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- Why have UK doctors been deterred from prescribing Avastin? (BMJ 2015;350:h1654)
- Attacks on publicly funded trials (*BMJ* 2015;350:h1701)
- US ophthalmologists plead with drug regulator not to restrict access to Avastin (BMJ 2015;350:h1266)
- Why using Avastin for eye disease is so difficult (BMJ 2012;344:e3012)

## Time to allow doctors to prescribe Avastin?

Why have doctors in the NHS been left seemingly unable to prescribe a cheap, safe, and effective drug despite its flourishing use elsewhere in Europe and in the US? **Deborah Cohen** investigates where the blame lies and whether the UK's drug appraisal system really acts in the best interests of public health

espite widespread critical coverage in *The BMJ* and elsewhere, use of the expensive drug ranibizumab (Lucentis) to treat wet age related macular degeneration remains dominant over cheaper bevacizumab (Avastin) in the UK.

New evidence uncovered by *The BMJ* raises questions about the legal and regulatory positions that have skewed clinical practice,

fuelled NHS drug costs, and left doctors confused about what they can and can't prescribe. And now clinical leaders are fighting back. Over 100 clinical commissioning groups (CCGs) in England have written to the health secretary, NHS leaders, and the General Medical Council, urging a resolution. The current situation is "untenable," they say. Allowing CCGs to use bevacizumab instead of ranibizumab could release £102m (€138m; \$152m) a year for patient services.

This is particularly unac-

ceptable when publicly funded trials have shown comparative effectiveness and a Cochrane meta-analysis published last year showed there was no difference in serious adverse events between bevacizumab and ranibizumab, they say.

But getting the evidence has been challenging. Drugs manufacturers didn't want to do the trials themselves, and when public

funds were found for a comparative and a dosing trial, they did all they could to scupper them—even turning to the charity Royal National Institute of Blind People (RNIB) for help. Then once the comparative trials were published, they embarked on a campaign to undermine and divert attention from the results, raising safety concerns themselves and via their paid opinion leaders and sponsored charities.



Under pressure: Alex Foss, chief investigator of the Tandem trial and an ophthalmologist, says Novartis tried to derail the trial

#### Research obstacles

Ranibizumab is a monoclonal antibody fragment derived from the same parent monoclonal antibody as bevacizumab. Both drugs act by inhibiting vascular endothelial growth factor (VEGF), preventing blood vessel growth. Roche, holds the intellectual property rights for both, although Novartis has the rights to market ranibizumab in Europe.

Roche, however, has never sought to develop bevacizumab for ocular use "due to corporate considerations."

The company's refusal to conduct trials of bevacizumab forced ophthalmologists to ask, in the *New England Journal of Medicine*: "Who pays for a drug in a clinical trial in which there is no pharmaceutical company or partner?"

The answer: the public purse, which has funded at least six comparative trials around the world. In the UK, the IVAN trial reported its outcomes in the *Lancet* in 2013.

The £10m trial was funded because it was perceived to be a priority for the NHS. As George Young MP put it in 2007: "If it goes ahead, the trial will provide good evidence that would allow regulators such as NICE to recommend the use of Avastin over Lucentis and save the NHS a considerable amount of money."

But generating the evidence base for ophthalmic use of bevacizumab has not been easy.

Barney Reeves, professorial research fellow in health services research at Bristol University and one of the IVAN trialists, told *The BMJ* that it was a difficult trial to do politically.

"The drug manufacturers didn't want it done," he said, adding: "Novartis tried to prevent UK ophthalmologists joining the IVAN trial, with their sales representatives lobbying potential principal investigators against the trial and telling them that the IVAN protocol was seriously flawed."

Emails obtained by *The BMJ* under a freedom of information request show that clinicians with ties to Novartis urged some primary care trusts to pull out of the trial. Novartis also approached ophthalmology centres to conduct trials for them at the same time IVAN was progressing. The company helped investigators obtain ranibizumab for Novartis funded trials but not for IVAN.

"It was a challenge to find a reputable source for the drug—it took months longer than it should have done," Reeves said. "Novartis and Roche could have provided the identical vials of the drugs if they had wanted to. At least one compounding pharmacy that we approached to produce bevacizumab in identical vials had to discontinue negotiations with us because larger contracts with one or other of the manufacturers were being jeopardised," he added.

In the end, the pharmacy at the Royal Liverpool and Broadgreen University Hospitals Trust agreed to provide the drug in prefilled syringes.

