Assessing the quality of hospitals

Hospital standardised mortality ratios should be abandoned

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Nick Black professor of health services research, London School of Hygiene and Tropical Medicine, London WC1E 7HT
nick.black@lshtm.ac.uk

Competing interests: The author has completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declares: (1) No financial support for the submitted work from anyone other than his employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouse, partner, or children with relationships with commercial entities that might have an interest in the submitted work; (4) He chairs the National Clinical Audit Advisory Group, a non-governmental public body that advises the Department of Health in England, and is a trustee of the Intensive Care National Audit and Research Centre.
Provenance and peer review: Not commissioned; externally peer reviewed.

Cite this as: *BMJ* 2010;340:c2066
doi: 10.1136/bmj.c2066

The quality of care provided by hospitals needs to be assessed objectively not only to stimulate clinicians and managers to make improvements but also to ensure public accountability, to enable patients to make informed choices, and to facilitate informed commissioning. Given the importance of all these activities, the measures used to assess quality must have sufficient validity and reliability. This is not true of the main measure being used in many countries, including the United Kingdom, the hospital standardised mortality ratio (HSMR).[1] Before considering practical and methodological shortcomings in England, many of which are considered by Lilford and Pronovost in the linked article,[2] the concept of using hospital deaths to judge the performance of a hospital needs to be considered.

A consequence of a failure to provide alternative forms of care has been that hospitals have taken on the role of providing a place for people to die. About half of us will end our days in a hospital bed. This makes it perverse to use a hospital's mortality statistics to judge its quality of care, given that deaths are often an expected and accepted outcome. The incongruity of using mortality to assess a hospital is exacerbated by geographical variation in the proportion of deaths that occur in hospital (40-65%), which reflect not only the availability of alternative forms of end of life care, such as hospices and community palliative services, but also cultural, religious, and socioeconomic characteristics of the local population. It is no surprise to find that the higher the proportion of all deaths in a population that take place in hospital, the higher that hospital's HSMR will be.[3]

Aside from the inappropriateness of the concept of using death as a measure of hospital quality, several practical problems arise from shortcomings in the data used to derive HSMRs. The first results from variation in the diagnostic behaviour of doctors and hospitals. This leads to problems if the method of calculating the HSMR does not include all causes (or diagnoses) of death, as is the case with one approach, which excludes 20% of deaths.[4] The resulting HSMR will partly depend on whether or not a death is ascribed to an included or excluded diagnosis.

Secondly, many secondary diagnoses (comorbidities), which are crucial for case mix adjustment, are commonly missing from hospital episode statistics, and those that are included often contain inaccuracies: in 2007-8, on average 17% were wrong, with an interquartile range of 8% to 26%.[5] The third, and most serious shortcoming of the data, is the failure of hospital episode statistics to recognise that many patients who die were admitted for end of life care. On average, hospital trusts report that only 4.5% of their patients who die were in this category, with many hospitals reporting none.[6] Even the hospital that reported the most (22%) in 2007-8 may have underestimated this figure, because a detailed review of case notes at one trust showed that the true proportion was 37%. When this was taken into account its HSMR fell dramatically from 105 to 68.

Given these shortcomings in the data, it is no surprise to see how unstable HSMRs are as a measure. Recent reports that hospital mortality fell by an unbelievable 7% in only 12 months overall in England, and in some hospitals by more than 30%, shows the lack of validity of HSMRs.[4] Their validity is also undermined by the finding that different methods for deriving HSMRs produce different results. For example, the mortality ratio for 2007-8 for Basildon and Thurrock Hospital derived by one company was 132 compared with 107 when derived by another.[7]

Despite international support for using HSMRs to determine the quality of hospitals, particularly among policy makers and regulators, the validity of this measure has not been established. Indeed, it has barely been investigated. This could be done by comparison with more detailed in-depth methods of determining the quality of clinical care. Meanwhile advocates of HSMRs question whether its accuracy matters. They claim that, regardless of all the shortcomings, the publication of HSMRs is justified because it stimulates hospitals to improve their performance. To support this they cite examples of secular changes in HSMRs, ignoring the fact that these apparent improvements do not distinguish between data artefacts (such as changes in coding practice and admission and discharge policies) and real improvements. This cavalier approach ignores the danger of unjustified and unfair criticism of hospitals, with the attendant risks of damaging staff morale and public confidence.[8] In addition, it may risk undermining staff and public confidence in quality assessment in general, encouraging scepticism about whether performance can ever be measured accurately.

