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

Austerity policies in Europe—bad for health

Health protection within the EU mandate is more relevant than ever

bmj.com/blogs
Read Aser García Rada's on the protests against privatisation of healthcare in Spain

Helmut Brand professor
helmut.brand@maastrichtuniversity.nl
Nicole Rosenkötter research associate
Timo Clemens research associate
Kai Michelsen assistant professor, Faculty of Health, Medicine, and Life Sciences, CAPHRI School for Public Health and Primary Care, Department of International Health, Maastricht University, 6229 GT Maastricht, Netherlands

Austerity measures introduced in many European countries as a consequence of the 2008-09 economic crisis have had many adverse effects on social determinants of health. These include falling incomes, high rates of unemployment, reduced funding for education, and higher taxation. Many people (particularly young ones) are out of work—in Spain and Greece over half of under 25 year olds are unemployed.[1] The combination of long term unemployment, inappropriate skills, and high entry barriers in rigid labour markets has created fears of a "generation jobless."[2] National austerity packages that have cut health budgets and resulting health policy reforms are additional drivers for adverse health outcomes, especially where health systems were less resilient or weak.

Health effects are accumulating in countries that were severely hit by the crisis, particularly Greece, Portugal, and Spain.[3] In a linked Analysis, Legido-Quigley and colleagues explore in depth the consequences of Spanish austerity on health policy.[4] They discuss lack of evidence that austerity policies work and the overall illogic of implementing serious health reforms in the current economic circumstances in Spain. Countries burdened by austerity policies have higher rates of poor health, particularly in the unemployed[5]; increased prevalence of mental health problems (such as depression, anxiety) and suicide attempts[3 4]; and increased incidence of infectious diseases, such as HIV.[3] Although not enough data are yet available for a comprehensive assessment of the impact of austerity, further adverse effects can be expected given the known effects of social determinants on health.

Health systems need to become more efficient and "lean," but governments must carefully consider which policies to implement lest people's health suffers.[6 7] Reforms to promote generic drug prescription and shift services from the inpatient to the outpatient setting are thought to improve efficiency and reduce costs, and many countries have made such changes.[6 7] However, at the same time, large cuts to hospital services have been made without adequate outpatient capacity in place,[7] user charges have been introduced or increased,[7] and labour costs of the health workforce have been cut.[3 7] Such measures lower the accessibility, efficiency, productivity, and quality of health systems.[6-8]

The number of operations performed fell by 6% in the first half of 2011 in Catalonia, Spain. At the same time, surgical waiting lists rose by 23%, with almost 17 000 people being affected.[9] In Latvia, massive reductions in hospital infrastructure had negative repercussions on planned hospital care.[8] Moreover, the number of people on waiting lists in Ireland increased by 9% from 2009 to 2010.[6] Wage cuts and dismissals have led to a rising number of health professionals emigrating, as indicated by reports from Ireland, Latvia, and Romania.[8] Furthermore, European governments have largely failed to invest in health promotion, remove non-cost effective services from publicly financed benefit packages, or move to integrated care systems.[6-8]

Should politicians be left to allow austerity policies to impinge on current and future health? The member states of the World Health Organization Regional Office for Europe agreed in Tallinn in 2008 on values and criteria for good governance of European health systems. The Tallinn Charter states that health policies should be based on shared values such as solidarity and equity; they should also foster investments in health, promote transparency and accountability, and engage stakeholders in developing and implementing policy.[10]

Measures taken in the economic crisis must be weighed against their future implications. Some policies that might save money in the short term could lead to higher long term costs if healthcare needs are unmet. These include policies that cannot easily be reversed, such as privatisation of healthcare systems and introduction of out-of-pocket payments. Health policy decisions need to take into account future demographic changes, such as changes to the structure of the workforce and increasing demands for chronic care services.

Importantly, well functioning social protection systems can buffer the health effects of the financial crisis in the longer term.[7 11] The WHO Health 2020 policy framework and the European Union Council conclusions on modern, responsive, and sustainable health systems offer further strategic guidance.[12 13] However, the emerging evidence suggests that, in times of financial and economic crisis, commitment to their objectives needs to be strengthened to steer health policy making.

