebmj.com

- Research News: Tight blood pressure control during pregnancy offers no clear benefits (*BMJ* 2015;350:h549)
- Editorial: Removing the hype from hypertension (*BMJ* 2014;348:g1937)
- Research: Telemonitoring based service redesign for the management of uncontrolled hypertension (*BMJ* 2013;346:f3030)

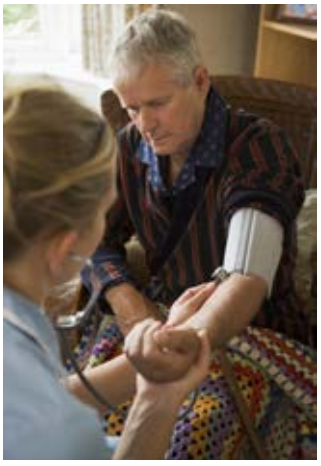
Initiation and follow-up of treatment for high blood pressure

Delays are associated with worse outcomes for patients

Jonathan Mant professor, Primary Care Unit, Department of Public Health and Primary Care, University of Cambridge
jm677@medschl.cam.ac.uk
Richard J McManus professor, Nuffield Department of Primary Care Health Sciences, University of Oxford

High blood pressure is the leading risk factor for disease worldwide.[1] Whereas strong evidence from randomised controlled trials is available for some aspects of the management of hypertension, uncertainties remain for others. In the linked article by Xu and colleagues, three of these uncertainties are investigated.[2] At what blood pressure threshold should treatment be intensified? How long after a high blood pressure is recorded should treatment be changed? And how long after treatment has been increased should the blood pressure be measured again?

Xu and colleagues used a large electronic database of primary care records from the United Kingdom—The Health Improvement Network (THIN) database—to construct a retrospective cohort of adults with a diagnosis of hypertension. For each patient, they split the data that they had into three time periods: a run-in period of at least 12 months to define baseline characteristics, a treatment period of 10 years from which the three key parameters (intensification threshold, time to intensification, and time to follow-up after intensification) were estimated, and an outcome assessment period. The third period continued until an outcome event had occurred (a cardiovascular event or death from any cause) or follow-up ceased. This elegant design allowed the researchers to answer important questions that do not lend themselves to prospective studies or randomised controlled trials.



Blood pressure thresholds for treatment remain controversial. Observational data suggest that the lower the systolic blood pressure the lower the risk of cardiovascular disease, at least down to 110 mm Hg.[3] Meta-analysis of data from trials suggest that the effect of lowering blood pressure is independent of baseline blood pressure.[4] However, recent trials of lower targets failed to show benefit, even in patients at higher risk.[5] Subsequently, no clinical guidelines for uncomplicated hypertension recommend treatment thresholds below 140 mm Hg and some have reined back on targets.[6 7] International guidelines vary as to whether drug treatment should be offered to everyone with a systolic blood pressure between 140 and 160 mm Hg (stage 1 hypertension) or only to those with raised cardiovascular risk, with only scant evidence available from randomised controlled trials at this treatment threshold.[6 8]

Treatment intensity

Xu and colleagues found no evidence of clinical benefit associated with an intensification threshold much below 150 mm Hg but acknowledge that they may not have enough power to detect a small effect.[2] These data can be viewed as confirmatory from both guideline perspectives—evidence of benefit associated with treating stage 1 hypertension, but not necessarily enough to outweigh the potentially substantial costs of treating the one in 12 adults with uncomplicated stage 1 hypertension.[9]

How quickly should we intensify treatment for raised blood pressure? Some delay is appropriate, given the variability of blood pressure and the need to confirm that it is truly elevated, whether through repeated measurements over time or use of ambulatory blood pressure monitoring, as recommended by the National Institute for Health and Care Excellence.[8] This analysis suggests that the confirmatory process should be completed within six weeks.