Some, although not all, of the shortcomings of HSMRs have been recognised by regulators who advocate their use,[4 9] and by the recent inquiry into poor care at Mid Staffordshire NHS Foundation Trust.[10] The proposed solution to methodological shortcomings is believed to lie in achieving a consensus among advocates on how to calculate HSMRs, while the problem of the public, managers, and the media misinterpreting the agreed measures is to be solved by improved understanding of their indicative rather than definitive role. Such caution is to be welcomed but is unlikely to be realised given the nature of the news media.

The inadequacies of HSMRs and the potential harm they may cause does not mean that we must abandon our attempts to measure the quality of hospital care. Instead we should turn to the increasing number of more specialised sources of data, in particular those established for national clinical

audits. Although these databases do not cover all conditions or services, they could provide meaningful comparisons of hospitals for many services such as myocardial ischaemia,[11] critical care,[12] lung cancer, trauma, and renal replacement therapy. An additional benefit is that many of them consider outcomes other than death (including morbidity and disability) and aspects of the process of care. A shift to this approach would gain the credibility and support of clinicians and provide a much richer and more valid account for the public of how a hospital was performing. These benefits have been recognised by the Department of Health in England with the introduction of hospital quality accounts from April 2010, one aim of which is to enhance hospitals' participation and use of these data sources. This should be accompanied by the abandonment of HSMRs, which are not fit for purpose.

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Pragmatic rehabilitation for chronic fatigue syndrome

Has a short term benefit, but supportive listening does not

RESEARCH, p 959

Rona Moss-Morris professor of health psychology, School of Psychology, University of Southampton, Southampton SO17 1BJ
remm@soton.ac.uk
William Hamilton consultant senior lecturer, Primary Health Care, University of Bristol, Bristol BS8 2AA

Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that: (1) They have no specified support for the submitted work; (2) RM-M has had no relationships that might have an interest in the submitted work in the previous three years; WH is a part time insurance medical officer for three companies offering income protection insurance and board member of one; his payments are fixed hourly rates and wholly unconnected to the acceptance or declinature of claims; (3) WH's wife is also a part time insurance medical officer for one company, with a similar payment scheme; and (4) AJW, first author of the FINE trial, has chaired a trial steering committee for a study on cognitive behavioural therapy for adjusting to multiple sclerosis where RM-M was the principal investigator. WH has no non-financial interests that may be relevant to the submitted work.

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

Cite this as: *BMJ* 2010;340:c1799
doi: 10.1136/bmj.c1799

Each full time general practitioner in the United Kingdom has as many as 10 patients with chronic fatigue syndrome (CFS/ME) on their list.[1] Many feel they have little to offer with regard to treatment.[2] Patients in turn are often left feeling misunderstood and poorly cared for.

Currently, the only evidence based treatments for this condition reviewed in the Cochrane Library and recommended by the National Institute for Health and Clinical Excellence are cognitive behavioural therapy and graded exercise therapy, with cognitive behavioural therapy in specialist care having the larger evidence base.[3-5] A primary care trial of brief cognitive behavioural therapy for CFS/ME offered by general practitioners who had received simplified training in the subject was unsuccessful.[6] Few patients with CFS/ME receive specialist services, partly as a result of limited access, but also because many feel that psychological treatments delegitimise their condition.[2] Thus, a treatment that includes aspects of the successful treatments, but in a more pragmatic fashion with less emphasis on psychology, is an attractive proposition. But does it work?