Internal Novartis emails, released as part of an Italian investigation into anticompetitive behaviour, show how concerned ranibizumab's European distributor was about the impact comparative trials would have on prescribing. "H2H [head to head] trials will... give physicians more confidence in Avastin," a Novartis email says. To combat this they

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400 mg

NDC 50242-060-02

(bevacizumab)

highlighted "methodological issues" with the comparative trials, funded their own trials, and seeded review articles favouring ranibizumab, internal Novartis documents sav.

The BMJ has also learnt of attempts by Novartis to derail a second publicly funded trial in the UK. TANDEM is an ongoing randomised controlled trial comparing high versus low doses of bevacizumab and monthly versus two monthly review intervals.

The trial's chief investigator is Alex Foss, an ophthalmologist at Queen's Medical Centre, Nottingham. He told The BMJ how, during the trial's planning stage in 2009, a Novartis representative tried to divert him to Novartis funded trial work, with the pros-

pect of future funds for personal research projects.

They met at a local pub, where the representative made clear that Foss must expect strong opposition to the trial. Foss, who took detailed notes of the meeting and circulated them to other researchers involved with TANDEM, told The BMJ: "He then stated Novartis would do everything they could to stop the TANDEM trial and would particularly challenge its ethics," Foss recalls. "He stated that the challenge would not come from Novartis itself but

from the RNIB, which he made clear would support Novartis."

According to Foss, the Novartis executive said that the RNIB had run a "highly successful" challenge campaign for patients with age related macular degeneration to receive ranibizumab before NICE approval and this campaign had been funded by Novartis.

In 2010, the eye charity, which counts Novartis among its regular donors, complained to the Health Research Authority about the TANDEM trial. The complaint came from the RNIB's policy and campaign's manager, Barbara McLaughlan. Today, McLaughlan is Novartis's head of external affairs for oncology.

> The charity took issue with the trial protocol and the patient information sheet, which it thought should warn people in the lower dose arm that they ran

> > "a significant risk of irreversible sight loss." McLaughlan also complained the trial was "really an access programme disguised as a trial," a ruse by the NHS to get more patients on bevacizumab and cut costs. The complaint was ultimately dismissed by the trial's ethics committee and the Medicines and Healthcare Products Regulatory Agency (MHRA).

A patient is injected with Lucentis to treat macular degeneration

#### **OFF-LABEL AND UNLICENSED**

The European Medicines Agency distinguishes between an unlicensed drugone with no licence—and a drug used "offlabel," outside the terms of its marketing authorisation (or licence). After consultation with its legal team, a spokesperson said: "The European Commission and the Agency are of the view that any use of medicines outside the terms of the licence, ie not in accordance with the authorised product information, is considered 'off-label." Notably, the EMA has confirmed that this includes repackaged bevacizumab for use in the eve.

EMA's definition would also apply to a wide range of drugs used in the NHS. It includes variation of dose, frequency, a condition outside the defined indications, routes of administration, or contrary to listed warnings.

Confusingly, however, the GMC in its latest prescribing guidance to doctors combines "off-label" and "unlicensed" into a single category, "unlicensed drugs."

The guidance, issued in early 2013, says that doctors "should usually prescribe licensed medicines in accordance with the terms of their licence." It concedes that "prescribing unlicensed medicines may be necessary," but only "where there is no suitably licensed medicine that will meet the patient's need."

The GMC told *The BMJ* that the MHRA agreed that the "plain English terminology used in our guidance is consistent with the legal framework surrounding the supply of off-label and unlicensed medicines.' But added to the complexity, the MHRA says that doctors should always follow a hierarchy—an unlicensed drug should be considered for a patient only if there is no licensed or off-label product that meets the individual patient's needs. This indicates there is a distinction.

The RNIB told The BMJ that it stands behind its ethical concerns and retains its independence, citing that last year only 0.3% of total income was from drug companies. A spokesperson said, "We stand by our decision to challenge this trial, which was motivated entirely by our aim to protect patients' right to timely sight-saving treatment."

