SUMMARY CARE RECORDS

RCGP supports use of summary care records

The Royal College of General Practitioners supports the use of the summary care record. We now believe that there are enough checks and balances to make it a significant move forward in patient safety and clinical care.

Important changes to security have been made since the scheme was first introduced. The record is now held securely and can only be accessed using computers attached to the NHS spine network. An audit trail is produced whenever the record is accessed, and patients can request information about access to their record.

The original model was based on patients opting out, but it is now “consent to view.” Patients will now, except in certain circumstances, always be asked before their record is accessed. They can still refuse to have a summary record, change their minds at any stage, and limit what is being shared. This is a reasonable model offering the best protection of confidentiality balanced against the best access to information when appropriate.

Some general practitioners see the summary care record as a threat to their position as they would have been had they not be able to place themselves in the same circumstance, always be asked before their record is accessed, or “should have been accessed” without their consent.

Patients cannot change their mind because once their summary care record has been accessed, or “should have been accessed” (whatever that turns out to mean), they will not be able to get it completely deleted. They will not be able to place themselves in the same position as they would have been had they opted out of a summary care record in the first place.

No one has asked me

The Royal College of General Practitioners’ assertion that it supports the use of the summary care record highlights how out of touch it is with frontline general practice. No one has asked me, a member, whether I support the summary care record either in principle or in the way in which it is being rolled out.

General practitioners, and their patients, have severe misgivings about this programme. Some GPs accept that, for a few people, increased availability of certain aspects of their medical data might be useful, but the summary care record is not the only way. There are better ways that also ensure that the patient remains in full control of all aspects of the data being shared and that trust between GP and patient is maintained. The decision whether information needs to be shared widely, and by what means, should be made by patients with the person who knows their medical history the best—their GP.

Many GPs do not accept that the summary care record should be created with implied consent, requiring patients to opt out to prevent their data being processed in this way. They also do not accept that patients’ summary care records should be “enriched” without their explicit consent.

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Whistleblowing

Crucial for a “world class” NHS

People’s willingness to highlight justifiable concerns is predicated on their working in a safe, sound, and supportive context. The term whistleblowing implies that such a function is special or exceptional. It should be a systemic and systematic part of any organisation’s gathering of feedback intelligence informing it how well it is doing. It seems perverse that the NHS, a “learning organisation”, is not regularly considering all available experiences and feedback to inform and optimise its functions.

The message from many who have worked with doctors who have blown their cover and any whistle and then lost their jobs and careers in the NHS is: “Don’t do it”—at least alone. The rhetoric and the policies are full of worthy words, but many doctors have mortgages and families to educate, as well as any duty of care to the public and those they manage, employ, or treat.

The best way to ensure that the NHS is never “world class” is to create the climates of fear, bullying, and despair that prevent good, honest, and aspiring employees from being able to talk about how they feel about their work and what they are asked, cajoled, or forced to do. It’s not good enough to expect individuals to do this alone: psychotoxic and, perversely, incentivised behaviours need to be rooted out from the top down. Many taxpayers and citizens have little or no understanding of how the NHS functions behind its front end. It is time they did—just like party political systems have come under scrutiny.

Conservative Party on health

GP commissioning

In his editorial on the Conservative Party’s health policies, Ham asks how family doctors will be motivated to commission services. The simple answer for many of us is, give us a system in which we can meaningfully commission.
During fundholding, we abolished our waiting lists, transformed our previously inadequate mental health service, set up new services such as practice based physiotherapy and cardiac rehabilitation, and brought about rapid change in several services provided by our regional hospital, such as day case cataract surgery and access to termination of pregnancy. And it was cheaper for the taxpayer and returned substantial sums to the health authority. At the time we advised patients to cancel their private health cover as it had few benefits over the NHS service we could offer them.

Several years into practice based commissioning, we are still waiting for any serious act of commissioning to take place, let alone one over which we have had any influence. When our award winning mental health team was recently privatised and broken up by the primary care trust, our wishes and the wishes of all the practices around were steamrollered by the commissioning primary care trust. We had told the trust that we viewed this as a test case of whether the intention to make commissioning practice based was real.

We can be motivated to improve services, encourage change, and make efficiency savings, but it requires some genuine participation in and influence over the process.

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Exit strategy is a vain hope

Ham is right to raise the issue of failure of providers and lack of clear exit strategies.1 As a former physician who chaired a first wave trust, I had to try to come to terms with the concept of markets.

A visit to the United States to see how its system performed was very enlightening on the fate of failed institutions—they disappeared. I asked the then health secretary, William Waldegrave, about the Conservative government’s strategy for dealing with failure and exit, and was told that its plan was so good that failure was inconceivable. Events have proved that his optimism was not entirely justified, but the one thing that has not happened is the development of any strategy about exit.

Ham is perhaps optimistic about any government’s willingness to accept failure and exit. In the current political climate it is unlikely to happen. The market does not have the capacity to replace the services in a way that would be acceptable to the voters, and they would not tolerate the disappearance of local (always “well loved”) institutions.

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Competing interests: None declared.