When should blood pressure be measured again after treatment intensification? Half of the maximal blood pressure lowering effect is achieved within a week, and the full effect is achieved within four weeks.[10] This is consistent with the 2.7 month window observed by Xu and colleagues before risks of cardiovascular events or death start to increase and concurs with trial evidence regarding the effectiveness of structured care and follow-up.[11]

Xu and colleagues' findings should be interpreted bearing in mind the limitations of observational research and of using electronic primary care records. The strength of association between exposure and outcome is likely to have been underestimated, as coding of cardiovascular events and recording of blood pressure are likely to be less accurate in this database than in a prospective cohort study. Furthermore, reducing blood pressure has a weaker effect on all cause mortality than on vascular events.[12] The possibility of confounding by indication exists, whereby thresholds or the timing of treatment and follow-up are influenced by patients' characteristics that were not measured or adjusted for. Confounding by quality of care is also possible—decisions on intensification and timings may be associated with other aspects of the general healthcare provided by the general practice looking after the patient. Finally, patient choice may have been important in the decision not to intensify treatment but will not be captured by this design.

Nevertheless, there are useful messages here for both general practitioners and patients. For general practitioners, this study provides some corroborative evidence for the treatment thresholds advocated by current guidelines and reinforces the importance of timeliness in establishing a diagnosis of hypertension, intensifying treatment when blood pressure remains above target, and scheduling follow-up after treatment intensification. The consequences of clinical inertia are starkly illustrated—60% of patients in Xu and colleagues' study waited longer than 18 weeks for treatment intensification, and this was associated with around a 20% increase in death or cardiovascular events.

One way of achieving better adherence to guideline thresholds, along with timely intervention and follow-up, is to give more control to patients. Patients who self manage their hypertension achieve lower blood pressures than do those managed with usual care, and patients who simply self monitor also have better control of their blood pressure.[13 14] In resource poor settings where access to primary care is limited, fixed dose drug combinations to treat hypertension may also have a role, as this might short circuit the need for further treatment intensification.[15]

Cite this as: *BMJ* 2015;350:h167

RESEARCH, p 11

thebmj.com

- News: GPs are told to warn parents that co-sleeping can increase risk of sudden infant death syndrome (*BMJ* 2014;349:g7422)
- Clinical Review: Managing infants who cry excessively in the first few months of life (*BMJ* 2011;343:d7772)
- Research: Hazardous co-sleeping environments and risk factors amenable to change (*BMJ* 2009;339:b3666)

Making informed choices on co-sleeping with your baby

Avoid smoking, alcohol, recreational drugs, and co-sleeping on the sofa

Peter J Fleming professor of infant health and developmental physiology
peter.fleming@bristol.ac.uk
Peter S Blair reader in medical statistics, Centre for Child and Adolescent Health, School of Social and Community Medicine, University of Bristol, St Michael's Hospital, Bristol BS2 8EG, UK

For most of human history, and in most parts of the world today, sharing a sleep surface ("co-sleeping") with the primary caregiver—almost always the mother—has been the normal experience of most human infants. Such close contact has benefits for the baby, including facilitating breastfeeding, and even in modern Western societies infant mortality is significantly lower among breastfed infants.[1] Routine co-sleeping is common in Western societies and is thought to be increasing with increased breast feeding; studies have shown a close bidirectional relation between breast feeding and co-sleeping.[2] On any given night in the UK, around one quarter of infants under 6 months of age spend part or all of the night sharing a sleep surface with a sleeping parent.[3]

Against this background is the recognition that, since the large fall in the number of sudden infant deaths that followed the "Back to Sleep" campaign, the proportion of such deaths occurring while co-sleeping has risen.[4] In some countries, notably the United States, many professionals have accepted that co-sleeping substantially contributes to unexpected infant deaths and should be discouraged.[5]

For parents who smoke, have drunk alcohol, or have taken recreational drugs co-sleeping is clearly associated with an increased risk of sudden infant death, and co-sleeping on a sofa or armchair even without these factors carries a substantially increased risk,[6] as does co-sleeping with an infant who was born preterm or at low birth weight.[7]

Co-sleeping by breastfeeding mothers

What is less clear is whether co-sleeping by breastfeeding mothers, in the absence of the other risk factors noted above, is associated with any increased risk of unexpected infant death.

