NEWS

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Critics question whether "friends and family" test is fit for Cameron's purpose

Patients are urged to boycott trials that do not guarantee publication, in new initiative



Iain Chalmers (left), Fiona Godlee, and Ben Goldacre are among the campaigners for full disclosure of trial data, without which the evidence on drugs is skewed

Zosia Kmietowicz BMJ

Campaigners for the publication of the results of all clinical trials have launched a public petition to increase pressure on researchers, funding bodies, and institutions to take action.

They are also urging people who are thinking of taking part in a clinical trial to agree to participate only in those trials that have been registered and that promise to publish the results in full.

The initiative (alltrials.net) is backed by Sense About Science, the *BMJ*, the Cochrane Collaboration, the James Lind Alliance (an alliance set up to identify priorities for research), *Bad Science* author Ben Goldacre, and the Centre for Evidence-Based Medicine at Bond University, Queensland.

Tracey Brown, Sense About Science's director, said, "Everybody agrees that clinical trials should be registered and that we should at the very least have clinical reports on what was found. There have been years of foot dragging and non-compliance with requirements. We expect regulatory bodies to evaluate the best available evidence, not half of it. The missing results from the last 20 years also represent lost opportunities to learn from all that research and to develop some of it in light of new discoveries."

The petition comes amid a number of schemes targeting the full disclosure of clinical trial data, including the *BMJ*'s first open data campaign, which aims to get the drug company Roche to release full reports on oseltamivir (Tamiflu).[1]

The House of Commons Science and Technology Committee announced in December that it would hold an inquiry into missing data early this year.[2] Other MPs, including the Conservative Sarah Wollaston, have asked the Commons Public Accounts Committee to conduct an inquiry into the waste of NHS resources caused by trial data being concealed.[3]

In an editorial this week Iain Chalmers, of the James Lind Alliance, Paul Glasziou, professor of evidence based medicine at Bond University, Queensland, and Fiona Godlee, editor in chief of the *BMJ*, explain why the withholding of trial results is important to people in trials.[4] They wrote: "This matters because participants in clinical trials assume that they are contributing to the advancement of medical knowledge; non-publication of study results negates this reasonable assumption and betrays those who have volunteered.

"Non-publication also matters because failure to publish all the results from clinical trials distorts the evidence base for clinical decisions."

EDITORIAL, p 8; FEATURE, p 18

Cite this as: *BMJ* 2013;346:f106

NHS's main regulator has lost the confidence of the public, say MPs

Adrian O'Dowd LONDON

The NHS's main regulator, the Care Quality Commission (CQC), has lost the confidence of the public and will have to work hard to regain trust, MPs have claimed in a new report.[1]

MPs on the parliamentary health select committee have also warned that the ongoing registration of general practices by the commission will be a major challenge and a test of whether the regulator has learnt from past mistakes.

The new report says that despite sustained criticism over a prolonged period and several scandals over standards of healthcare the commission has not yet successfully defined its core purpose or earned public confidence.

The MPs conclude that the commission's main focus should be to ensure that the essential standards it enforces could be interpreted by the public as a guarantee of acceptable standards in care.

"We do not believe that the CQC's essential standards in their current form succeed in this objective," says the report. "As a result, patients, residents and relatives do not have confidence in the CQC's standards or the outcomes of inspections."

The commission has been through a year of changes, say the MPs, mentioning the resignation of Cynthia Bower as chief executive in February 2012, her replacement being David Behan, and the resignation of its chairwoman, Jo Williams, in September, her replacement (in December) being David Prior.

Launching the report, the committee's chairman, Stephen Dorrell, said, "The CQC needs to ensure that its inspections represent a challenging process which is designed to find service shortcomings where they exist; ensure, when appropriate, that service providers address them rapidly; and report promptly both to providers and users of the service. The CQC also needs to show that it treats feedback from the public as free intelligence."

