

comment

It's striking, and impressive, how well some other professionals have laid out what they can do and what resources they need to do it

NO HOLDS BARRED Margaret McCartney

Third way for Scottish GP contracts?

The proposed Scottish GP contract is clearly intended to shore up doctors and support primary care, and there's much in it to like. It effectively underwrites premises so that younger GPs won't be dissuaded from joining a practice that owns its buildings. It includes a minimum income expectation for 40 hour full time GP equivalents, some 20% of whom in Scotland earn less than the proposed minimum of £80 000.

It contains impressive statements on the link between workforce morale and patient experience and says that not all patients need a doctor's expertise to be treated. And help is promised through pharmacists and physiotherapists stepping in and up, as well as nurses and receptionists being trained to do more. It reads as though GPs, taking on the role of expert medical generalist and team leader, will become quasi-salaried.

The critical issue for me is this: health boards, under the new contract, will be responsible for managing the team to which the GP provides clinical leadership. Some of this may make sense, and district nurses and health visitors in my area have long been employed by the health board. But it's also a recipe for fractured relationships.

Morale comes, often, from team support. Make the team a group of temporary, ever moving players, and we lose that sustenance and create administrative mess. A team of regular district nurses whose coffee cups are stored in the tearoom, who know the staff and patients, is a different proposition from a team who can't offer



patients continuity of care (and who don't know what the octogenarian down the road likes—or what she's usually like).

Another big issue with the contract is its reliance on advance care planning to reduce admissions despite large uncertainties about whether this is possible. My fear is that GPs will continue to fill the gaps created around work that others don't take on—and that we may have little choice in what that work is.

It's striking, and impressive, how well some other professionals have laid out what they can do and what resources they need to do it. I don't think that GPs, as a group, have ever articulated this well enough.

I can see two futures. One is where GPs see the most complex patients, filling in workforce gaps where needed and doing lots of paperwork. The second is where we become salaried and clearly define what it is that we do and what resources we need. As it stands, this would inevitably lead to waiting lists for GP appointments.

What about incorporating another way—a rigorous and bottom-up identification and exclusion of the administrative and system waste that GPs don't need to do? I have little doubt that the will to make a good contract is there. But, as proposed at present, we retain responsibility without necessarily the resources to discharge it.

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Vital role of perinatal pathologists in reviews of stillbirth

Families and medics benefit from specialist involvement

The secretary of state for health, Jeremy Hunt, has called for coroners to be granted special powers to investigate stillbirths.

The extent of these powers has yet to be clarified. There is, however, already a mechanism in place for the coroner to investigate certain categories of sudden unexplained neonatal and infant death, and it is not appropriate to extend these powers to all stillbirths and early neonatal death. All encompassing, non-pejorative, and timely local reviews carried out by a multidisciplinary team would lead to a better understanding of the factors leading to serious injury or stillbirth, and may help reduce the death rate.

In the UK the rate of stillbirth remains higher than in many similar

countries. Despite this, it is often a hidden grief with devastating consequences.

Perinatal pathologists have a vital role in the ongoing care of these families, not only from the point of diagnosis, but by providing information which may inform care in the next pregnancy. Examination of the placenta, alongside detailed autopsy, is regarded as the gold standard for investigating these deaths. But even then, the cause of death may be “unexplained” in a significant number of cases because of the many possible contributing factors.

Every parent has a right to seek answers. Open, non-pejorative review—as modelled by the aviation industry—may be the best way to tackle concerns. I regularly refer to



PRIYA SUNDARAM

The placenta is pregnancy's “black box”: it gives insight into in utero life and the mother's health

the placenta as the “black box” of pregnancy as it gives insight into the in utero life of the fetus and the mother's health.

To enable an in-depth assessment of all events during pregnancy and labour, and facilitate effective transparent review, we need to bring professionals together. This is too important to be left to one person. A robust, informed conclusion by the review panel requires access to all clinical notes, cardiotocography traces, the postmortem report, and

Are seven day service standards thorny or thriving?

Abraham Lincoln is often quoted as having said, “We can complain because rose bushes have thorns, or rejoice because thorn bushes have roses.” This often seems pertinent to the quality and scope of NHS care. An important example is NHS England's summary on acute hospitals' performance against four of 10 key national indicators for delivering seven day services.