A spokesperson for Novartis told The BMJ: "Novartis is committed to high standards of ethical business conduct and has a comprehensive compliance programme in

### **COMMENTARY**

### Avastin and Lucentis: a guide through the legal maze



David Locke QC asks if a doctor is acting lawfully when prescribing bevacizumab for patients with wet AMD

#### Prescribing a drug "off-label"

Every drug for clinical use needs a marketing authorisation, commonly called a licence, before it can be lawfully marketed by a drug company in the UK. The marketing authorisation defines the patient group for which the drug can be advertised. A drug that does not have a marketing authorisation is unlicensed and (broadly) can be sold in the EU only if there are no licensed alternatives. But the licensing regime does not impose legal obligations on doctors to use drugs only for the conditions set out in the licence. Using a licensed drug for conditions that are outside those described in the licence is commonly called "offlabel" prescribing.

Bevacizumab is licensed for treatment of cancer, but Roche cannot advertise it for wet AMD because the company has not subjected it to the testing regime needed for a licence for this condition. Use of bevacizumab for AMD would be off-label. No court has stopped a clinician from using bevacizumab rather than ranibizumab, and an attempt by Novartis, which holds the European intellectual property rights for ranibizumab, to get a German court to prevent a company from providing syringes prefilled with bevacizumab for wet AMD failed.1

### Could a doctor who prescribes bevacizumab for wet AMD be

### prosecuted for a breach of the criminal law?

There is nothing to suggest that a doctor who appropriately prescribes bevacizumab for someone with wet AMD acts in breach of the criminal law.

## Could a doctor who prescribes bevacizumab for wet AMD be sued in negligence?

It is highly unlikely that a doctor would breach a duty of care by appropriately prescribing bevacizumab provided the patient made an informed choice to select the drug. NHS patients who come within the clinical guidelines set by the National Institute for Health and Care Excellence for ranibizumab

place to help ensure we consistently act in a responsible manner. Novartis will not tolerate unethical behaviour by its associates in any country and we take all necessary steps to ensure compliance with the Company's Code of Conduct and all applicable laws."

### **Legal uncertainty**

While the studies have been ongoing, changes to General Medical Council (GMC) guidelines have left doctors fearful of acting

on the results. Its latest guidance discourages the prescribing of "unlicensed" medicines where there is a licensed alternative, as in the case of bevacizumab and ranibizumab (box).

But *The BMJ* has learnt that this guidance was the subject of a major U turn by the GMC. An earlier version contained a clause that encouraged doctors to prescribe off-label for reasons of cost. Although doctors' organisations and NHS bodies were "overwhelmingly

supportive," both the Association of British Pharmaceutical Industry and the MHRA, acting on behalf of the government, lobbied against the clause. They argued that the changes would undermine the licensing process and have serious implications for patients' safety and the health of the industry—not least in being a direct threat to innovation.

The GMC has said that its decision to drop the clause was influenced by legal advice relating to a European ruling against the importation of unlicensed generic medicines-when there was a licensed alternative—on the grounds of cost. However, because it refused to provide The BMJ with the advice-the public interest was best maintained by not releasing it and it attracted "legal professional privilege, the GMC said—it is unclear how this judgment applies to bevacizumab, which is neither generic nor unlicensed; it also refers to marketing not prescribing. Nonetheless the GMC has told doctors that it is unlawful to prescribe an "unlicensed" medicine on the grounds of cost.

The GMC's definition of "unlicensed" includes both off-label use of a licensed drug and use of a completely unlicensed drug. This has raised a new anxiety about whether bevacizumab for ophthalmic use is

#### WHAT OTHER COUNTRIES ARE DOING

In the US, surveys indicate that bevacizumab has about 60% of the market for ophthalmic use—although there may be changes afoot that threaten its use.

Ophthalmologists in the US have criticised the Food and Drug Administration for issuing guidance that would potentially restrict the use of bevacizumab for eye conditions, and some critics have suggested that the agency's advisory committee has conflicts of interest.

The World Health Organization has also backed bevacizumab for ophthalmic use, adding the drug to its Essential Medicines List.

In Europe the situation is far from clear cut. Last year the French and Italian governments passed laws to allow the reimbursement of off-label medicines, specifically referring to bevarizumab

However, three trade groups representing the drug industry have filed a complaint with the European Commission against Italy and France for expanding the off-label use of medicines. Last year, an investigation by Italy's competition authority led to a £150m fine for Roche and Novartis for allegedly colluding to prevent the use of bevacizumab for macular degeneration. In December, an Italian court dismissed an appeal by industry and Italy's health ministry has announced that it will seek damages of €1.2bn (£890 000; \$1.3bn).