Cite this as: *BMJ* 2013;346:f124

Approval of more than 100 firms to run NHS services sparks concern

Gareth Iacobucci BMJ

More than 100 private firms have been given the green light to provide a host of NHS services in England under the government's "any qualified provider" scheme.

Department of Health figures show that 105 private companies have been approved to run services such as physiotherapy, adult hearing services, and community diagnostics, alongside 140 NHS organisations.

Firms such as Care UK, Virgin Care, and BMI Healthcare are set to increase their share of NHS service provision through the new policy, which allows accredited private, NHS, and not for profit providers to operate a range of NHS community and mental health services without undergoing a full tendering process.

The policy is part of the government's drive to offer patients more choice and control over their care by increasing the number of providers at a local level. But it has sparked concerns among doctors that the array of providers may lead to fragmentation of services.

The health department said that 87 providers were already up and running and providing services to patients under the scheme: 38 from the private sector, 26 NHS organisations, and 23 social enterprises or not for profit organisations.

A recent report suggested that social enterprises and charities were being squeezed out of the market to provide services by a small number of private companies that dominate the sector.[1]

Among companies making inroads are Inhealth, which told the *BMJ* that it had won 36 contracts—mostly for adult hearing services and ultrasonography—and the high street chain Specsavers, which has won adult hearing contracts in 33 areas.

Care UK, which already provides primary care, diagnostic, and elective care services to more than 15 million patients in England, said that it had won around 35 new contracts under the scheme, more than half of which are for community based ultrasound diagnostic services.

Richard Branson's Virgin Care has been accredited in 10 areas of the country where it has applied to run services, including dermatology, ophthalmology, ultrasonography, and musculoskeletal services.

Richard Vautrey, deputy chairman of the BMA's General Practitioners Committee, said that the committee had "serious concerns" that the disparate spread of providers could fragment the care of patients.

Cite this as: *BMJ* 2013;346:f156

Union president Paul McKeown (right) has called a meeting to discuss the pay of George McNeice (left)

Irish doctors are angry as their union boss leaves with €9.7m package

Muiris Houston GALWAY

The chief executive of the Irish Medical Organisation has taken early retirement amid concerns among members about the body's ability to fund his retirement package.

George McNeice has left with a package worth around €9.7m (£7.9m; $12.6m), including a pension fund of about €4.5m, a contractual termination payment of €1.5m, and delayed pension payments of €3.75m.

However, it has emerged that the terms of his contract entitled him to an overall settlement of €20m. The organisation said in a statement that after negotiations it had succeeded in reducing the amount by more than 50%.

The revelation has caused widespread anger among the organisation's 5000 members. Some have taken to social media sites such as Twitter to announce their resignation from the organisation. Many have called for an extraordinary general meeting to allow for a full debate on the issue.

Although a general meeting has not been ruled out, the organisation's president, Paul McKeown, has announced a "special" meeting of members for Saturday 12 January. On the agenda is the financial position of the organisation. Acknowledging the disquiet among members, McKeown said, "I share the anger which I have no doubt all members will feel in relation to this matter."

Doctors expressed annoyance that their annual subscriptions, in the region of €1250 for GPs and €800 for junior doctors, may be needed to fund the substantial settlement, but McKeown reassured members that their future membership subscriptions were protected and would not be needed.

In 2003 the organisation granted McNeice, who is in his early 50s and who has had a total of 30 years of service, an annual salary of €250 000 together with a discretionary performance related bonus of 30% of salary. In addition, one third of a previous year's bonus was to be automatically consolidated in the salary for that year and would form the basis for his remuneration from then on. It also committed itself to making an annual pension contribution of 35%. His current salary is €492 355.

The organisation acknowledged that McNeice acted within his rights, given his contractual entitlements. However, although his pension plan was originally to be based on defined contributions, it has emerged that in its place a former president of the organisation negotiated a defined benefit arrangement with McNeice.

The financial implications of funding a defined benefit pension from when its chief executive reached his contractual retirement age of 55 led to concerns about the organisation's financial stability.

