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Refined bleeding estimates in adults starting anticoagulants

New tools for a difficult job

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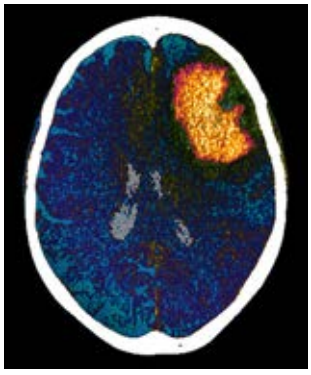
Oral anticoagulation is prescribed for the treatment and prevention of both venous thromboembolism and systemic embolism or stroke. Although treatment of acute events may require only short term use of anticoagulation, long term use is often prescribed, particularly for stroke prevention in patients with atrial fibrillation. The long term risk of bleeding associated with anticoagulation becomes a major consideration in decisions about treatment. While newer anticoagulants are associated with a lower risk of intracranial bleeding,[1] ongoing or future risk of serious bleeding remains a contraindication to use of these agents.

Therefore, although guidelines on anticoagulation for patients with atrial fibrillation have been generally based on an objective assessment of stroke risk,[2 3] they acknowledge that providers should also consider the patient's risk of bleeding. Yet doctors have few objective tools that are broadly recommended. Unlike scores quantifying the risk of stroke, which were used to stratify patients in randomised trials of anticoagulation,[1 4] no randomised study has tested the withholding of anticoagulation based on an increased risk of bleeding.



ZEPHYR/SPL

To avoid this

While several scores have been developed to predict the risk of bleeding in patients with atrial fibrillation taking anticoagulants,[5-7] they are limited by the consistent, prevalent use of anticoagulation in derivation cohorts; the inconsistent availability of score components in clinical practice; and relatively low power. Few provide robust estimates of absolute bleeding risk in patients not receiving anticoagulation or in patients starting such treatment. Therefore the QBleed models presented in the linked paper by Hippisley-Cox and Coupland represent important contributions to our assessment of the risk of bleeding.[8]

The investigators studied only new users of anticoagulants (versus non-users) in primary care in the United Kingdom. This is an important feature since the risk of bleeding is often highest in the period shortly after initiation of treatment; the score may, however, have limited applicability among existing anticoagulant users.

Additionally, the analysis included more than 9000 intracranial haemorrhages and more than 20 000 major upper gastrointestinal bleeding events among 1.4 million patients in the derivation cohort. This is among the largest of the outpatient derivation cohorts used in this specialty to date and provides extra power to develop more robust predictive models using more candidate covariates than other scores.

Such a model represents a change in our approach to assessing bleeding risk, from simple, point based scores, to a more inclusive, complex model. While there may be implications for implementation, this progression may make sense clinically—there are often patient subtleties and characteristics that inevitably increase the risk of bleeding but are not captured in simpler scores. A more comprehensive model may adjust for these factors, giving doctors and their patients a more refined estimate of absolute risk, analogous to that provided by the Society of Thoracic Surgeons perioperative mortality calculator.[9] While calculating bleeding risk is no longer "simple," neither is the decision to use long term anticoagulation.

Several limitations

Of course the QBleed models do have limitations. The derivation cohort, although large, is within a single specialty in a single system, with a relatively homogeneous population; and there were important baseline differences between new users and non-users in the source population. The investigators also report a validation study; however, this was an internal validation—they appropriately acknowledge that the algorithms need to be validated in external datasets from different populations before widespread use in practice. Proper external validation should also help users assess the impact on performance of using deprivation measures other than the Townsend score. Additionally, users should be aware of the details of the outcomes reported—inpatient admissions or deaths related to upper gastrointestinal or intracranial bleeding. Major bleeding in other sites or major events that did not require hospital admission is not predicted by these models.

Few adults were starting treatment with non-vitamin K oral anticoagulants, so the final risk calculator should not be used in patients receiving such drugs

Lastly, the authors point out that few adults in their cohort were starting treatment with non-vitamin K oral anticoagulants, so the final risk calculator should not be used in patients receiving such drugs. Further validation and refinement is necessary. However, the QBleed risk estimates for patients not treated with anticoagulation still provide valuable information.

Several questions remain about how doctors should use estimates of bleeding risk when making decisions about treatment: What magnitude of risk is too high? Is the threshold the same for every patient and every indication? Patients tend to fear ischaemic events, such as stroke, more than bleeding, and thus the tradeoff may not be one to one. Can the same model be used for both venous thromboembolism and stroke prevention in atrial fibrillation? Are there patients for whom the extra risk of anticoagulation is negligible, compared with their underlying, baseline risk? How do doctors measure and manage changes in risk over time?