The 10 standards were drawn up by Bruce Keogh, national medical director, and his colleagues at NHS England in 2013, informed by an Academy of Medical Royal Colleges report from 2012. They were subsequently included in the Department of Health's mandate to the NHS and then adopted. The four most exigent standards were selected



Given the workforce crisis, maintaining performance levels is extraordinary

for implementation by 2020—hence the progress monitoring.

Recently, 153 hospital trusts were asked to submit performance data through an online self assessment tool: 148 responded, and the results were published in November. The *Health Service Journal's* headline (majoring on thorns) was “Quarter of patients denied rapid review—even on weekdays.” This was unduly pessimistic, I reckon.

So, what were the standards and the performance against them? The first was “Patients who had an initial consultant review within 14 hours of admission,” a target 73% of trusts met on weekdays and 70.3% at weekends. Second was “Patients who received daily ongoing consultant reviews” (90.9% of trusts on weekdays, 69.7%

on weekends). “Patients with same day access to diagnostic tests” was third (99.7% weekdays, 92.1% weekends), and fourth was “Consultant directed interventions available to patients” (95.2% weekdays, 91.9% weekends).

Interventions included emergency surgery, stroke thrombolysis, urgent dialysis, and interventional cardiology. Performance on these measures was well over 90% over all seven days. Only in interventional radiology and urgent radiotherapy did performance fall well below this. I'd suggest that, given the crisis in the radiology and gastroenterology workforces, maintaining performance levels is extraordinary. Credit is due.

For “daily consultant review,” of course we want patients seen frequently by senior doctors, and this

placental histology. It also requires parental input.

Handing the investigation of all stillbirths to the coroner represents a misperception of what needs to be done to fully investigate these deaths.

Police interviews

Staff interviewed by police as agents of the coroner may feel vulnerable, ill at ease, and defensive when discussing complex clinical issues with those who may not have a clear understanding of the clinical processes. This could lead to distraction on overstretched units, compounding the shortage of staff available to provide frontline care.

If coronial investigations were extended to stillbirths and every early neonatal death, autopsy may become a requirement in law, with no further parental discussions regarding the type of autopsy. As professionals involved in the care of these families we need to be able to discuss the autopsy openly, enabling parents to make an informed choice.

The shortage of perinatal pathologists may lead to delays as the baby and placenta are transferred to a hospital with specialist services or to forensic pathologists. Delays in carrying out the autopsy can prevent

parents from following customs, thus compounding their grief.

Perinatal pathologists routinely take samples looking for information that may affect future management, as well as assigning a cause of death. Will the coroner pay for the detailed histology, microbiology, virology, and genetics tests? There is a risk that pressure could be applied to take fewer samples in order to be more cost effective.

The pathologist may not be able to discuss the case with local clinicians and the report may not be completed in time for local review. This could lead to misinterpretation or overemphasis of pathological findings.

Communication is key to decreasing the number of stillbirths. Local staff must engage with and take ownership of the review process, and pathologists must be part of this. Information gleaned from reviews must be shared within the NHS so that lessons can be learnt and changes made. In this way we will gain a better understanding of stillbirth, and ensure improved care and a reduction in these deaths in all parts of the UK.

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happens at weekends far more than it used to, partly because of the seven day focus. But, with no workforce expansion and many unfilled posts, having more consultants on inpatient wards at weekends will inevitably hamper weekday service provision.

I'm not sure how much value is added by ensuring a consultant sees a patient every day, just to tick a box. We might add greater value by seeing some three times a day and others three times a week.

Finally, for "consultant review within 14 hours," weekend performance matches that on weekdays. Dig deeper and, even in an acute admitting unit where consultants are present until 10 pm, it's quite possible that patients wouldn't be clerked, investigated, and ready for senior review until the consultants had gone home. Yet

they'll be seen by a consultant the next morning even if this isn't until 11 am—16 rather than 14 hours after admission, and prompt nonetheless.

In many specialties there are not enough consultants for 24 hour cover, and we don't want to encourage "gaming" of the target where consultants review the care plan and put something in the notes before they've seen the patient.

Trying to deliver such standards is a good ambition. It's also worth exploring the variation in hospital datasets. But, in a service under extreme pressure, with fewer medics and less kit than many countries, let us rejoice in what we're delivering—not all roses, but certainly not all thorns.

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BMJ OPINION Nishma Manek and David Haslam

Denigration of GPs is still rife

"If you students don't start working harder, you risk ending up as paediatric cardiothoracic surgeons."

Can you imagine anyone ever saying that? It would be ridiculous. Replace the last four words with "GPs," however, and the sentence will sound more familiar.