Cite this as: *BMJ* 2013;346:f97

Scheme highlights "hidden nasties" in food

Annabel Ferriman BMJ

The UK government launched a series of advertisements this week to encourage healthy eating. Part of its Change4Life scheme, the advertisements highlight how much sugar is in an average can of cola and how much fat in an average pizza.

By signing up to the scheme families will receive a compilation of healthy recipes and be able to receive offers on food products at more than 1000 Asda, Aldi, and Co-operative Food shops across the country.

The scheme was criticised by Jeanette Longfield, children's food campaigner at the food and farming charity Sustain, who said that she was disappointed that the government had opted for a voluntary approach. She called for a ban on companies marketing junk food to children.

Cite this as: *BMJ* 2013;346:f119

Primary care complex offering public and private healthcare to 30 000 opens in Somerset

Gareth Iacobucci BMJ

A new health complex providing primary and secondary care services to tens of thousands of patients under one roof has officially opened its doors.

The £10.5m Frome Medical Centre, developed in a new purpose built complex in the Somerset town, will house 130 health professionals, including more than 30 GPs and a host of consultants—making it one of the biggest integrated primary care buildings in the United Kingdom.

The centre, which has been in development for more than a decade, aims to offer patients a one stop shop for accessing NHS and private health services on their doorstep, rather than travelling to hospital facilities out of town.

The building, located opposite the existing community hospital in Frome, has been funded and developed by partners at the Frome Medical Practice, who have invested £100 000 each to fund the project.

As well as offering routine GP appointments, blood testing, and other primary care services to almost 30 000 patients, the centre will provide NHS outpatient services in areas such as minor surgery and mental healthcare, alongside private services such as a pharmacy, opticians, chiropractic, and plastic surgery.

ANDREW CARPENTER

Services at the centre include minor surgery, a pharmacy, chiropractic, physiotherapy, and acupuncture

A private physiotherapist, podiatrist, acupuncturist, and an aesthetic practitioner will also rent space in the 4400 square metre building, as will the nearby Beckington Family Practice, serving an additional 8000 patients.

The centre was initially conceived 12 years ago but has only now come to fruition after the practice secured the funding and planning permission it needed to make the move. It has been designed with a focus on healthy living and includes a café, a staff gym, and incentives to staff and patients to use alternatives to driving to the new centre.

Tina Merry, senior partner at the Frome Medical Practice, said that the new centre would see consultants and GPs collaborating more for the benefit of the local population.

Cite this as: *BMJ* 2013;346:f130

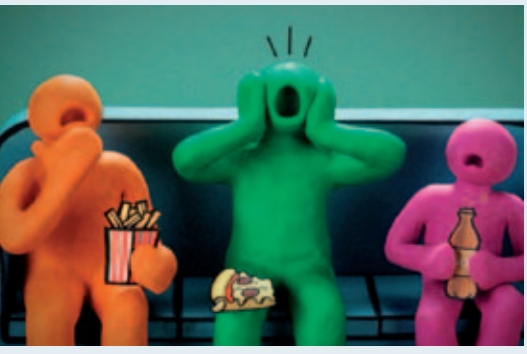
GPs don't have "time or inclination" to make changes to NHS, report says

Nigel Hawkes LONDON

Clinical commissioning groups will need an unusual combination of skills to meet the challenges that the NHS in England faces, new research concludes.[1]

And it is far from clear that GPs—the chosen instruments for exercising clinical leadership under the reorganisation of the NHS—have either the time or the inclination to make it work.

John Storey and Richard Holti of the Open University studied the role of clinical leadership in the redesign of sexual health and dementia services in London and Manchester. They said that clinical leadership was often seen as the answer to the problem of managing rising demand without any more money, but such declarations often underestimated the actual challenge.



In three of the four service redesigns they examined, GPs had little involvement: clinical leadership came from the hospital sector. "This has implications for the new CCGs which will take charge of the largest part of the NHS budget from April," they wrote.