Two recent meta-analyses used patient level data collected in large scale population based case-control studies to investigate whether co-sleeping in the absence of other known risk factors was associated with an increased risk of unexpected infant death.[8 9] The first study pooled data from

GETTY IMAGES

five case-control studies and concluded that, even in the absence of parental smoking, alcohol use, or drug taking, co-sleeping was associated with an increased risk of infant death.[8] However, the second study, which used data from two UK studies, concluded that the increased risk of infant death was almost entirely accounted for by the effects of parental smoking, alcohol use, and inappropriate sleep environments (such as co-sleeping on a sofa).[9] The first meta-analysis was larger but had limited data on parental alcohol consumption and used imputation to estimate the incidence of alcohol consumption from whole studies and potentially heterogeneous populations where this information was missing. The second study was limited to data in the UK but both contributory case-control studies had detailed information on smoking, alcohol use, and sleep environment.

Because of this uncertainty the UK's National Institute for Health and Care Excellence (NICE) was asked in 2014 to investigate the evidence linking co-sleeping and the risk of unexpected infant deaths and produce evidence based guidance. The resulting guidance, published in December 2014,[10] goes some way to meet the needs of parents but stops short of providing the correct emphasis given the risks involved.

Sofa sharing is a rare but lethal infant care practice that warrants far more emphasis

The NICE panel reviewed several large case-control studies as well as the two meta-analyses.[8 9] Although the NICE report recognised the extreme difficulty in investigating contributory factors to rare and unexpected events such as sudden infant deaths, it was critical of the lack of information on various potentially contributory factors in the studies reviewed. The panel did not, however, contact study authors to identify whether such information was available.

The guidance notes the reported association between co-sleeping and unexpected infant death but recognises the complex nature of such an association, and emphasises the lack of evidence of a causal link. However, it accepts that "some of the reviewed evidence showed that there is a statistical relationship between SIDS [sudden infant death syndrome] and co-sleeping."

While recognising that co-sleeping may be intentional or unintentional, the guidance recommends that parents should be informed that "there is an association between co-sleeping and SIDS," that this association "is likely to be greater when they or their partner smoke," and that the association "may be greater with parental or carer alcohol consumption, or drug use or low birthweight or premature infants."

Unfortunately the guidance does not mention the reported increased risk associated with co-sleeping on a sofa or armchair, despite the fact that this relation was found to be highly significant in four studies from the UK and Ireland[6 11-13]; a high prevalence of deaths on sofas has also recently been reported in Wales.[14] Bed sharing is relatively common in the general population whereas sofa sharing is not (prevalence <1%); given that recent UK studies suggest a sixth of sudden infant deaths occur in such an environment,[4 6 14] this is a rare but lethal infant care practice that warrants far more emphasis, especially if parents are under the misconception that co-sleeping on a sofa is no more dangerous than sharing a bed.

The guidance should be welcomed for making transparent the lack of evidence of a causal relation between co-sleeping and sudden infant death, while encouraging health professionals to be honest in informing parents of the potential risks arising from co-sleeping—particularly in relation to parental smoking, alcohol, and drug use.

By conflating all forms of co-sleeping and not recognising the much greater risks reported from co-sleeping on a sofa than on a bed, the guidance has missed an opportunity to inform parents and thus potentially to protect infants. Seeking to dissuade parents from this practice carries no identifiable risk and may help reduce the number of avoidable sudden infant deaths.

Cite this as: *BMJ* 2015;350:h563

Solving the health problems that patients face must prevail over the self serving desire to treat data as hoarded treasure

Why data sharing should be the expected norm

The Institute of Medicine takes a step in the right direction but we should move even faster

Harlan M Krumholz professor of medicine, Yale University School of Medicine, New Haven, CT 06510, USA
harlan.krumholz@yale.edu

The Institute of Medicine (IOM), a venerable American institution that seeks to provide authoritative recommendations to decision makers and the public, released a report last month on *Sharing Clinical Trial Data*.[1] The report is a welcome codification of guiding principles and frameworks. It reinforces many arguments for data sharing and urges that stakeholders "should foster a culture in which data sharing is the expected norm."[1] The IOM joins many other organisations, including drug companies,[2 3] the European Medicines Agency,[4] the National Institutes of Health,[5] and the Bill and Melinda Gates Foundation,[6] in making clear that study reporting and data sharing in medical research are imperative and the questions ahead are how, not whether.