When we were students, things like this were said to both of us—two doctors at the opposite ends of our careers. We were both furious. Fortunately, it didn't stop either of us becoming GPs, and we hoped that such attitudes were dying out.

However, all too little seems to be changing. The Royal College of General Practitioners has published a survey of around 3700 medical students, and it confirms that denigration of general practice is still rife in medical school and behind hospital doors. The report is littered with disheartening statistics. For example, 76% of students said that they've encountered negativity towards general practice from academics, clinicians, or educational trainers by their final year, and 70% of this was in a clinical setting.

Some of the comments cited—such as "a lot of GP consultations aren't proper medicine" or "don't you dare think about going into general practice—have some aspiration for God's sake!"—show how deep the prejudice still runs.

Yet many of these consultants won't have stepped foot in general practice since their student days. Consider the amount of time a student spends in a hospital setting compared with general practice. Very quickly these off-the-cuff remarks add up, leaving general practice with a reputation that's hard to shake off.

Disparaging remarks about GPs carry another implication: that their patients shouldn't expect the best or the brightest doctors. Yet as patients, much of our NHS contact will be through GPs, who we would probably like to be the best and the brightest. It's hard to reconcile those two observations.

This isn't just about secondary care: we as GPs need to be equally mindful. The survey found that GPs interacting with students on placements have the most influence on students' perceptions of the career. Mostly these were positive, but there were examples of negativity from GPs.

Let's be clear, this isn't about censorship. Nor is it about eliminating banter. It is about confronting systematic denigration within medical training, and fostering mutual respect between specialties.

This matters more than ever, because multimorbidity is becoming the new norm. We need to be training a workforce with the needs of our future patients in mind: a workforce of generalists.

Nishma Manek, GP trainee, Cambridge

David Haslam, chair, NICE



"Disparaging GPs implies patients shouldn't expect the best or brightest doctors"

ANALYSIS

Concern is increasing that use of transvaginal mesh devices to treat stress urinary incontinence and pelvic organ prolapse has exposed women to avoidable harms. Part of the problem may lie with the governance of medical devices, which has enabled devices to be brought to market with inadequate evidence, and more than 100 000 litigation cases are now under way.¹ We consider how improvements to both regulatory approvals and the structures supporting evidence based practice among clinicians could help prevent similar problems in the future.

Clinical background

Mesh has been used to treat stress urinary incontinence and prolapse for the past 20 years because it overcomes the need to harvest native tissue, is less invasive, takes less surgical time, and has been thought to reduce the risk of recurrent prolapse. Transvaginal mesh made from polypropylene is used to treat stress urinary incontinence. This operation involves creating a bladder sling using a strip of mesh (referred to as tape) that is inserted through vaginal and abdominal incisions. Similar techniques are used to treat pelvic organ prolapse, with vaginal mesh made from the same material used to support the tissues which hold the vaginal walls and uterus in place. Although the evidence for use of bladder slings is to some extent reassuring,² that for vaginal prolapse mesh has been controversial.³

The many different brands of mesh devices available are predominantly polypropylene based. However, they differ in pore size and fibre configuration; fibres can include a non-absorbable coat with a thin layer of porous collagen, and surface area can vary.⁴ Polypropylene mesh shrinks substantially after implantation, by up to 50% after four weeks, which may be associated with serious complications such as severe pain, dyspareunia, and tissue erosion, and often requires repeat surgical intervention.⁵

Bacterial contamination is another cause of problems and is found in

Carl Heneghan and colleagues describe how failings in the process for marketing approval may have exposed women to avoidable harms and how to prevent their repetition

Transvaginal mesh failure: lessons for regulation of implantable devices

up to a third of removed meshes.⁶ Infected multifilament meshes have to be removed,⁹ and colonisation can occur whatever intraoperative sterility procedure is used.¹⁰ Because meshes are designed to encourage ingrowth of nerves that accompany tissue and blood vessels (the aim of which is to reinforce weakened pelvic tissues), when complications occur mesh can be difficult to remove.^{11 12}

The accumulating reports of harms attributed to mesh have resulted in more than 100 000 women suing manufacturers globally. More than 1000 women have brought cases in the UK,^{13 14} and more than 3000 are reported to be in litigation in Canada.¹⁵ The number of US cases outweighs FDA spontaneous reports by 25 times (100 731 litigation cases v 3979 FDA reports), suggesting substantial under-reporting of harms to regulatory bodies. What went wrong?