In October 2014, the French medicines regulator also wrote to Roche to gather more information about the safety and efficacy of bevacizumab. It is seeking to issue temporary authorisation to use the drug for age related macular degeneration.

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## Some CCGs have provided patients with a choice for several years without being subject to a legal challenge

have a legal right to be prescribed it on the NHS. Doctors should inform relevant patients of that option. They should also explain that unlike ranibizumab, bevacizumab has not been through a formal testing procedure to secure a product licence (because the manufacturer has not applied for a licence). Doctors may explain that as ranibizumab has a product licence patients have additional legal rights to sue the manufacturer if the drug proves faulty. However, doctors would also be entitled to say that the two drugs have been shown to be largely equally effective and that it is better for the NHS generally if the cheaper drug is used because the

money saved can be used to treat other patients. If, having this information, the patient chooses bevacizumab rather than ranibizumab, the doctor is highly unlikely to be acting negligently.

## Could a doctor who prescribes bevacizumab for wet AMD be reported to the GMC?

There is a theoretical possibility that a doctor could be reported to the General Medical Council for prescribing bevacizumab rather than ranibizumab for wet AMD. GMC guidance requires doctors to make resource allocation decisions that take account of their responsibilities towards patients and the wider population. However, the GMC guidance about

prescribing off-label suggests that doctors should not make prescribing decisions for resource allocation reasons. GMC guidance does not explain how doctors should respond when a clinically proved drug is "off label" only because the drug company has not applied for a licence. The pharmaceutical industry lobbied the GMC about its guidance in this area, which may explain why it has not resolved the tension between the guidance about off-label prescribing and the doctors' duty to make the best use of scarce NHS resources for the benefit of patients generally.

Doctors in the UK have been prescribing bevacizumab rather than ranibizumab for wet AMD for many years (both in the NHS and privately), and there is no record of any doctor being formally investigated by the GMC for doing so.

## Can a CCG make arrangements to provide bevacizumab for NHS patients?

Because NICE has conducted a technology assessment of ranibizumab¹ clinical commissioning groups (CCGs) must fund the drug for patients who meet NICE criteria. However, this does not prevent CCGs offering alternative treatments to NHS patients. No court has ruled that CCGs should not offer bevacizumab but equally no court has ever ruled it is lawful to offer patients a choice. Some CCGs have provided patients with a choice for several years without being subject to a legal challenge. Novartis has advanced arguments against giving patients a choice but these seem unlikely to succeed.

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unlicensed. David Lock, QC, says there is a theoretical possibility that a doctor could be reported to the GMC for prescribing bevacizumab instead of ranibizumab for wet AMD (see commentary). However, there is no record that any doctor has been investigated by the GMC for doing so.

The legal confusion could have been resolved if the courts had ruled on the case of the Southampton, Hampshire, Isle of Wight and Portsmouth (SHIP) Primary Care Trust (PCT), which introduced a new policy to fund bevacizumab to treat wet

age related macular degeneration. Novartis forced a judicial review in 2012, but according to a letter from Novartis to former health secretary Andrew Lansley, the company wanted "to resolve this issue without recourse to the courts." *The BMJ* has learnt that the government was reluctant for the case to go ahead. SHIP agreed to withdraw the policy, bringing the judicial review to a close.

"One cannot be certain of the reasons for the case not proceeding," said Daphne Austin, a public health consultant. "But it cannot be because the PCTs were convinced they were acting unlawfully, this I know at least to be true, and it seems to me, and many others, there were many interested parties not wanting the courts to settle the question," she told *The BMJ*. Indeed, other PCTs that offered patients a choice between ranibizumab and bevacizumab did not end up in a judicial review.

### Is the tide turning?

What prospects are there for a better solu-

tion for doctors and their patients? NICE has announced it will produce new guidance on age related macular degeneration, although it is not clear if this will include bevacizumab. The RNIB and the Royal College of Oph-

thalmologists have called for NICE and the MHRA to evaluate bevacizumab for use in the eye. Meanwhile, pressure is building from patients. A letter to Jeremy Hunt and Andy Burnham from a patients' participation network in London in February urged them to mandate the licensing of intravitreal bevacizumab.

There is no sign that the government plans to intervene. A reply on behalf of Hunt said that if he were to do that "he might be open to accusations of interfering in pharmaceutical markets."