Moving forward, the QBleed scores represent important contributions to the assessment of bleeding risk in clinical practice, as the identification of which patients not to treat remains an important challenge. While additional validation is needed before broad implementation, powerful risk calculators such as QBleed could serve as risk assessment tools in much needed future studies of anticoagulation tailored to risk of bleeding.

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RESEARCH, p 10

thebmj.com

- News: Patients with long term conditions can hold health and social care budgets from 2015 (*BMJ* 2014;349:g4578)
- News: Labour's plans for health and social care would not require more "top-down" NHS changes, says Burnham (*BMJ* 2013;346:f568)
- News: Scottish government unveils plan to better integrate health and social care (*BMJ* 2011;343:d8228)
- News: Health department chooses 14 projects as exemplars of integration of health and social care (*BMJ* 2013;347:f6628)

A new settlement for health and social care?

Alignment, adequacy, and affordability provide its analytical framework

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A story currently circulating in English social services tells how, at the end of the world, there will be four living organisms left on our planet. Two will be cockroaches and the other two will be trying to integrate health and social care. Despite this weary practitioner view, politicians and managers see integration as the solution to the underperformance of both the NHS and local government in the care of older people with complex needs. The King's Fund has now published the interim report of the Commission on the Future of the Health and Social Care in England (the Barker report), *A New Settlement for Health and Social Care*.[1] It opens with a discussion of the history of relations between health and social services, makes a plea for "better integration," and warns of "hard choices" ahead.

While the history is a useful corrective to professional and public ignorance about how health and social care have evolved, the Barker report has little to add about the mechanisms of integration across disciplines, sectors, and agencies. There is a paucity of robust systematic reviews or peer reviewed articles providing quantitative evidence, particularly of cost effectiveness, in integrated health and social care.[2] A recent King's Fund survey of health and wellbeing boards found that most have not identified integrated care as a priority.[3] We know that the necessary ingredients for integration are close knit professional networks, a mutual sense of long term obligation, little concern about reciprocation, a high degree of mutual trust, and an acceptance of joint working arrangements as core business.[4] We also know that there are traps for unwary integrators, as outlined in Leutz's five rules (box).

Integration of services: Leutz's rules[5]

- You can integrate all of the services for some of the people or some of the services for all of the people, but you can't integrate all of the services for all of the people
- Integration costs before it pays
- Your integration is my fragmentation
- You cannot integrate a square peg and a round hole
- The one who integrates calls the tune

The added value of the Barker report appears when the term integration is used more sparingly and the authors consider instead the alignment of health and social care, the adequacy of services, and their affordability. These three "A"s provide an analytical framework that could be used internationally as well as in the political debate that the King's Fund wants to stimulate in England before next year's general election.

Demolition derby

The report demolishes three myths and misconceptions that are repeated in many debates about the fragmentation of care for older people, such as those triggered by the stories from the Mid Staffordshire inquiry[6] or by television exposés of care home malpractice.[7]

> More than half of all NHS expenditure in England goes on those under 65, as does virtually half of social care expenditure

The first myth to be demolished is that population ageing causes unsustainable inflation of health and social care budgets. This correction is not new. The drivers of rising healthcare costs were clearly identified as technology and professional practice, not ageing, in the landmark paper "Apocalypse No,"[8] but this King's Fund report supports this argument with evidence and gives it authority. More than half of all NHS expenditure in England goes on those under 65, as does virtually half of social care expenditure.

The second myth is that spending on health and social care cannot continue to rise in the long run without damaging the economy. The Barker report shows that this argument is not just unsound but a misconception with political undertones. Tightening eligibility rules (in response to budget cuts) has reduced access to publicly funded social care, so much so that there can seem little left to integrate. As Fernandez and colleagues have shown, the number of older people receiving state supported community based social care in England has fallen substantially, by at least 31% between 2005-6 and 2012-13.[9] This has been achieved without much public debate, just as the transfer of care homes from the public sector to the commercial occurred quietly in the 1990s.

What happened to the other two?

The third myth is that a heroic restructuring of health and social care is needed. The report dismisses this but does not deny that a short term problem needs solving. One part of this problem is that the baby boomer generation wants to keep and pass on its wealth while having its care paid for by a third party. Another part is that underinvestment in social care means that social services cannot keep up with hospital discharge, causing bed blocking. Spreading responsibilities and budgets between health and social care, as occurs with continuing healthcare funding in England, leads to cost shunting as each sector tries to protect its budget. The consequences are disputes, complaints, and inconsistencies in provision.

Solving the short term problem requires additional funding to be mobilised, especially for social care. The Barker report outlines the options available, from restricting the healthcare offer (no more tattoo removal), through increased copayments (charges for general practitioner consultations and the like), to tax changes that reflect the unprecedented affluence of the older population.