Service redesign was "inherently difficult," the report said, because it involved changes that were both clinical and non-clinical, including areas such as organisation of clinics, booking systems, IT systems, and tariffs. To change the way a service was delivered involved challenging established habits in a wide range of occupational areas and in several distinct organisations. In contrast to the government's mantra that reconfiguration should be locally led, the report found that it was facilitated by national strategy.

Such strategic direction provided the material for local leaders to work with, it said. "Exhortation for more clinical leadership needs to be balanced by continuation of the effort in developing national strategies for particular clinical areas," it said. Money to facilitate change was also important; modernisation of sexual healthcare in London, for example, required £5m.

The experience of those involved in the four case studies showed many pitfalls. In some cases, managers objected to clinicians getting involved at all; in others, enthusiastic leaders eager for reform failed to carry colleagues with them.

Faced with the difficulties, some clinicians had become passive and fatalistic, while others restricted their ambitions on local leadership to a unit level. Relatively few had the necessary combination of persistence and skill to make widescale change happen.

Holti told the *Times*, "Formal project planning is not enough; rather, informal, lateral leadership is important. This is needed in order to bring along clinical colleagues, to reassure them and to win their cooperation and ideas. The most effective service redesigns were achieved when both of these processes worked in tandem."[2]

Cite this as: *BMJ* 2013;346:f102

IN BRIEF

Campaign for voluntary euthanasia will continue: The widow of Tony Nicklinson, who campaigned for the right for a doctor to end his life, has won the right to take his case forward. Jane Nicklinson will argue that the current law on assisted suicide is incompatible with a person's right to respect for dignity and autonomy under article 8 of the European Convention on Human Rights. Tony died in August 2012 after losing a High Court battle for voluntary euthanasia.[1]

Achievements of joint commissioning are questionable: No evidence exists that joint commissioning in health and social care improves local outcomes, found a study that examined selected sites of "best practice."[2] One of the authors of the report, Helen Dickinson, said, "If the government does not have a clear sense of what joint commissioning should deliver then there is a question over whether it should be pressurising CCGs and local authorities to combine budgets."

β blockers improve lung cancer survival: Patients with non-small cell lung cancer survive longer if they take β blockers while receiving radiotherapy, shows a study of 722 patients.[3] The 155 patients who were taking β blockers for other conditions, such as high blood pressure and heart disease, survived for an average of 23.7 months, whereas the 567 patients who were not taking β blockers survived for an average of 18.6 months.

Evidence on homeopathic flu remedy is inconclusive: A Cochrane systematic review has found that there is insufficient good evidence to say whether the homeopathic treatment Oscillococcinum helps to prevent or treat flu and flu-like illness.[4] One of the authors, Robert Mathie, said, "The findings do not rule out the possibility that Oscillococcinum could have a clinically useful treatment effect but, given the low quality of the eligible studies, the evidence is not compelling."

Consultation opens on next round of QOF indicators: The new list of 14 Quality and Outcomes Framework indicators for 2014-15 is open to public consultation (http://bit.ly/UBx1mH). It includes four proposed indicators relating to dementia and two potential indicators to improve the care of people who have a history of stroke or transient ischaemic attack.

Cite this as: *BMJ* 2013;346:f109

MICHAEL DONNE/SPL

The difference in incidence may partly be the result of variation in case definition, experts think

UK has fifth highest rate of type 1 diabetes in children, new figures show

Gareth Iacobucci BMJ

The United Kingdom ranks fifth of 88 countries in the incidence of type 1 diabetes in children, a new analysis has shown.

A league table compiled by the charity Diabetes UK from data from the International Diabetes Federation shows that each year 24.5 in every 100 000 children aged up to 14 years are given a diagnosis. Only Finland, Sweden, Saudi Arabia, and Norway have a higher incidence.