Up-to-date and relevant health information is needed to improve governments' stewardship and the design and evaluation of the effects of health policy. There is a need to improve national health information systems and the speed of data availability, the selection of a key set of indicators for timely monitoring, and linkage of health information to social determinants of health. For proper governance of health systems we need to know what we are dealing with and have useful and useable information at our fingertips.

What role should the EU play in protecting the health of European populations? European austerity policies infringe population health and health system organisation at the national level. The EU has linked emergency loans (bail-out packages) to requirements to reduce public expenditure and gained tighter oversight on national budgets in the framework of the European Semester. This has led to detailed demands for health system reforms for some countries by European bodies.[14] With the EU playing a stronger role in member states' health policy reforms, good governance criteria that are relevant at the national level must now also hold true at the EU level. Good governance requires, among other things, that health needs are rigorously assessed and the performance of health systems carefully evaluated when pushing for structural and financial reforms in times of austerity. The expert panel on health investments at EU level is a new source of advice for member states undertaking healthcare reforms.[15]

Owing to the growing relevance of EU decisions on national health policies, experts at a conference on the 20th anniversary of the Maastricht Treaty (and the introduction of a health mandate) emphasised the need for a real commitment to consider health matters across all EU policy areas. The EU mandate to protect the health of the European population becomes more relevant than ever.[16]

Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;346:f3716

FEATURE, p 16
ANALYSIS, p 18

For patients on general medical wards, the well documented risks of multidrug resistant infections, and the adverse effects and costs of antibiotic use, are not worthwhile

Antibiotic prophylaxis after urinary catheter removal

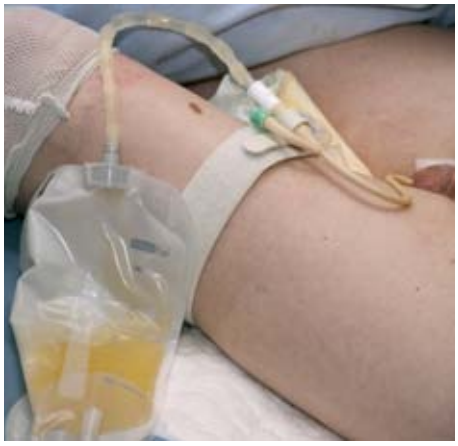
Could be considered for patients who have had urological procedures but not for all

Manisha Juthani-Mehta associate professor of medicine, Yale University School of Medicine, Department of Internal Medicine, Section of Infectious Diseases, PO Box 208022, New Haven, CT 06520, USA
manisha.juthani@yale.edu

For patients in hospital, catheter-associated urinary tract infection (CAUTI) is common and preventable. The most effective strategies for reducing such infections are to limit catheter insertion or promptly remove catheters when they are no longer indicated. Automatic stop orders have been used to reduce unnecessary catheterisations.[1] Nitrofurazone coated catheters could reduce the rate of CAUTI and be cost effective in the United Kingdom's health system,[2-4] but current international guidelines do not recommend the routine use of prophylactic antibiotics to prevent CAUTI at the time of catheter removal.[5]

The linked paper by Marschall and colleagues is a meta-analysis of antibiotic prophylaxis for CAUTI prevention after urinary catheter removal.[6] This meta-analysis evaluated data from six randomised controlled trials (five published, one unpublished) and one comparative study of two urologists' practices. Overall, patients receiving antibiotics had an absolute reduction in CAUTI of 5.8%, and 17 patients were needed to receive antibiotics to prevent one CAUTI. Although these results suggest that antibiotic prophylaxis has a benefit, they need to be viewed in the context of the following limitations.

Firstly, the comparative study of two urologists' practices in men after radical prostatectomy by Pinochet and colleagues[7] contributed 47% of patients (713 of 1520) to the meta-analysis. Men receiving a radical prostatectomy represent a unique subset of patients in hospital who are catheterised. Marschall and colleagues appropriately repeated the analyses without the comparative study. The risk ratio remained the same as in the main analyses, suggesting that the overall results are not biased by this one study. However, the next largest study (n=288) was the unpublished randomised controlled trial by Brandenburg and colleagues, of patients undergoing general surgery. This unpublished trial was vulnerable to selection, performance, and attrition bias as judged by two authors. In addition, the median duration of catheterisation was much higher in the control group than in the antibiotics group (33 days *v* 3 days). Marschall and colleagues should be commended for repeating the analyses without the patients from the Brandenburg study, and for showing that a benefit towards antibiotic prophylaxis persisted. However, they did not present the results of analyses if both the Pinochet and Brandenberg studies were removed. These two studies contributed the most patients to this meta-analysis, who were all at the postsurgical stage. When the analyses were limited to surgical patients only, the risk ratio remained unchanged, suggesting that these results might be generalisable for postsurgical populations.