The Barker report invites responses to the options it outlines. Restricting the healthcare offer and extending copayments look to us like solutions that will raise more indignation than money. Tax changes seem more realistic as sources of investment but are outside the remit of the health service or local government. These are the "hard choices" for politicians that will probably need cross-government, all party agreements to make—the Barker report's new settlement..

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PERSONAL VIEW, p 22

thebmj.com
- Letters: New Zealand leads the way in banning smoking in prisons (*BMJ* 2013;346:f3923)
- Analysis: Promoting health in prison (*BMJ* 2013;346:f2216)
- Editorial: Managing the health of prisoners (*BMJ* 2013;346:f3463)

Tobacco use in prisons

None is best, but complete bans are not the answer

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CHRIS LESCHINSKY/PHOTOLIBRARY/GETTY IMAGES

The long term benefits of a total ban are likely to be limited—only a few detained people maintain their abstinence on release

Tobacco use in prisons is a long neglected public health problem. Until recently, a permissive attitude regarding its use prevailed. But this has changed over the past two decades. Either partial bans (where smoking is permissible in designated areas) or complete bans have been introduced in prisons in Europe, Australia, New Zealand, and the United States.

These changes have had a substantial impact on health, as shown by Binswanger and colleagues' linked cross sectional survey of all state prisons in the US.[1]

Tobacco-free indoor bans introduced between 2001 and 2011 were associated with a fall in mortality attributable to smoking (cardiovascular and pulmonary deaths) in prisoners. Cancer mortality fell when bans exceeded nine years. Overall, the lowest crude smoking related mortality was seen in states with the most restrictive bans.

The few earlier studies in this area described the high prevalence of tobacco use among prisoners, the types of bans, the treatments, and the improvements in air quality and self reported health among small groups of interviewees.[2] By contrast, Binswanger and colleagues evaluated the impact of bans on mortality, using robust statistical analysis to calculate smoking attributable mortality, years of potential life lost, and any effect of the introduction of smoking bans on smoking related deaths.[1]

Experience argues against kneejerk response

What should we do with these findings? Experience gained from working with illicit drug users would argue against a kneejerk response. Tobacco use in prisons could usefully be considered within the framework of Switzerland's four pillar drug policy, which initially introduced a package of complementary actions covering prevention, treatment, harm reduction, and regulation, and is now extending them to licit substances too.[3]

Regulations are necessary in an environment where 50-83% of prisoners smoke, if only to reduce exposure to secondhand smoke. However, regulation (action oriented towards the environment in which people live and work) is not a tobacco control policy in itself, but only one essential component of such a policy. Further steps are needed, particularly to support reduction and cessation in smoking.

Another essential component is the provision of access to treatment, which is rare in prisons.[4] Those who would like to reduce or stop smoking (prisoners and staff) must be given the means to do so.[5] And lastly, harm reduction is part of any comprehensive tobacco control policy. This is a welcome development after the years of "yes or no" discourse around the use of tobacco.[6] In prisons too, smokers should have access to less hazardous tobacco products (such as electronic cigarettes and smokeless tobacco), just as they would have outside of prison.

Examples of guidelines for tobacco control in prisons exist.[7 8] Their implementation should follow the prevailing principles of drug policies, such as cooperation among diverse actors (health staff and prison administrators), coherency and consistency, scientific evidence, and human rights.[9] Coherency and consistency can be read at two levels: between the different substances involved—for example, treatment for tobacco cessation may be unavailable in prisons, although treatment for illicit drug use is provided—and with regard to the tobacco control policy prevailing in the general community. As long as tobacco smoking remains legal outside of prison, its control should not be tackled in a more extreme way in prisons—for example, by completely banning its use. This is inequitable and discriminatory.

Binswanger and colleagues recognise the limits of the regulations on individual autonomy, a basic principle of human rights.[10] If autonomy is defined as the ability for people to decide for themselves (provided they have the relevant information to do so[11]), then a total smoking ban seriously undermines it by denying choice. And the long term benefits of a total ban are likely to be limited—only a few detained people maintain their abstinence on release.[12]

Policy makers need to include prisons in their national strategies for drug and tobacco control.[13] Binswanger and colleagues' article should help these people decide on comprehensive and human rights based policies, not those that include isolated prohibition.

There is a risk that health benefits become a pretext to impose excessive rules that result in coercive change. It would be wrong for reduced mortality, even well corroborated by statistics, to become an argument in favour of greater prohibition of a legal substance in restricted environments while at the same time there is increasing debate about the decriminalisation of illicit substances in society at large. Efforts to explore strategies other than restrictive regulation to reduce smoking related mortality must be continued, and existing comprehensive tobacco control policies are showing the way.