The UK rate was more than double that of France (12.2 diagnoses in every 100 000 children) and Italy (12.1). The lowest reported rates were in Papua New Guinea and Venezuela, where just 0.1 diagnoses were made per 100 000 children.

The charity's table lists the 88 countries with available data on the incidence of type 1 diabetes.

Diabetes UK said that it was vital that people in the UK were aware of the symptoms of type 1 diabetes, given its high incidence. It warned that just 9% of parents were currently aware of the "four Ts" of type 1 diabetes symptoms: toilet (frequent urination), thirsty (excessive thirst), tired (extreme tiredness), and thinner (unexplained weight loss).

It said that this lack of awareness was one of the main reasons why a quarter of the 2000 UK children a year who developed diabetes were given a diagnosis only once already seriously ill.

Barbara Young, chief executive of Diabetes UK, said, "We do not fully understand why more children in the UK are developing type 1 diabetes than almost anywhere else in the world. But the fact that the rate is so high here in the UK means it is especially important that parents know the symptoms.

Young added, "The fact that the UK has a relatively high number of children developing type 1 diabetes also means it is vital that we are able to offer first class healthcare once children are diagnosed. Too many children are not getting the recommended checks and have high blood glucose levels, while another big issue is that young people are also being lost in the system when the time comes to transfer from paediatric to adult services."

Kamlash Kunti, professor of primary care diabetes and vascular medicine at the University of Leicester, said that some of the variation could be attributed to the way that cases were classified. He said, "We know there are some people in the age range 10-14 who may have type 2 diabetes but are classed as type 1. If your case definition is not tight, then you can get these discrepancies."

He added: "It [the UK rate] is in line with all other developed countries that we would compare ourselves to. There's not a huge difference between our rate and the US, Australia, and Canada."

Cite this as: *BMJ* 2013;346:f22

Hormone releasing IUD should be used more in primary care for menorrhagia, study concludes

Zosia Kmietowicz BMJ

Women with menorrhagia reported more improvement in bleeding and quality of life with the levonorgestrel releasing intrauterine system than with other treatments available in primary care, a two year study in England has found.[1]

Women fitted with the levonorgestrel releasing intrauterine system (also known as LNG-IUS or Mirena) were also more likely to stick with treatment, found the study, called the Effectiveness and Cost-Effectiveness of Levonorgestrel-Containing Intrauterine System in Primary Care against Standard Treatment for Menorrhagia (ECLIPSE) study.

Researchers from the Universities of Birmingham and Nottingham randomised 571 women to treatment with either LNG-IUS or another standard medical treatment, such as tranexamic acid, mefenamic acid, combined oestrogen and progestogen, or progestogen only.

Expert warns some health and wellbeing boards are too "pink and fluffy"

Adrian O'Dowd LONDON

Some of the new bodies that bring together the NHS, public health, and local authorities to coordinate health services in England lack the "stiffness of spine" to make actual improvements in healthcare, MPs have been told.

The local health and wellbeing boards were discussed during an evidence session of the parliamentary communities and local government committee on 7 January.

Chris Bentley, an independent consultant on population health who has been working with local authorities on health, said, giving evidence, that he was sceptical of the positive effect that health and wellbeing boards would make when they became fully operational from April.

Trying to close the gap in health inequalities between people from the most deprived areas and the most affluent was difficult, he said.

"Looking at the way the new arrangements are coming into place, I am a little worried that they don't have the kind of firmness or the stiffness of spine that is going to be necessary to drive forward measureable change at population level from local authorities," said Bentley.

"That [change] is happening in a number of places that I have been working with, but I wouldn't say it was universal. There are some areas where I would say the arrangements are a bit 'pink and fluffy' and are not going to necessarily enable people to drive forward changes. Nowhere I have seen has got it perfect yet."

Many boards were planning to hold only four meetings a year, he said. "If you are only going to have four meetings a year, you've got to have some sort of pretty durable structures that can do things between the meetings."