DR P MARAZZI/SPL

No need for antibiotics on catheter removal

Secondly, only two studies[8 9] comprised mixed patients in hospital, and evaluating these two studies alone showed no significant advantage of the intervention. There is significant heterogeneity in the population of patients in hospital who require short term catheterisation. Patients at the postsurgical stage, particularly those having undergone a urological procedure, do not share the same risk of CAUTI as patients on general medical wards who may be catheterised. These data do not provide sufficient evidence to support the use of antibiotic prophylaxis at the time of catheter removal for patients on general medical wards.

Thirdly, meta-analyses are limited by the variability in protocols used in the contributing studies. The Centers for Disease Control and Prevention attribute infections that occur up to two calendar days after catheter removal as CAUTI[10]; however, the observation period for development of CAUTI in these seven studies ranged from four days to six weeks. Variable time windows for attribution of an infection to a catheter could affect CAUTI rates. The catheterisation period is a known risk factor for CAUTI, and the median period of catheterisation ranged from 1.9 days to 11 days in the antibiotic group, and from 1.8 days to 33 days in the control group, thereby inherently increasing the risk of CAUTI in the control group. Choice of antibiotic and duration of treatment also varied between studies. Antibiotics used for prophylaxis included ciprofloxacin, trimethoprim/sulfamethoxazole (TMP/SMX), nitrofurantoin, and cefotaxime. Duration of treatment ranged from one dose to three days. Lastly, other infection control measures that might affect the development of CAUTI (for example, use of antibiotic coated catheters or routine stop orders) could not be controlled for, to determine the individual contribution of antibiotics alone.

These findings suggest that although antibiotic prophylaxis could have a role in preventing CAUTI, there is insufficient evidence to suggest its widespread use at the time of catheter removal. For the patients on general medical wards, there is also insufficient evidence to warrant antibiotic use at the time of catheter removal. Without demonstrable benefit, the well documented risks of multidrug resistant organisms, such as *Clostridium difficile* infection, and adverse effects and costs from antibiotic use are not worthwhile. On the other hand, for postsurgical patients—particularly those undergoing urological procedures—use of antibiotics at the time of removal may be considered. This meta-analysis provides further evidence for considering antibiotics at the time of catheter removal in surgical patients. Future randomised controlled trials of antibiotic prophylaxis in populations at high risk of CAUTI are warranted.

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2013;346:f3938

RESEARCH, p 12

bmj.com
Analysis: Strengthening primary healthcare in India: white paper on opportunities for partnership (*BMJ* 2012;344:e3151)

The strength of primary care systems

Stronger systems improve population health but require higher levels of spending

Jeannie L Haggerty associate professor, Department of Family Medicine, McGill University, Montreal, Canada
jeannie.haggerty@mcgill.ca
Jean-Frédéric Lévesque chief operating officer, Bureau of Health Information, Sydney, Australia
William Hogg professor, CT Lamond Primary Health Care Research Centre, Bruyere Research Institute, Ottawa, Canada
Sabrina Wong associate professor, School of Nursing, University of British Columbia, Vancouver, Canada

A recent article in *Health Affairs* by Kringos and colleagues seems destined to take its place with other seminal studies that support the importance of investing in a strong system of primary care for a well functioning health system, better population health, and maybe even greater health equity.[1-3]

The team of researchers from the Netherlands Institute for Health Research used statistical databases and government reports from 31 European countries to measure the strength of five primary care dimensions—structure, access, coordination, continuity, and comprehensiveness. They looked at the association between each dimension and healthcare spending, patient perceived quality of care, potentially avoidable admissions to hospital, population health, and health inequality according to socioeconomic status.

They found that population health was better in countries that had a strong primary care structure and robust mechanisms to support coordination and comprehensiveness. The strength of primary care systems was measured by the density of primary care providers and the quality of their work environment. Stronger systems were associated with lower rates of avoidable admissions to hospital and fewer potential years of life lost for most of the conditions studied. These benefits were also linked to gatekeeping with other healthcare professionals (coordination) and a mix of primary care practitioners who deliver a broad range of services (comprehensiveness). These findings confirm the hypothesised effects of a strong primary care system.