PAPERS WITH INDUSTRY TIES

Classic confounding conflicts

The paper by Jagsi et al in Cancer examining conflicts of interest in published clinical cancer research and reported by Tanne may be an example of classic confounding.1,2 The industry funded trials may differ from non-industry funded trials in a way—for example, the treatments used—that is associated with the outcome. The treatments they compare are actually more effective.

The authors themselves note this, though not very clearly. Industry funded trials may not distort results at all (which is not the impression left in the reader’s mind after reading the BMJ), but they address different questions.

They may choose to investigate areas of cancer where success is likely to be greater. The questions they address and the designs of the studies may be different. This is bias, but of a very different nature from the idea that they distort results. The evidence is they tend to interpret similar results with a more positive spin, but the results themselves are not distorted.

Had Jagsi et al compared like with like in terms of the types of trials they may (or may not) have found similar results. The paper in Cancer has not answered the correct question.

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Competing interests: None declared.

Up and downs of balloon times

In the United States, treatment of ST elevation myocardial infarction by primary percutaneous coronary intervention is most effective if given within 90 minutes after admission to hospital.1 In the United Kingdom, the 90 minute door-to-balloon time is likely to be adopted as a hospital indicator of performance of percutaneous coronary intervention.

Management of acute coronary syndromes in all 228 acute hospitals in the UK is monitored nationally.2,3 We compared the recording of door-to-balloon time with in-hospital mortality during 2004-7 in the five largest centres performing percutaneous coronary intervention.

Patients who died in hospital were over 50% more likely to have incomplete data on door-to-balloon time than those who were discharged (relative risk 1.6, 99% confidence interval 1.2 to 1.9). Conversely, patients were more than twice as likely to have died in hospital if their door-to-balloon time was missing (2.1, 1.4 to 3.2).

This systematic bias introduced by incomplete data recording could lead to an inappropriate assessment of a centre’s performance. If the door-to-balloon time is to be used as a performance measure for ST elevation myocardial infarction, the reporting bias in national data must be tackled.

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COMMUNITY CLOSTRIDIUM DIFFICILE

Clostridium difficile infection

Rangiah and colleagues comment that currently used tests for Clostridium difficile toxin are not very sensitive.1 However, the specificity of these commercial assays also ranges from 97% to 99%, meaning that approximately 1-2 out of every 10 positive results using these kits are incorrect.2 False positive results are even more likely when testing faecal samples from the community, where the prevalence of C difficile infection is expected to be much lower than in hospitals.3 Alerts have recently been issued about the poor accuracy of these methods with the advice that laboratories do not rely on single tests for the detection of C difficile toxin.4

Competing interests: None declared.

The authors emphasize the importance of recent hospital admission and antibiotic treatment as major risk factors for community associated *C. difficile* infection, quoting a study by one of us (MWH). However, this study (and others) also shows that about a third of community-associated cases of *C. difficile* infection have neither of these risk factors. Thus, general practitioners should not rely on these risk factors alone to arouse suspicion of community-associated *C. difficile* infection. Recent guidelines state: “All cases of diarrhoea among people in the community aged 2 years and above should be investigated for *C. difficile* infection unless there are good clinical or epidemiological reasons not to.”

All laboratories should be using the same testing criteria for *C. difficile*, so that cases are not missed and the value of mandatory surveillance data is not reduced. Suboptimal tests also undermine surveillance and potentially control measures. The optimum use of available tests, including combinations of assays, needs to be defined.

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Competing interests: None declared.

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LAPAROSCOPIC SURGERY TRAINING

Try fresh frozen cadavers

Virtual reality simulation in training for laparoscopic surgery has advantages, but a more realistic training for teams can be achieved with fresh frozen cadavers. The storage and use of cadavers for the purposes of laparoscopic training is authorised under the Human Tissue Act 2004, which replaces the Human Tissue Act 1961, the Anatomy Act 1984, and the Human Organ Transplants Act 1989. Our two specialist colorectal centres currently use such cadavers for laparoscopic colorectal training for the national training programme. Cadavers are fresh frozen and thawed before use, providing a realistic operative experience for trainees and the team in terms of:

- Perfect reproduction of laparoscopic anatomical landmarks
- Realistic flexibility and consistency of tissue
- Tactile feedback from tissue handling
- Gravity and retraction making simulation more realistic
- Technical steps being identical to those in live operations.

Simulation based training occurring outside the clinical setting risks isolating the trainer from the team, and creates an oversimplification of a complex reality. Laparoscopic training using fresh cadavers allows all members of the team to train together. The team also gains experience of operation room set-up, use of instruments, and patient positioning and safety.

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Competing interests: None declared.


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PAYING FOR EXPENSIVE MEDICINES

Oncologists and top-ups

Oncologists believe that their patients would benefit from licensed drugs that either are not yet the subject of guidance from the National Institute for Health and Clinical Excellence (NICE), or not approved by NICE. Analysis of requests for discretionary payments for off-label treatment for BUPA (British United Provident Association) members with malignant disease also shows that they believe their patients would benefit from off-label chemotherapy and biological treatment.