Cite this as: *BMJ* 2013;346:f136

Leeds surgical team performs first hand transplantation in UK

Susan Mayor LONDON

A surgical team has reported encouraging results of the United Kingdom's first hand transplant operation, which used a new technique to amputate the recipient's non-functioning hand during the procedure, enabling the surgeons to accurately rebuild nerve structures to the transplanted hand.

The team at Leeds General Infirmary carried out the complex eight hour operation on 27 December 2012, after a donor limb became available. Its tissue matched one of the two patients listed to receive a hand transplant, 51 year old Mark Cahill, who was unable to use his right hand because of severe gout.

"This operation is the culmination of a great deal of planning and preparation over the last two years by a team including plastic surgery, transplant medicine and surgery, immunology, and rehabilitation medicine," said Simon Kay, the consultant plastic and reconstructive surgeon who led the operation.

"The team was on standby from the end of November awaiting a suitable donor limb, and the call came just after Christmas," he explained. "It is still early days, but indications are good and the patient is making good progress."

Hand transplantation was pioneered in Lyon, France, in 1998. Kay works closely with the transplant team in Lyon, where several successful hand transplantations have been carried out. But this was the first time that a patient's hand had been amputated during the procedure to attach the transplanted hand.

Two surgical teams worked at nearby hospitals at the same time, one removing the donor's hand while a second amputated the patient's hand. They mapped the nerves, blood vessels, and tendons very precisely before transplantation, marking them up on each hand.

LEEDS INFIRMARY

Simon Kay (left) used a new technique to transplant a hand for Mark Cahill (right)

This enabled them to connect the nerves, blood vessels, and tendons and bones in the patient's wrist very accurately to those in the donor hand. After attaching the bones and some tendons, the team connected the blood vessels to restore circulation to the transplanted hand. The remaining tendons were then connected and the nerves repaired.

A hospital spokesman said that the patient could not yet feel the transplanted hand but that he could move the fingers slightly. The spokesman said, "The team considers that the transplant is doing better than some other similar transplants at this stage," adding that it was too early to comment on the success of procedure, given the risks of transplantation.

Cite this as: *BMJ* 2013;346:f79

After six months all patients reported improved outcomes, but women treated with the LNG-IUS improved significantly more than did other women. On the menorrhagia multi-attribute scale women with the LNG-IUS scored a mean increase of 32.7 points, whereas among other women the mean increase was 21.4 points. The difference between the two groups remained significant after two years (mean difference over two years 13.4 points (95% confidence interval 9.9 to 16.9),

SATURN STILLS/SPL

Women need to know about treatments for menorrhagia, including LNG-IUS

and improvements were shown in all the domains measured by the scale, including social life, work and daily routine, and psychological wellbeing.

After two years nearly two thirds (64%) of the women fitted with the LNG-IUS were still using it, compared with just over a third (38%) of women using the other treatments. At the end of the trial about half the women who were receiving the usual treatments switched to LNG-IUS.

A study author, Joe Kai, a GP and professor of primary care at the University of Nottingham, said, "Heavy menstrual bleeding can be very debilitating, but we know that many do not seek help. We need to make women more aware that beneficial treatments are available and to offer options such as LNG-IUS more often."

Another author, Janesh Gupta, professor of obstetrics and gynaecology at the University of Birmingham and who is based at Birmingham Women's Hospital, said, "Insertion of IUDs is not part of primary care in all healthcare settings and in some circumstances requires gynaecologist consultation. This trial should encourage the use of IUDs in primary care."

Cite this as: *BMJ* 2013;346:f100

AFP/GETTY IMAGES

Marion Larat, 25, sued Bayer after she had a stroke while taking a third generation contraceptive pill

French doctors are told to restrict use of later generation pills

Sophie Arie LONDON

France is taking steps to stop the overprescription of third and fourth generation oral contraceptives after a legal case highlighted the fact that many women are running an increased risk of serious side effects by taking the pills when alternatives are available.