But the health department has indicated that NICE is free to evaluate bevacizumab for ocular use. So what will NICE do? Novartis has previously argued against a NICE appraisal of bevacizumab on the grounds that the drug is not routinely used in the NHS for ophthalmic conditions. But this is a circular argument. If doctors are worried about being sanctioned by the GMC for using "unlicensed" intravitreal bevacizumab, it is little surprise that uptake is low.

Austin points to the double standard in the whole debate. "Everyone knows that these drugs are offered as a matter of course in the private sector," she says. "The proposition that it is ethical to provide the cheaper drug to a private individual, but unethical when the payer is the public purse, is a demonstration of contempt for both the taxpayer and the patients whose care is sacrificed as a result," she says.

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2015 AWARDS FINALISTS

★ GASTROENTEROLOGY TEAM OF THE YEAR

★ CLINICAL LEADERSHIP
TEAM OF THE YEAR

the**bmjawards** 



## Gastroenterology team of the year finalists 2015

Patient empowerment and the use of new technology are the common factors that link the short listed entries for this award, finds **Nigel Hawkes** 





The Gastroenterology Team of the Year award is sponsored by Takeda and Crohn's and Colitis UK. The awards ceremony takes place on 6 May at the Park Plaza, Westminster Bridge. London. To find out more go to thebmjawards.com

### SCARRED LIVER PROJECT



In Nottingham, a team from the university and the hospital trust led by Guruprasad Aithal and Neil Guha has transformed the diagnosis of chronic liver disease by identifying those at risk from GP records and inviting them to clinics held in GP practices where they are scanned to assess any scarring of their liver. The technique identifies twice as many patients with cirrhosis, the vast majority of whom had no symptoms and had normal liver function tests, illustrating, says Guha, the inadequacy of these widely used enzyme tests in flagging up chronic liver injury. The scan also detects early asymptomatic liver disease at a stage when it is still reversible.

"We screened over 20 000 patients in four GP practices, targeting factors such as diabetes and alcohol rather than liver enzymes," he says. "All these patients were offered appointments for a scan, which is done by a trained nurse. We use a FibroScan, an ultrasound scanner, to measure the stiffness of the liver—it's well established in secondary care but not in primary care, which is actually a better place to implement it."

"The patients who had elevated scan readings were seen by consultant hepatologists, again in GP practices, and offered advice"

The 200 patients who had elevated scan readings were seen by consultant hepatologists, again in GP practices, and offered advice. The benefit is much earlier detection, a great improvement on identifying them only when they are admitted to hospital as an emergency. The technique is inexpensive and money spent on the portable scanner is saved because fewer liver biopsies and outpatient visits are then needed.

### INFLAMMATORY BOWEL DISEASE— SSHAMP (SUPPORTED, SELF HELP AND MANAGEMENT PROGRAMME)



Better management of patients with inflammatory bowel disease was the target set by Luton and Dunstable Hospital. A paper based self management programme had run into problems, including patients disappearing from surveillance and only reappearing when they had developed cancer. The solution, says consultant Matthew Johnson, was a web based system using the Patients Know Best website. "The opening page is an index of symptoms, which patients complete, and behind that there is a calculator that scores them as green, orange, or red," he says.

"The scheme costs less, has improved management of the condition and increased patient satisfaction, while freeing clinic capacity and providing a safe community-based management system"

The website can be accessed by consultants to detect any deteriorating patients, enabling them to act in time to prevent unnecessary admissions and emergency appointments. Patients can use it for advice and support. "After three years' experience with the first 425 patients, 16 had required advice on therapy, which was given over the phone. Only three had to come back to hospital for emergency outpatient appointments and we had had no hospital admissions," Johnson says. "By the end of this year we expect to have 800 patients on the system."

The scheme costs less, and has improved management of the condition and increased patient satisfaction, while freeing clinic capacity and providing a safe community based management system. "Very few patients are unwilling to try it," Johnson says.

@doctor mattwjohnson

## MANAGEMENT OF PAEDIATRIC CHRONIC INTESTINAL PSEUDO-OBSTRUCTION



A rare but devastating condition that occurs in around one in 40000 births—15 a year in the UK—was the challenge that faced gastroenterologists at Great Ormond Street Hospital in London. Children born with chronic intestinal pseudo-obstruction (CIPO) have abnormalities in the nerves or muscles of the intestinal tract and present with the symptoms of obstruction. Up to half need parenteral nutrition to keep them alive and are likely to undergo surgery to clear obstructions that don't exist. Around 30% will die.