The general support for data sharing in the IOM document will be familiar to *The BMJ*'s readers, as this journal has long advocated the importance of transparency in scientific research and the need to report results and share data.[7] The report provides what should be easily achievable recommendations for the research community. The committee called for data sharing only for new trials, though it urged consideration of sharing older studies. It stated that 18 months could elapse after the completion of a trial before investigators were asked to share. The committee also determined that sharing raw data would be too burdensome and that such data should be made available only on a case by case basis. The report states that summary level results should be publicly reported within 12 months of study completion, including lay summaries to trial participants.

Those of us who are eager for a change in the scientific culture remain impatient for even more progressive action plans. The harms of not reporting results and not sharing data are well established.[8 9] But people who continue to caution about the harms of data sharing have yet to provide persuasive examples where data sharing has harmed the public.

Among other problems, the absence of data sharing creates the important problem of information asymmetry among researchers. Those with the data can assert authority over interpretation and diminish the ability of others to debate key points, muffling scientific discourse. Confirmation bias can lead a group of investigators to see their data through a particular lens, while others could reasonably interpret the data differently and provide another perspective. Even independent expert reviewers come to different conclusions when provided with the same individual patient level data.[10]

Share and share alike

One of the peculiarities of clinical research is the challenge of replicating a study. A tenet of the scientific method is reproducibility. And yet, for clinical trials, reproducibility is often precluded by cost or logistic, ethical, or business reasons. As a result, direct replication by repeating the experiment in a different laboratory is not an option. This constraint makes it even more important that independent scientists can study the raw data.

Challenges surrounding replication are not unique to medicine. It is not feasible to independently repeat experiments conducted with the Hubble telescope or the Hadron collider. Instead, astronomy and physics researchers conduct an experiment and then share the results widely for scientists to study and produce more knowledge and insight. Such collaboration strengthens the trust in research, expands the volume of research that can derive from single experiments, and includes investigators who otherwise would be unable to fund such experiments. Unfortunately, what occurs every day in medical research is akin to a few astronomers with access to the most powerful telescope interpreting for us what they saw without allowing us to look for ourselves.

Fortunately, in medicine, the remedies to the current culture are coming. Industry is already making voluntary major steps to share data. Concurrent with the release of the IOM report, Johnson and Johnson, with the Yale Open Data Access (YODA) project, agreed to release its medical device trial data going forward, the first commitment to a broad release of that type of data.[11] Johnson and Johnson, along with other major companies, is already releasing data from drug trials.[2 3] There is some variation among companies and many data remain out of public view, but there is notable progress. The United States National Institutes of Health responded to concerns about non-publication and is receiving public comment on a rule requiring reporting of its studies.[5] The agency's next step should be to promote sharing of raw data. The Gates Foundation, in the most audacious show of leadership, stated that it will soon require data sharing at the time of publication.[6]

Part of medical research's code of conduct

Yet it will take more to transform the current culture and we need to move quickly.[8 9] All trials should be reported promptly after study completion and, if possible, published in peer reviewed journals. And any data generated in the course of medical research that might help fight disease and alleviate suffering should be shared as soon as possible. To delay knowledge generation by restricting access to such data should be considered counter to medical research's code of responsible and civil conduct. Solving the health problems that patients face must prevail over the self serving desire to treat data as hoarded treasure.

Yes, there are challenges. We need financial support for data sharing in grants. Academics must find ways to credit those who produced the data. Companies need time to get their products approved. And there are others. But time wasted in reporting and sharing can cost lives, and we need to push forward. We should heed the implicit message that the Gates Foundation is sending: solving the world's health problems is more important than protecting the opportunity for researchers to have exclusive access to data. It's time for us to create a collaborative scientific culture in which investments in trials are leveraged through sharing with the broader community and to move past the reasons for why doing so is hard.

Cite this as: *BMJ* 2015;350:h599