Inadequate regulatory processes

In the US, transvaginal meshes were initially class II devices (lower risk), permitting them to be cleared for marketing on the basis of equivalence to existing products (box on p 403).¹⁹ Over time, multiple submissions can lead to predicate creep, whereby the authorised product is very different from the original predicate device.

KEY MESSAGES

- Thousands of women are suing manufacturers after developing complications from vaginal mesh devices
- Many of these devices were approved on the basis of equivalence to older approved devices despite important changes
- Evidence consistently pointed to a lack of long term data to inform use of vaginal mesh devices
- Regulation of implanted devices needs to recognise the higher potential risk
- Registries should be required for all implantable devices to track any problems

In our linked *BMJ Open* paper we traced marketing clearance for 61 mesh devices back through a chain of equivalence claims to only two unique originating devices approved in 1985 and 1996.¹⁷ We found no evidence of any new clinical trial data at the time of approval, with empirical evidence of effectiveness from randomised trials emerging on average five years after approval (range 1 to 14 years).

Design changes should have alerted regulators to technological differences that should have negated equivalence.⁴ As an example, the Protegen sling, an early device made from polyester, continued to be used as a predicate for more modern devices even though they were made from polypropylene, and despite the Protegen sling being taken off the market.

Reliance on animal testing

Before marketing, meshes are assessed to determine toxicity to cells (cytotoxicity), how irritative it is to skin (intracutaneous studies), and whether a material contains chemicals that cause adverse local or systemic effects after prolonged exposure (sensitisation studies). Cytotoxicity is generally examined using mouse media containing fibroblasts in culture, which are then examined for 48 hours for signs of reactivity. In the intracutaneous studies, which may use as few as two animals,²⁰ observations for erythema are carried out for up to 72 hours after intracutaneous injections. Such studies are unlikely to reflect the benefit-harm profile of implantable devices that remain in humans for decades.

However, arguably the most important test is measurement of how biologically compatible a device is. Mice, rats, and rabbits are routinely used to evaluate biocompatibility.²⁰ However, it is uncertain how closely animal models predict human responses. When a device is to be implanted it is vital that studies should closely approximate intended clinical use to provide a reasonable assessment of potential harms.²²

Slow emergence of long term evidence

In 2005, a Cochrane review of surgery for stress urinary incontinence or pelvic organ prolapse highlighted

US AND EUROPEAN DEVICE REGULATION

In the US the Food and Drug Administration is responsible for all aspects of device regulation. Lower risk devices (class II) can be cleared for marketing through the less burdensome 510(k) review process. This requires the manufacturer to show that the device is substantially equivalent to, or at least as safe and effective as a legally marketed device or “predicate.” The mechanism allows for a chain of equivalence, in some cases leading back to devices approved before 1976,¹⁶ before clinical evidence was required.¹⁷

In Europe device approval is managed through more than 50 commercial organisations known as notified bodies. A manufacturer selects a notified body to certify a device.¹⁸ That body assesses conformity to the essential requirements in three legal directives. If the notified body approves the application, it issues a certificate of conformity, which allows the product to be marketed across Europe. Clinical data to show equivalence to previous devices can be as limited as a critical narrative review of the relevant scientific literature.

the need for studies with longer term follow-up.²³ At the same time, NICE stressed the need to inform women about the lack of long term data.²⁴

The longer term evidence, however, identified serious concerns. In 2009, a review of 127 cases of transvaginal repair using synthetic mesh cited tissue erosion rates over 10%,²⁵ and complications requiring reoperation were reported to be more common with vaginal mesh kits than with traditional vaginal surgery.²⁶ A 2010 randomised trial of colpopexy versus prolapse repair with mesh was stopped early because of high erosion rates in the mesh group (16% at three months).²⁷ A 2011 systematic review of 110 studies of vaginal prolapse repair with graft materials materials (91 of which were non-absorbable synthetic mesh materials) reported an overall erosion rate of 10.3% (range 0% to 30%). Dyspareunia was described in 70 studies and occurred at a rate of 9.1% (range 0% to 67%).²⁸

In 2011, the FDA published a systematic review of studies from 1996 to 2011 and reported some pressing problems, overturning its

2008 advice that complications were rare.²⁹ The FDA also used information reported to its Manufacturer and User Device Experience database. It cited 3979 reports of serious complications associated with urogynaecological surgical mesh products. The most common complications included erosion of mesh into surrounding tissues, followed by pain, infection, bleeding, dyspareunia, and organ perforation.²⁹ Contrary to previous FDA statements, the review concluded that “while transvaginal repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair.”