"Diagnosis is often delayed and children are given unnecessary or inappropriate treatment," says Nikhil Thapar, consultant gastroenterologist at Great Ormond Street. "We believed that timely and accurate diagnosis and treatment would preserve bowel function and would ensure appropriate treatment for those found not to have CIPO, which turned out to be almost half."

The national service provided by Great Ormond Street has reduced the time to diagnosis, and improved outcomes. Of the first 46 children seen, 24 were diagnosed with CIPO. The prognosis is better for those with stomas formed under the age of 5, 10 of whom have come off parenteral nutrition either partially or wholly. Another 22 were found not to have CIPO, nine of them avoiding surgery that might otherwise have been carried out.

"We believed that timely and accurate diagnosis and treatment would preserve bowel function and would ensure appropriate treatment for those found not to have CIPO, which turned out to be almost half"

### INTESTINAL FAILURE TEAM



Patients who suffer intestinal failure need parenteral feeding, which delivers nutrients intravenously to compensate for the failure of the normal digestive process. This can be done at home, once patients are trained in the technique. But in Wales in the 1990s such training was unavailable unless patients were willing to travel either to London or to Salford. A team at Cardiff and Vale Health Board, starting in 2004, commissioned a service for training in home parenteral nutrition for Welsh patients.

"The scheme has been a success, with low rates of infection, an average of 0.43 catheter-related infections per 1,000 patient days. Patient satisfaction is high, with 97% pleased with the training they received, and costs are lower than when patients had to be sent to England for training"

When the service started, there were 22 patients in Wales on home parenteral nutrition—now there are 106. "Training is vital because if you don't use the full sterile technique you get fevers and have to be rushed into hospital," says Barney Hawthorne, the consultant gastroenterologist who chaired the group responsible for commissioning the new service. "And each time a new line has to be put in, you run a risk of damage to the big veins."

The scheme has been a success, with low rates of infection, an average of 0.43 catheter related infections per 1000 patient days. Patient satisfaction is high, with 97% pleased with the training they received, and costs are lower than when patients had to be sent to England for training.

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## Clinical leadership team of the year

Clinical leadership is about identifying problems and solving them, often by doing things differently. That requires ideas, enthusiasm, and the capacity to carry others with you, qualities exemplified by entries shortlisted for this award, finds **Nigel** 

**Hawkes** 



### General Medical Council

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The Clinical Leadership Team of the Year award is sponsored by the Faculty of Medical Leadership and Management and the GMC. The awards ceremony takes place on 6 May at the Park Plaza, Westminster Bridge. London. To find out more go to thebmjawards.com

### ANTENATAL CARE INITIATIVE



Sometimes problems conceal themselves in plain view. Stillbirth rates in the UK have been the highest in Western Europe and have remained unchanged for 20 years. "Two thirds of these deaths were classified as unexplained, and many took that to mean unavoidable," says Jason Gardosi, director of the Perinatal Institute, a national not-for-profit organisation set up to improve the quality of maternity care. "People just shrugged their shoulders. It took a long time to change that and raise the profile of stillbirth."

"A pilot programme in the West Midlands saw stillbirth rates falling to their lowestever levels. The customised growth charts have now been rolled out nationally"

The institute conducted research that identified unrecognised growth restriction in the womb as a major cause of stillbirth, and developed individualised growth charts that could be used by midwives and doctors to detect babies at risk by accurately plotting their rate of growth. "Detection is important as the only treatment we have is inducing labour at the appropriate time. These babies need to be delivered from danger, before they die," said Gardosi.

A pilot programme in the West Midlands saw stillbirth rates falling to their lowest ever levels. The customised growth charts have now been rolled out nationally and in 2013 there were 500 fewer stillbirths in England compared with the average for the previous 10 years. "Implementing new ways of working is not easy, and in maternity care the additional challenge is the multidisciplinary nature of the specialty. However, with the help of an enthusiastic team, we found that most clinicians are keen to listen to evidence and improve the safety of their practice," he added.

@periinstitute

### DIABETES CARE WITH STYLE (SAFE TRANSITION TO YOUNG ADULT LIFE)



"The answer was to invest more effort into the transition period, using social media and providing age-relevant information packs, arranging joint handovers from the paediatric to the adult team, making appointments more flexible with drop-in clinics at the local university"

At Portsmouth Hospitals NHS Trust, the issue was increasing attendance rates for young people with diabetes. The problems arose, says consultant diabetologist Partha Kar, when patients moved out of paediatric care and into adult care, a transition marked by uncertainty and lack of engagement. "We noticed that most of the patients who didn't attend clinics fell into this age group," he says. "As many as 60% of clinics were empty."