The linked randomised controlled trial by Wearden and colleagues, assesses pragmatic rehabilitation for CFS/ME offered in primary care.[7] The rehabilitation consists of providing patients with detailed explanations for their symptoms combined with a carefully graded exercise programme, delivered by supervised general nurses after training. Patients randomised to this treatment became significantly less fatigued and depressed, and they slept better than patients who received usual care. However, one year later no significant difference was seen between the groups.

This suggests that pragmatic rehabilitation works, but only in the short term. Why then did an earlier randomised controlled trial of pragmatic rehabilitation with a single skilled therapist show large changes in fatigue and disability at one year of follow-up?[8] Wearden and colleagues explain that their patients had more comorbidity and disability than patients in the earlier trial,[7 8] and indeed most other trials. Increased disability is a recognised predictor of poor outcome of cognitive behavioural therapy in this condition.[9 10] This may be even more relevant for a minimal intervention from less experienced practitioners. A recent trial found that guided self instruction cognitive behavioural therapy, accompanied by minimal support from a therapist, reduced fatigue and disability in patients with less severe rather than more severe CFS/ME.[10] Therefore the best approach may be stepped care, in which patients with less disability are offered minimal intervention, whereas more severely affected patients are offered intensive specialist input. Alternatively, having more sessions of pragmatic rehabilitation for longer may build on initial improvements. In Wearden and colleagues' trial, patients received fewer sessions (eight hours in total) than most successful trials of cognitive behavioural therapy and graded exercise therapy.

A further question is whether generalists are as successful as specialists in offering behavioural interventions. A large Dutch trial showed that 16 hours of cognitive behavioural therapy delivered by a range of recently trained health professionals was effective for at least a year, although the improvements were less than those obtained for highly skilled therapists.[11] The effectiveness of these treatments may be a product of therapists' skill and the number of sessions, with less experienced therapists needing more sessions. To understand these interactions further, trials comparing short and longer term treatments with skilled and unskilled therapists are needed. These should also examine the cost effectiveness of different levels of therapeutic skill. The economic and personal burden of CFS/ME is large, yet data on cost effectiveness are scarce.

Wearden and colleagues' trial also investigated supportive listening therapy for CFS/ME. This approach is often used by

PAUL DOYLE/ALAMY

counsellors and is more accessible to general practice than cognitive behavioural therapy or exercise therapy. Importantly, this treatment was ineffective—patients receiving supportive listening had significantly more disability at the end of treatment than those receiving usual general practitioner treatment. This may be because supportive listening did not include a graded activity component. Cognitive behavioural therapy protocols without this component seem to be no more effective than usual care for CFS/ME.[4] The large UK based PACE trial should soon provide answers in this regard.[12] PACE compared cognitive behavioural therapy and graded exercise therapy, which focus on increasing activity, with adaptive pacing therapy, which matches activity levels to the amount of energy available to patients.

Pragmatic rehabilitation as a treatment in primary care for CFS/ME has short term benefit, but supportive listening does not. Before it can be recommended, more work is needed to determine for whom pragmatic rehabilitation works best, the optimum number of sessions needed, and the required skill of the therapists. Some of these questions may be answered by further analysis of the current trial. For instance, moderator analysis, examining interactions between patient or therapist characteristics and treatment outcome, could investigate whether less disabled patients responded better to treatment than those with greater disability. Similarly, it might be useful to study the effect of therapists' competence on outcome. Finally, pragmatic rehabilitation has the real advantage of being an acceptable treatment. Few patients dropped out of treatment, and it may be less stigmatising for some people than cognitive behavioural therapy. This last point is crucial, and if the successful elements of pragmatic rehabilitation can be identified, it may provide an additional option to the currently limited list of possibilities.