In the 12 months to 31 August 2008, 162 different off-label regimens were assessed for discretionary payment using an algorithm similar to that published for interventional procedures. Seventeen were for unlicensed drugs. Of the remaining 145 for licensed agents, 75 were for malignancies not specified on the licence, 42 for unlicensed combinations with other drugs, 25 for a different line of treatment, and three for a different stage of disease.

Bevacizumab featured in 48 requests: 16 for cancers for which it was not licensed, 18 for unlicensed combinations, and 14 for an unlicensed line of treatment. Lapatinib featured in six requests, trastuzumab and sorafenib in five each, bortezomib and rituximab in four each. The modal number of requests per agent was one.

Twenty of the regimens were declined funding because they were unsupported by evidence—for example, thalidomide and dexamethasone for hormone resistant prostate cancer. Fourteen were funded in the context of trials (but not otherwise), 115 as one-offs because of the patient’s clinical circumstances, and 13 routinely at this first request and subsequently.

These data suggest that the use of top-ups in the United Kingdom may be more common than Desai and colleagues anticipate, and that these episodes are commonly clinically justifiable.

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Competing interests: BUPA offers private medical insurance but not a top-up product.


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DRUG HYPOGLYCAEMIA

Hypoglycaemia in mental illness

Suzuki and colleagues describe hypoglycaemia induced by second generation antipsychotic agents in schizophrenic non-diabetic patients. Since 2003 we have tested all patients treated with antipsychotic drugs at the university psychiatric centre in Belgium using a standard protocol including an oral glucose tolerance test. From November 2003 to July 2007, 2223 tests were conducted in 707 non-diabetic patients with severe mental illness screened for metabolic disturbances. Of the 2223 tests, 19.2% yielded a glucose concentration at 120 minutes of <3.9 mmol/l; 26.6% were between 3.9 and 3.3 mmol/l, 5.9% between 3.3 and 2.8 mmol/l, and 2.7%<2.8 mmol/l.

Multilevel regression of hypoglycaemia at 120 minutes found that increased risk was not associated with insulin resistance, antipsychotic drug, diagnosis, age, race, or sex. The risk of hypoglycaemia was negatively associated with fasting glucose concentration, fasting

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Multilevel regression of hypoglycaemia at 120 minutes found that increased risk was not associated with insulin resistance, antipsychotic drug, diagnosis, age, race, or sex. The risk of hypoglycaemia was negatively associated with fasting glucose concentration, fasting
insulin concentration, body mass index, and a worse overall metabolic profile in multivariate regression models with covariates for age, sex, race, antipsychotic drug, and diagnosis.

None of the patients presenting with a glucose concentration below 3.9 mmol/l had previously been diagnosed with reactive hypoglycaemia or complained of possible hypoglycaemia before the test. Also relevant is the finding that 7.4% of military draftees had a 2 hour postload glycaemia below 2.7 mmol/l in an oral glucose tolerance test, and occasionally values as low as 1.9 mmol/l are found in asymptomatic healthy individuals. Thus the prevalence of hypoglycaemia in our patients was not unusually high and second generation antipsychotics seem not to induce reactive hypoglycaemia.

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NON-COMMUNICABLE DISEASES

Please redress the balance of millennium development goals

The landmark millennium development goals provide a road map for reducing the disease, poverty, and hunger faced by millions worldwide. Unfortunately, the progress they have instigated is at risk of being undermined by new threats.1 Cancer, cardiovascular disease, diabetes, and other non-communicable diseases (NCDs) currently claim more than 35 million lives each year, accounting for 60% of all deaths worldwide. When measured in disability adjusted life years (DALYs), they also account for nearly half of the entire burden of disease globally. Fortunately, many interventions simultaneously prevent many of them, thus improving cost-benefit ratios. Their effective control also requires the strengthening of health service structures, thereby providing benefits that encompass infectious diseases, although the reverse is not the case.

The impact of NCDs can be felt in all regions of the world and all age groups. Most (80%) deaths from them occur in low and middle income countries, where they often strike at much earlier ages. Cancer alone accounts for around 5.7 million deaths annually in low and middle income countries—more than 70% of all cancer deaths. In many respects, the millennium development goals define the world’s public health agenda. They establish funding priorities and direct the actions of ministries, healthcare institutions, and non-governmental organisations. Regrettably, NCDs, the world’s leading causes of death and disability, are not specifically addressed in them.

Last year the International Agency for Research on Cancer predicted that global cancer incidence could more than double by 2030, with 27 million incident cases of cancer and 17 million cancer deaths annually. Yet, with a few honourable exceptions, there has been no acknowledgment or proportionate response by governments to this crisis. We already know many of the steps to control NCDs. We must now summon the political will to act. We urge the members of the forthcoming annual ministerial review of millennium development goals, due to meet in Geneva on 6-9 July 2009, to consider the grave impact that NCDs, including cancer, have on human health and wellbeing, and to take steps to balance the millennium development goals so that they truly encompass all major causes of death and disability worldwide.

The full version of this letter is on bmj.com

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Competing interests: None declared.
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