In the first case of its kind in France, Marion Larat, 25, sued the German drug company Bayer and the head of the French drug regulatory board, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), in December after she had a stroke while taking Bayer's third generation pill Meliane (gestodene with ethinylestradiol). She believes that the drug should have been withdrawn from the French market.

Her case has provoked alarm in a country where half of the five million women taking oral contraceptives are using later generations of pills. These products are known to reduce side effects caused by previous versions, such as weight gain and acne. Studies have shown that the risk of venous thromboembolism is twice as high for women using third and fourth generation pills than for those using earlier versions, although it remains low.[1] ANSM has advised that later generation pills should never be used as a first choice and only if patients have problems with earlier versions.

The regulatory body has insisted that the newer pills should remain on the market, as they are beneficial to some. But it has announced that from April they will no longer be reimbursed by the social security system. Doctors are being urged to refrain from prescribing the later versions. Health officials are also expected to announce further steps, which may include stripping midwives and nurses of their power to prescribe contraceptives or introducing systems to oblige patients to try older pills first.

"It's a peculiarity of the French system that when a new drug comes along it gets prescribed a lot," said a spokesperson for ANSM. "Today, third and fourth generation contraceptives are the pill of choice for young people. We are working to reverse that trend and get back to the correct usage."

Bayer said in a statement that it was waiting for detailed information about the allegations against it but defended Meliane. "Based on a thorough assessment of the available scientific data by regulatory authorities, external independent experts, and Bayer scientists, combined oral contraceptives are safe and effective and have a favourable benefit risk profile when used as directed," the company said.

In the United States Bayer has paid out $750m (£470m; €570m) in compensation after nearly 3500 legal claims that its third generation pill Yasmin caused deep vein thrombosis or pulmonary embolism, the company said.[2] Another 3800 cases are pending there. Larat's lawyer has indicated that some 30 other women are now preparing to launch similar legal proceedings against several different drug companies.

Cite this as: *BMJ* 2013;346:f121

Changing colour of antiepileptic pills raises risk of non-adherence

Susan Mayor LONDON

Changing the colour of antiepileptic tablets is associated with an increased risk of patients with seizure disorder stopping taking them as prescribed, a US study has found.[1]

Researchers analysed a national database of prescription records of patients with health insurance who started taking an antiepileptic drug between 2001 and 2006. They identified 11 472 patients as being "non-persistent," defined as failing to fill a prescription within five days of the date required to take the drug as prescribed.

They assessed changes in pill colour and shape of generic drugs dispensed in the two refills before patients became non-persistent and compared them with 50 050 controls who had no delay in refilling their prescription, matched for age, sex, and duration of antiepileptic treatment.

"We found that changes in pill colour significantly increase the odds that patients will stop taking their drugs as prescribed," said Aaron Kesselheim, assistant professor of medicine at the Brigham and Women's Hospital in Boston, Massachusetts. He was the principal investigator of the study, which was funded by the Agency for Healthcare Research and Quality, the US federal organisation that works to improve the quality, safety, and effectiveness of healthcare.

Non-persistent patients were 27% more likely than controls to have seen a change in colour of the antiepileptic tablets in their two previous prescriptions. Tablet colour changed in 136 non-persistent cases (1.2%) and in 480 controls (0.97%), giving an odds ratio of 1.27 (95% confidence interval 1.04 to 1.55).

The impact of colour change was even more pronounced in people with confirmed seizure disorder (odds ratio 1.53 (1.07 to 2.18)).

"Pill appearance has long been suspected to be linked to medication adherence, yet this is the first empirical analysis that we know of that directly links the physical characteristics of pills to patients' adherence behavior," said Kesselheim.

"Non-adherence is a really important issue, not only in epilepsy but also in other conditions," he said. The study showed that generic antiepileptic drugs were dispensed in a wide range of colours. For example, patients received extended release carbamazepine in eight different colours, ranging from pink to blue-green.

Cite this as: *BMJ* 2013;346:f19