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Prostate cancer and deprivation

Less radical treatment corresponds with higher deprivation, but the effect on survival differences is unclear

RESEARCH, p 961

Kari A O Tikkinen urology resident, Department of Urology and Clinical Research Institute HUCH Ltd, Helsinki University Central Hospital, Haartmaninkatu 4/Tutkijatilat H3011, PO Box 105, 00029 Helsinki, Finland
kari.tikkinen@fimnet.fi
Anssi Auvinen professor of epidemiology, Tampere School of Public Health, University of Tampere, 33014 Tampere, Finland

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- News: Doctors are asked to tackle inequality throughout cancer care pathway (*BMJ* 2010;340:c1653)

The Alma-Ata Declaration of 1978 states: "The existing gross inequality in the health status of the people particularly between developed and developing countries, as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries."[1] Many studies have shown large disparities in the burden of cancer according to race or ethnicity and socioeconomic status. Indeed, socioeconomic factors such as poverty, inadequate education, and lack of health insurance are more important determinants than biological differences.[2 3] In the linked study, Lyratzopoulos and colleagues use a population based cancer registry to assess variations in the management of prostate cancer in patients of different socioeconomic status.[4]

Prostate cancer is the most common non-cutaneous cancer in men in most industrialised countries. Stage at diagnosis and mode of treatment are the main determinants of the outcome for most cancers.[5] Differences in survival from prostate cancer according to socioeconomic status, after adjustment for stage at diagnosis, are well documented.[5] However, the effect of socioeconomic status on therapeutic decisions is less clear. A study of patients with prostate cancer in the United States found that those with the lowest socioeconomic status were less likely to receive surgery and radiotherapy (independent of age, ethnicity, disease stage, and geographical region).[6] Similarly, a recent study in the United Kingdom found that men from more affluent areas were more likely to receive radical treatments.[7]

Lyratzopoulos and colleagues assessed the relation between initial radical treatment (radiotherapy and radical surgery) and socioeconomic status, measured using a small area deprivation index. Incident cases of prostate cancer (35 171 men aged over 50 diagnosed 1995-2006) were identified from the population based cancer registry in Cambridge, which covers 5.5 million people. Information on cancer stage was available for 16 020 patients (45.5%).

Radical treatment was less common in patients from the most deprived areas even after adjustment for stage at

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diagnosis. Among the most affluent, about 8% were treated with radical surgery and 29% with radiotherapy, whereas the corresponding figures were about 4% and 21% for the most deprived. These socioeconomic differences in odds of treatment use were also found in the multivariate analyses after adjustment for age, diagnosis period, and morphology. The authors concluded that the differences are unlikely to be artefactual and probably reflect true differences in clinical management.[4]

Their study confirms earlier findings that lower socioeconomic status is associated with less frequent use of radical treatment for prostate cancer.[6 7] Possible explanations are behavioural (values, attitudes, health behaviour), social (communication skills, social support, economic resources, insurance), and clinical (comorbidity, choice of treatment, access to health care).[5] Interpretation of the results should consider the potential limitations—individual socioeconomic status was not assessed, which could reduce differences, and no information was available on comorbidity or ethnicity.

The study provides no explanation for the variation in treatment seen. Factors involved in treatment decisions include contraindications for treatment (comorbidity and functional status), complications, and patients' preferences. Furthermore, we do not know how eliminating these differences in treatment would reduce inequalities in survival. Strategies to reduce disparities in survival related to socioeconomic status must be based on an understanding of their cause.

One possible reason for variations in management by socioeconomic status is the lack of evidence about the relative merits of treatments. Several treatments are available (including surgery, radiation, cryotherapy, hormonal treatment, combination of these treatments, and expectant management) and few trials have compared them.[8-10] Hence, treatment decisions cannot be made on evidence alone but require a doctor's judgment and negotiation with the patient. Better educated patients may process information more easily, and doctor-patient communication may be more effective or fluent when doctor and patient have similar social backgrounds.[5 11]

Prostate specific antigen (PSA) testing has increased the detection of prostate cancer and resulted in overdiagnosis and overtreatment.[12] Yet Lyratzopoulos and colleagues think of undertreatment as a potential problem in patients with a low socioeconomic status.[4] The most deprived men could be having too few radical prostatectomies and radiation treatments or the most affluent could be having too many. Because the reasons for these socioeconomic disparities are unclear and the best way to reduce them is unknown, future studies should investigate the contribution of various prognostic factors to differences in survival. It would also be useful to evaluate such differences within the treatment arms of randomised trials.

Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No non-financial interests that may be relevant to the submitted work."

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

Cite this as: *BMJ* 2010;340:c2043
doi: 10.1136/bmj.c2043

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How cognitive biases affect our interpretation of political messages

What we hear is often very different from what we are told

Martin McKee professor of European public health, London School of Hygiene and Tropical Medicine, London WC1E 7HT
martin.mckee@lshtm.ac.uk
David Stuckler research fellow, Christchurch College, University of Oxford, Oxford OX1 1DP

Cite this as: *BMJ* 2010;340:c2276
doi: 10.1136/bmj.c2276

British readers of the *BMJ* will soon get to vote on the competing visions of the political parties at the general election. Although the mainstream parties each claim the middle ground, there are important differences in how they will approach the economic challenges that lie ahead, with potentially major implications for health and health care. How fast and how deep should cuts in public spending be? Are targets a good or a bad thing? What is the appropriate role of private healthcare providers?

Voters must decide which of the different answers they agree with, yet—as seen in recent disputes between leading economists about how to tackle the government deficit—it is possible for two well informed groups of people faced with the same evidence to reach completely different conclusions about what should be done. How do voters interpret such complex information and what influences them?

There is considerable evidence that people presented with balanced arguments place weight on those they already agree with,[1] exhibiting what is termed confirmation bias.[2] A recent study from the United States randomly allocated one of four versions of an authoritative news story about diabetes to people who had declared different political allegiances.[3] Each story was identical except for how they described the cause of diabetes. One said nothing about the cause (the control), whereas the three others cited genes, individual lifestyle choices, and social determinants. They were then

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asked whether they agreed with two statements on the reason people get diabetes, one specifying social determinants and the other genes. Democrats were most likely to agree that social determinants were a cause, regardless of which version they read. Independents reading the version where social determinants were the cause were more likely to agree with this explanation than those who read the control story, but the social determinants version had no effect on Republicans' views. Each group was then asked about collective actions to tackle diabetes, such as restrictions on junk food. Democrats reading the social determinants version were significantly more likely than controls to support action but Republicans were less so. In a second US study, subjects were initially categorised on a conservative-liberal scale and then exposed to factually incorrect stories on the effect of US tax cuts and weapons of mass destruction in Iraq followed by an authoritative correction. If they sympathised with the initial message the correction either failed to change their misperception or actually reinforced it.[4]

Another study examined possible neurological mechanisms involved in interpreting political messages in the run-up to the 2004 US Presidential election. Fast magnetic resonance imaging of the brain was used in people exposed to contradictory pairs of messages that were attributed to politicians of both parties and to neutral commentators.[5] Whereas those registered as Republicans clearly identified the contradictions voiced by Democrat politicians, they saw minimal contradiction in the statements by Republicans, and vice versa. Participants were equally capable of spotting the contradictions by the neutral commentators. Rejection of obviously contradictory evidence arose from a combination of switching off neurones associated with distress and switching on those associated with positive emotions. Perversely, the latter provided a "positive reinforcement" for making biased decisions, which one of the authors described elsewhere as giving a new meaning to the term "political junkie."[6] Crucially, this processing of information and updating of preferences occurred extremely rapidly, bypassing circuits normally associated with reasoning, and it was thought to be outside the realm of conscious control.