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RESEARCH, p 11

I have written to the principal investigators of all the relevant clinical trials, asking them to make the data available or to explain why they will not

Statins and *The BMJ*

Lots of lessons, but we still need the data

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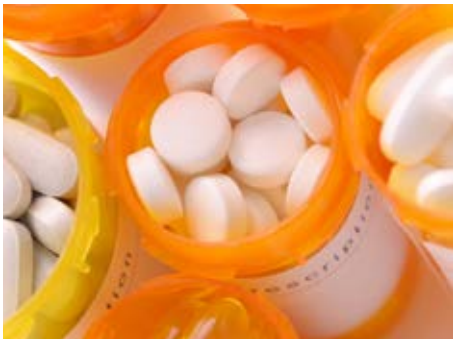

An expert panel convened by *The BMJ* has concluded that two articles published last year[1 2] and corrected in May should not be retracted.[3] The panel's report comes after a lengthy and public row over proposals to extend the use of statins to healthy people at low risk of heart disease.[4] What are the lessons from this episode for *The BMJ* and the scientific community? And what does it mean for the wider debate on statins?

The panel of seven internationally respected clinicians and researchers met seven times over two months. They acted independently of the journal, undertook a detailed statistical review of the two articles, received written evidence from all parties, and reviewed the journal's processes. They concluded that the only unequivocal error had been corrected and "were unanimous in their decision that the two papers do not meet any of the criteria for retraction."

The panel was itself under fierce public scrutiny. While those who had called for retraction questioned the panel's independence,[5] the Retraction Watch website said that the panel's report was "the most detailed justification for a journal's decision not to retract a paper that we've seen in a long time, perhaps ever."[6] This is reassuring. So too is the panel's conclusion that *The BMJ* used due diligence and acted appropriately.

However, the journal doesn't escape criticism. The panel suggested improvements to some of our processes, including additional statistical review and greater editorial scrutiny of controversial articles. It also found that we were slow in correcting the articles and has recommended "a significant event audit . . . to identify what would need to have been in place to ensure that the correction was made in a more timely fashion."

I said at the outset that we would implement all the panel's recommendations.[7] *The BMJ* has no plans to reduce its coverage of controversial issues: quite the reverse. It exists as a forum for scientific debate and will continue to challenge the status quo wherever necessary to improve health and healthcare. We recognise that doing this safely and effectively incurs extra responsibility. Additional checks and peer review of debate and opinion articles are already in place. As for a system that will ensure that necessary corrections are made promptly, we will be more proactive from now on: we will identify rapid responses that make substantive critical points about a published article, ask authors whether a correction is needed, and, where necessary, seek external expert advice.

As part of our commitment to transparency, all documents submitted to and produced by the panel are published online (thebmj.com/statins). The documentation includes the submitted versions of both articles, the peer reviewers' and editors' comments, and the revised and edited versions. Next month we will launch a long planned initiative to post such prepublication histories for all our research and analysis articles.

The panel stuck closely to its remit and resisted straying into discussion of the benefits and harms of statins. But it made three important contributions to this wider debate. Firstly, it confirmed that the debate on statins is legitimate and should not be shut down. Secondly, it asked that the debate be conducted primarily in medical journals rather than in the lay media. And thirdly, it called for the anonymised individual patient data from the clinical trials of statins to be made available for independent scrutiny.

This last is a key point. Currently only the drug companies, the trialists, and the Cholesterol Treatment Trialists (CTT) collaboration in Oxford have access to individual patient data from the statin trials. As I understand it, even CTT does not have the data on adverse events, which were specifically excluded when the collaboration was established. Nor does CTT have the right to share data with third parties. The Cochrane review group did not have access to the individual patient data. It based its analysis on the published information, including the published CTT analysis.[8]

This is not acceptable. As highlighted by the AllTrials campaign (alltrials.net), such debates will not be satisfactorily resolved in the public interest unless legitimate third parties are given access to the clinical study reports and the anonymised patient level data. At the very least this will allow greater understanding of the data's limitations. As a first next step towards this goal, I have written to the principal investigators of all the relevant clinical trials, asking them to make the data available or to explain why they will not. My letters and any replies I receive will be published at thebmj.com/statins.

For this approach to succeed, however, there needs to be a trusted group of people who can receive and analyse the data. There are at least three possible candidates: John Abramson and colleagues, who authored the main article in *The BMJ*,[1] though they will be considered by their critics to be too partisan; Rory Collins and his colleagues within the CTT, although they too may be considered by their critics to be insufficiently independent; and the Cochrane Collaboration, which had a key role in obtaining and analysing the industry clinical trial data in the case of oseltamivir (Tamiflu) (see thebmj.com/tamiflu). I have written to Collins to ask him whether he has now requested the data on adverse events and serious adverse events from the statins trialists and whether he will now call for these and all other data to be made publicly available. I have also written to the Cochrane statins review group to ask whether they would be willing to take on the central role in the next phase of this saga. Other candidates may also emerge.

As always, we welcome your comments on the report, on the wider debate on statins, and on these next steps towards greater transparency.

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