However, and contrary to hypotheses, countries with stronger primary care structures also had higher levels of healthcare spending, after adjusting for gross domestic product per person. It had been expected that primary healthcare would deliver similar services at a lower cost than specialist services and would reduce overall costs through avoidable admissions to hospital and preventive care. This study suggests that health dividends cannot be obtained without financial investment, but the good news is that increased comprehensiveness is associated with a lower rate of growth in healthcare spending. Comprehensiveness was measured by the diagnostic and therapeutic technologies available to permit problem solving at the primary care level, and by the availability of nurses and other healthcare professionals to promote and maintain self care. Although investing in robust primary care systems rather than specialist care might not save money in the short term, it buys good outcomes at a population level and slows the rise in healthcare costs.

One of the study's intriguing findings comes from the analyses of health inequality by socioeconomic status. Contrary to the researchers' hypothesis and many reports,[3 4] the strength of the healthcare structure, access to healthcare, coordination, or comprehensiveness could not explain why poor health is concentrated in lower socioeconomic groups. This runs contrary to the common belief that the needs of poorer groups are covered by community based primary care, whereas specialist care tends to be used by higher socioeconomic classes.[5]

Giving patients an experience of respect, validation, and empowerment may translate into lower health inequality

However, the exception was continuity of care. Countries with a more formal affiliation between practitioners and their patients, in which more patients were highly satisfied with interpersonal dimensions of care, had more equality of self rated health (although not the prevalence of asthma or diabetes). Most advocates of the power of primary care to improve the equity of healthcare would have expected a link to the structure of primary care and access, rather than the continuity of care between doctors and their patients.[3 4] To interpret this finding, it must be remembered that health systems, not individual clinicians and patients, were the unit of analysis in this study.

A plausible explanation at the system level is that more egalitarian societies invest more in primary care and that relationships between providers and patients are more equal in such societies. Reasons for investments in primary care, more than just the size of such investments, might relate to deep rooted cultural factors that make such investments possible and also support affiliation between patients and providers. Again though, this suggests a link to structure and comprehensiveness rather than continuity.

Alternatively, the association with continuity might reflect the cumulative effect of long or strong clinician-patient relationships. Many studies have shown that strong relations between patients and their doctors are associated with better compliance with recommendations, more preventive care, fewer emergency admissions to hospital, and lower costs.[6]

No studies have shown that continuity can reduce inequality in perceived health, although analysis of aggregate data (across and within countries) suggests that such an association might exist.[7 8] They posit that one mechanism for the negative health effects of being in a lower socioeconomic group stems from the psychological anxiety that comes from being perceived by others as lower status: devalued, looked down on, powerless. Respectful clinician-patient interactions might therefore result in better self perceived health, if not disease prevalence.

A mountain of evidence shows that low socioeconomic status is one of the highest risk factors in those presenting to primary care. It is therefore possible that health systems that support and value high quality clinician-patient relationships may give patients—most of whom are in a lower social class than their clinicians—an experience of respect, validation, and empowerment that translates into lower health inequality.

Although Kringos and colleagues' findings pertain mainly to health system design and investment, they depend on a strong foundation of well trained and competent clinicians. When combined with sufficient resources and technological platforms, the result is improved population health outcomes and reduced avoidable hospital admissions. The combination of a whole person approach, respectfulness, and continuity of personal care serves to counter the burden of health inequality.

Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;346:f3777

bmj.com
The *BMJ* series on uncertainties is at bmj.com/bmj-series/uncertainties-page

How not to reduce uncertainties in care

US Office for Human Research Protections messes up

Neena Modi professor of neonatal medicine, Imperial College London, London SW10 9NH, UK
n.modi@imperial.ac.uk

The randomised controlled trial has justifiably been embraced as necessary to the delivery of evidence based medicine. Randomisation reduces confounding by unknown factors, ensures every patient has a fair and equal chance of receiving the best (as yet unknown) treatment option, and is the gold standard approach to identifying effective treatments for future patients. In an ideal world every treatment uncertainty would be dealt with in this way. Recent experience in the United States highlights the unexpected barriers to doing this.