The answer was to invest more effort into the transition period, using social media and providing age relevant information packs, arranging joint handovers from the paediatric to the adult team, and making appointments more flexible with drop-in clinics at the local university. "We asked them what they wanted from the service, then saw what we could do," he says. "It didn't cost a lot but the results were quite eye opening. 'Did not attend' rates fell from 40-50% to 10-15% and acute admissions secondary to diabetic ketoacidosis, a common reason for admission in this group, fell by 17%."

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# 2025

### BUILDING THE EMERGENCY DEPARTMENT SERVICE



Emergency departments often struggle, but at East Surrey Hospital the problems were especially acute, with there being a poor physical environment, a reliance on locum staff, high nursing vacancies, and negative feedback from trainees. It ranked as one of the worst emergency departments in 2011-12 and the General Medical Council had warned that trainees might be withdrawn.

A fresh team, led by Julian Webb, launched a recruitment drive, finding a number of senior middle grade doctors to work nights so that others could be attracted by the lure of not having to do so. Recruits came from Spain and Hungary, building up from four to 10 consultants; a fully staffed middle grade rota was established; and nurse recruitment increased numbers and eliminated vacancies.

"A fresh team launched a recruitment drive, finding a number of senior middle – grade doctors to work nights so that others could be attracted by the lure of not having to do so"

Webb pays tribute to the hospital's chief executive, who he says was hugely supportive. "A lot of chief executives still don't understand that emergency departments fall over from the exits being blocked," he says. Feedback through the Friends and Family test and staff surveys show that the perception of the department has changed. "At a time when emergency medicine has struggled nationally, ours has gone from strength to strength," he says. Two areas where it was pioneered are in the creation of the cadre of night doctors and the creation of a group of extended practitioners.

### TIME TO HEAL



"In the scheme's first year, 84% of patients were offered accommodation, and 76% took it, compared to none the year before"

Homeless people are five times as likely to be admitted to hospital through emergency departments, and typically stay longer than other patients. Pippa Medcalf, at Gloucester Royal Hospital, says, "Often they don't have a GP and have nowhere else to go. We would treat them and when they were well, we would send them home. But we closed our eyes to the fact that they were going back on the streets."

She set up a collaboration with a housing officer and nurse from the local Homeless Healthcare Team who acted together to ensure that they had somewhere to go on discharge. The Time to Heal project aims to ensure that nobody is discharged without some planned housing and support. In the scheme's first year, 84% of patients were offered accommodation, and 76% took it, compared to none the year before. Most were men, with the majority being alcohol or drug misusers or with poor mental health. Average length of stay was reduced by a day, saving £52000.

Funding the scheme has nonetheless been a struggle; the first six months with a grant from the Department of Health, and the second by money from Gloucestershire Clinical Commissioning Group. Medcalf says, "I feel angry and sad we haven't got better facilities to support these people. There are always going to be people who are not going to be able to function normally in society."

### NURSE INTRAVITREAL INJECTIONS



New treatments for age related macular degeneration and diabetic eye disease have transformed the treatment of these conditions, but have imposed demands on ophthalmologists, the only group currently licensed to give the regular injections.

Moorfields Eye Hospital in London decided to break down the barriers by training nurses to give the injections.

"By now, 40 nurses have been trained and perform about half of Moorfield's 23000 eye injections a year. The scheme's success has changed the view of the Royal College of Ophthalmologists, which was initially opposed"

The nurses needed specialist training, but there were also legal obstacles, says hospital fellow Joanna da Costa. "We took legal advice and got indemnity cover from the NHS Litigation Authority, as well as clearance from the hospital's audit, clinical governance and management committees. New nursing consent forms and information leaflets were written."

The first nurses to be trained began giving injections into the eye in January 2012. By now, 40 nurses have been trained and perform about half of Moorfields' 23 000 eye injections a year. The scheme's success has changed the view of the Royal College of Ophthalmologists, which was initially opposed. Although the main cost of the treatment is the expensive drug, using nurses rather than consultants has saved a significant amount of money, offset by the modest cost of training them.

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## And the winner is...

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