In 2012, the FDA asked 33 manufacturers to conduct 119 new safety studies.¹⁷ Our linked *BMJ Open* study shows that in response, the manufacturers instead ceased market distribution in 79 (66%) cases and changed the indication in 26 (22%). One manufacturer reported it was no longer in business and one reported its device was not a mesh. In four orders the manufacturer requested their multiple orders be consolidated into one, leaving seven studies under way to assess the risks of harms.¹⁷ The FDA reclassified vaginal mesh for pelvic organ prolapse repair from a class II device to a class III device in 2016.³⁰

In the UK the Medicines and Healthcare Products Regulatory Agency (MHRA) published an assessment of the clinical effectiveness of transvaginal meshes for stress urinary incontinence and pelvic organ prolapse in 2014, based on data from an overview of systematic reviews and reports of adverse events.³¹ The MHRA stated that the evidence from published reviews was insufficient to assess the benefit to harm balance of meshes for specific procedures; however, it noted differences in patient characteristics,

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Anti-mesh campaigners protest outside the Houses of Parliament in October

USAGE AND RESPONSE TO EVIDENCE

Annual numbers of NHS operations for stress urinary continence rose by 28% from its introduction in 1997-98 through to 2005-06. Similar trends have been observed for mesh use in prolapse. For example, use increased by 19% between 2003 and 2006.⁴² Vaginal mesh procedures also increased in the US. Numbers tripled between 2005 and 2010,⁴³ despite emerging evidence highlighting the need for better data on long term outcomes²⁴ and an FDA safety alert in October 2008. It was not until after the FDA ordered postmarketing studies to assess safety and effectiveness in January 2012 and evaluate risks in April 2014 that use of mesh for prolapse began to decrease in the US.²⁹



surgical expertise and experience, and aftercare, which can affect susceptibility to adverse events.

Although the MHRA included only data from randomised trials in its literature review, it largely failed to report between group comparisons for mesh versus native tissue repair surgery and did not report the quality of the evidence for the outcomes assessed. Since 2005, the MHRA has received 110 reports of adverse events with vaginal mesh implants for pelvic organ prolapse: the most common reports were pain (39), extrusion/erosion (65), infection (21), relapse of conditions/urinary symptoms (20), perforation (16), and dyspareunia (18). In contrast to the FDA, the MHRA concluded that the “benefits outweigh the risks.”

In 2016, Cochrane updated its review of the surgical management of pelvic organ prolapse and reported

In a UK trial of transvaginal tape in 344 women, only 177 provided data at five years

higher reoperation rates for women treated with mesh than with native tissue. Evidence from 37 trials, including 4023 women, reported that, compared with native tissue repair, mesh probably reduced the awareness of prolapse and repeat surgery for prolapse. However, around 10% of women with mesh would require reoperation for prolapse, urinary incontinence, or mesh exposure.³²

Although these reviews have attempted to explore long term outcomes, they are hindered by methodological shortcomings, high drop-out rates, and sparse long term data. In a UK trial of transvaginal tape in 344 women, only 177 (51%) provided data at five years, and full subjective and objective data were available for just 121 (35%) women.³³ The FDA considers that mesh trials have been poorly designed and conducted, and have failed to account for variable lengths of patient follow-up.²⁹

Changes to device regulation

In recognition of the problems, many countries have reclassified mesh as high risk, and NICE is recommending it should not be used to treat vaginal prolapse because of safety concerns.³⁴ New EU regulations, published in May 2017, mean that clinical investigations for class III and implantable devices will be required to provide evidence of safety and performance.³⁵

Notified bodies will also be redesignated under the new regulations, and those assessing high risk devices will be scrutinised to ensure compliance. Notified bodies will have to inform competent authorities of their high-risk approvals, and the competent authority will be able to request further advice from expert panels about safety and

performance, an important change from previous regulations. However, there is a three year transition period before these rules come into force, in May 2020. We think these changes are insufficient, and the long delay in implementation does not represent a timely response to patients’ needs. The FDA’s decision in 2016 to make mesh a high risk device means that in the US manufacturers already have to provide clinical trial evidence of their products before approval.