This research highlights how views about the relationship between the individual and society, which underpins many health policies—even if they are often poorly articulated[7]—influence and are influenced strongly by political beliefs. Yet these beliefs are not immutable and are also shaped by circumstances, often acting at a subconscious level.[8] Americans living in areas where most welfare recipients are the same race as themselves are more sympathetic to welfare than those in areas where recipients are of a different race.[9] The media plays a part, especially where some outlets rejoice in labelling any collective action as a manifestation of the "nanny state."[10]

One study took advantage of the natural experiment in which Fox News, an outlet widely identified with a right wing agenda, was rolled out across cable networks in American towns between 1996 and 2000.[11] The inclusion of Fox News in cable packages was associated with a shift in voting preferences to the right, and was estimated to have persuaded 3-8% of voters to shift allegiance to the Republicans.

Politicians are often criticised for being all things to all people and for making promises that they then fail to keep. However, as this growing body of evidence shows, the problem may be less what the politicians are actually saying but rather how their words are heard and interpreted.

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Competing interests: Both authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No non-financial interests that may be relevant to the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.

Has the European Clinical Trials Directive been a success?

The academic community expresses concerns about its implementation

J Apperley chair of haematology, Department of Haematology, Imperial College, London W12 0NN **j.apperley@imperial.ac.uk** on behalf of the Road Map Initiative for Clinical Research in Europe

Cite this as: *BMJ* 2010;340:c1862
doi: 10.1136/bmj.c1862

The laudable aims of the European Clinical Trials Directive (EU 2001/20/EC) were to improve the safety and efficiency of both commercial and investigator driven clinical trials and to provide the basis for improved European competitiveness. Unfortunately, even before the directive was finalised, concerns were voiced about potential adverse effects on studies designed to test and implement scientific discoveries in clinical practice (translational research) in Europe.[1 2] Today, five years after implementation, evidence shows that the directive has had a negative effect on translational research.

The directive was designed to optimise patient safety, increase the numbers of patients entered into clinical trials, improve the efficiency of trial implementation, ensure best practice in ethical review and regulatory procedures, and harmonise these procedures across Europe. In fact, the implementation of the directive by individual EU member states has caused legislative differences between the different nations and obstacles to the conduct of clinical trials.[3] Although practice has improved in some areas of Europe,[4] in general the regulatory requirements are highly demanding and expensive, irrespective of the level of risk to which the patient will be subjected by participating in the study; trial implementation is now slower; and investigator (rather than drug company) driven studies are decreasing in number and complexity. All these effects are compounded in the context of multinational studies, where it has been impossible to comply

Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No non-financial interests that may be relevant to the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.

with each nation's ethical and regulatory requirements that are theoretically similar but different in practice.[5-11]

The EU has responded to the concerns by funding initiatives to identify the impact of the Clinical Trials Directive and others to promote international collaboration; to date, nine European organisations have participated in four such collaboratives (table). All have identified problems with the interpretation of the directive in member states and will feed into the review of the directive due in October 2010.

In addition, the scientific standing committee of the European Science Foundation has recently completed a "Forward Look" on investigator driven clinical trials.[12] The European Science Foundation has made 25 recommendations to improve the conduct of translational research in Europe that include not only revision of the regulatory issues but also the need for training and education and adequate funding for approved studies. The four collaboratives (table), whose focus was restricted to the regulatory issues, together with the European Organisation for Research and Treatment of Cancer (EORTC), have identified concerns that overlap with each other and mirror many of the recommendations of the European Science Foundation. These five organisations have now shared their experiences and have identified possible solutions to the most important obstacles to clinical trials in Europe (box).

The directive will undergo formal review in 2010, and this will provide an opportunity to develop practical and concrete proposals for consideration within the EU. From 2009 to 2010 CLINT (facilitation of international CLINical Trials in stem cell transplantation), ECRIN (European Clinical Research Infrastructure Network), EORTC, and ICREL (Impact on Clinical Research of European Legislation) each hosted one or more workshops designed to provide input into a concept for modification that will promote clinical research in Europe. This enterprise culminated in a final meeting in March 2010, organised by EFCGP (European Forum for Good Clinical Practice) at which the results of each were summarised, discussed, and prioritised with the aim of designing a proposal for consideration by the commission. The crucial factor in the success of this initiative was to engage all the key stakeholders (commercial and non-commercial sponsors, investigators from all areas of medicine, ethics committee members, competent authorities, funding bodies, and patients). The voice of academics was unusually silent during the development of the directive—now is the time to be heard.