Most uncertainties in healthcare relate not to new experimental treatments but to those already in wide use. The administration of oxygen to premature babies is an example of this. A long-standing uncertainty about the treatment—the optimum saturation target—was put to the test of a randomised controlled trial. Preterm babies with respiratory immaturity often need additional oxygen, but too much oxygen is associated with a proliferative retinal vasculopathy—retinopathy of prematurity—a cardinal cause of lifelong visual impairment and blindness. For this reason, the accepted standard of care oxygen saturation range of 85-95% is used to avoid levels that are too low or too high.

Investigators in the United Kingdom, Australia, New Zealand, and the US set about designing a randomised controlled trial to refine this range and determine whether targeting the lower end of the accepted range (85-89%), rather than the upper end (91-95%), reduced the incidence of retinopathy of prematurity. The US SUPPORT trial found that babies given oxygen at the higher end of the recommended range did have a greater incidence of retinopathy of prematurity, but, unexpectedly, babies at the lower end had a higher risk of death.[1] The data monitoring committees of the UK, Australian, and New Zealand BOOST2 trials reviewed interim data, confirmed the higher risk of death in babies randomised to the lower saturation range, and stopped further recruitment.[2]

These trials recruited thousands of babies and advanced knowledge and preterm care,

What's his optimal oxygen saturation?

yet in March 2013 the lead investigators for the SUPPORT trial received a letter from the Office for Human Research Protections informing them that they were "in violation of the regulatory requirements for informed consent, stemming from the failure to describe the reasonably foreseeable risks of blindness, neurological damage, and death."[3] A commentary in the *New England Journal of Medicine* pointed out that the SUPPORT consent form, approved by no less than 23 US institutional review boards, explained the prevalent equipoise and state of knowledge "fairly and reasonably."[4] The higher risk of death at the lower saturation range would never have been recognised had it not been for the SUPPORT trial. Finding researchers at fault for not foreseeing an unexpected outcome and suggesting that babies were at greater risk from randomisation when they received oxygen within accepted standard of care limits has led to confusion and mistrust among parents and the public. It has also set back attempts to reduce treatment uncertainties.[5]

Illogical regulation and poor integration of research with day to day clinical practice delay the incremental advances that are essential to improve care

As with all sciences, there are no absolute truths in medicine, only a progressive reduction in uncertainty with each null hypothesis rejected. Illogical regulation, as reflected in this response, and poor integration of research with day to day clinical practice delay the incremental advances that are essential to improve care. To redress this, a paradigm shift is needed, involving acceptance of randomised allocation of treatments already widely used as a standard of care, an approach that has been used successfully in developing treatment protocols in oncology. Continuing uncertainty will ultimately result in many more patients being disadvantaged or harmed by receiving the (unknown) worse treatment. It is also noteworthy that infants in both higher and lower saturation target arms of the SUPPORT trial had a lower rate of death than infants who were not enrolled. It is time to be honest and tell patients and parents that the fairest chance of receiving the (unknown) best treatment is through randomisation because the choice of treatment is not affected by clinician bias. There is also likely to be benefit, regardless of allocation arm, from participating in methodologically rigorous comparisons of standard treatments, because care will be delivered along a closely monitored pathway.

In adopting this approach, peer review and explanation would remain unchanged. The involvement of patients can help ensure that the design of comparisons is acceptable and explained clearly, and regulatory approval should be proportionate. The key difference is that randomisation would be the recommended default and that patients would be offered the opportunity to opt out, rather than invited to opt in. This would reduce the burden of decision making at difficult and stressful times. It would also reduce the risk of "injurious misconception," where participation is inappropriately rejected because of an exaggerated and disproportionate perception of risk,[6] and speed up trial completion. Data can increasingly be extracted from electronic clinical records, reducing costs and the burden on busy clinical teams.[7] This approach would fulfil the four cardinal principles of research ethics—autonomy, justice, beneficence, and non-maleficence—and uphold the responsibility enshrined in General Medical Committee guidance that doctors must "strive to reduce uncertainties in care."[8]

Competing interest statement: I am chair of the BMJ Ethics Committee, chair of the Royal College of Paediatrics and Child Health "Updating Guidance for Children's Researchers" working party, and a clinical academic conducting research involving patients and healthy volunteers.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2013;346:f3786