Possible solutions to obstacles to clinical trials in Europe

- Require only one clinical trials authorisation (CTA) for all multinational clinical trials, irrespective of the numbers of participating nations, either by development of a single CTA application across Europe or mutual recognition of authorisations by competent authorities
- Simplify and harmonise the procedures for clinical trial approval (for example, use just one set of forms) and safety reporting (EudraVigilance and reporting rules)
- Better define and harmonise the roles and review processes of ethics committees (achieve the so called single opinion) and competent authorities
- Adopt a risk based approach—adapt the regulatory requirements to consider the risk associated with the trial with regard to safety reporting (for example, limited safety reporting for commercially approved drugs), data monitoring, insurance, application dossiers, substantial amendments
- Allow co-sponsorship in the case of multinational trials, with the aim of facilitating collaboration between research groups
- Better define terms and concepts (for example, investigational medicinal product (IMP), interventional study, substantial amendment)
- Increase public financial support for investigator driven clinical trials
- Harmonise insurance requirements—for example, uniform costs per country, minimum and maximum indemnity payments, total duration of coverage, and time to permit claims

Initiatives set up to investigate the impact of the Clinical Trials Directive and promote international collaboration

Acronym	Full name and objective	Participating organisations
CLINT	European Group for Blood and Marrow Transplantation (EBMT) CLINical Trials in stem cell transplantation: aims to facilitate international multicentre studies in stem cell transplantation	EBMT; University of Central Lancashire; Imperial College, Centre for Blood and Marrow Transplant Research (CIBMTR)
ECRIN	European Clinical Research Infrastructure Network: aims to provide information, consultation, and services to investigators and sponsors in the preparation and conduct of multinational clinical studies	AEMPS, ATCRIN, BMBFv, DCRIN, EORTC, FINN-MEDI , HECRIN, HRB, ICRIN, Inserm, IRFMN, ISCIII, ISS, MRC, NIHR-CRN, SweCRIN, UBERN
ELN	European Leukaemia Network: focused on initiation of international investigator driven trials from successful national leukaemia study groups	More than 400 university based haematology departments across Europe; coordinated by the University of Mannheim and represented by the University of Frankfurt (European Leukaemia Information Centre)
ICREL	Impact on Clinical Research of European Legislation: focused on the effect of the Clinical Trials Directive	EFGCP; ECRIN; EORTC; ethics committee, Medical University of Vienna; Hospital Clinic I, Provincial de Barcelona

AEMPS=Agencia Española de Medicamentos y Productos Sanitarios, Spain; ATCRIN=Austrian Clinical Research Infrastructures Network; BMBFv=Bundesministerium für Bildung und Forschung, Germany; DCRIN=Danish Clinical Research Infrastructures Network; EORTC=European Organisation for Research and Treatment of Cancer; HECRIN=Hungarian Clinical Research Infrastructures Network; HRB=Health Research Board, Ireland; ICRIN=Irish Clinical Research Infrastructures Network; Inserm=Institut National de la Santé et de la Recherche Médicale; IRFMN=Istituto di Ricerche Farmacologiche, "Mario Negri"; ISCIII=Instituto de Salud Carlos III, Spain; ISS=Istituto Superiore di Sanita, Italy; MRC=Medical Research Council; NIHR-CRN=National Institute for Health Research Clinical Research Network; SweCRIN=Swedish Clinical Research Infrastructures Network; UBERN=University of Bern, Switzerland; EFGCP=European Forum for Good Clinical Practice.

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