In the case of vaginal mesh devices, evidence from large pragmatic trials did not emerge until 20 years after the first products were introduced^{36,37} and 12 years after the call for longer term studies.^{23,24} In our view, to be considered safe and approved for widespread use, long term implantable devices should have been evaluated in studies with follow-up of at least five years. Limited access could be provided through temporary licences that restrict use to within clinical trials with long follow-up. This would ensure that safety and effectiveness data were available before full marketing authorisation.^{38,39} Our proposed model for device development, which is based on methods used for drugs and the IDEAL-D framework, works towards this (table).

Finally, we recommend that a patient registry should be established for all implantable devices to enable long term follow-up and surveillance. Twenty years after the first use of vaginal mesh, manufacturers, the FDA, and professional organisations established the pelvic floor disorders registry. Such registries should include unique device identification so that any shortcomings can be more readily tracked, patterns of use monitored, and patients later judged to be at risk more easily identified.

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Proposed model for device development (adapted from Barkun et al⁴⁰ and Sedrakyan et al⁴¹)

	Phase 0: innovation	Phase I: development	Phase II: exploration	Phase III: assessment	Phase IV: long term
Drugs	Preclinical studies/microdose pharmacology	Single and multiple dose safety studies	Studies over the target dose range in patients	Studies of efficacy and adverse events	Postmarketing studies
Devices	Preclinical studies or first case reports	Prospective or cohort studies for initial development	Larger prospective or cohort studies for further exploration	Studies of efficacy and adverse events, preferably randomised	Postmarketing studies with registries
No of participants*	Single digits	Up to 100	Up to 300	Up to 3000	General population

*Numbers of patients will vary depending on power calculations that take account of the expected effect size, but our numbers also take account of the detection of rare adverse events for phase III assessment.

FUTURE OF THE FRAMEWORK

QOF is a unique information resource

Regarding the Quality and Outcomes Framework, Marshall and Roland say that we should “move on and do better” (Editorial, 4 November).

Can we find a way to build on and develop the best of the framework? Many measures are instrumental process measures for the NHS. They are of similar importance to publicly available immunisation or screening rates and provide a framework for improving effectiveness, efficiency, and safety.

The data could provide information about priority clinical indicators for long term conditions, standard public health measures, over-ordered investigations, safety indicators, and an age defined denominator to age standardise for better comparability.

It would be a tragedy if the lessons learnt over a decade of high quality data entry with agreed code sets, universal data extraction, and reporting and organisational comparisons were lost in the dash to jettison the administrative components of this unique national resource.

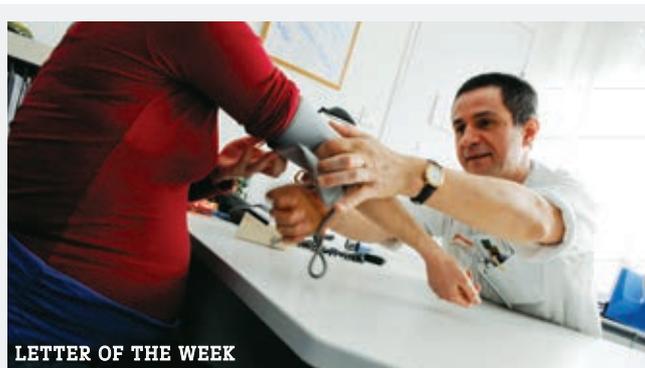
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Focus should be on wellbeing and health

QOF (or its replacement) must account for fundamental features of general practice that are not currently captured. This would focus on wellbeing and keeping people in good health rather than on specific diseases, based on a person centred approach that prioritises patient empowerment and continuity of care. It should minimise burden on practices while allowing flexibility to tailor care to



LETTER OF THE WEEK

Judging value in primary care

Watson and colleagues make a convincing case for basing primary care's priorities on the idea of value (Analysis, 11 November). Although driving the process with evidence based policy and investment is fundamental, we must also use data on practice population outcomes. How can you judge value without measuring outcomes?

The balance between benefits and harms for mild hypertension, for example, do not mean that policies to detect and manage moderate hypertension are no longer needed. A higher proportion of the practice population being on hypertension registers is associated with lower mortality, indicating that undetected hypertension remains responsible for many potentially avoidable deaths. As Watson and colleagues point out, health checks are unlikely to be the solution.

Observational studies have shown an association between the supply of family doctors and population mortality in the US and England. Practices in areas with not enough doctors might consider monitoring their outcomes to prompt policy makers to increase the resourcing of primary care.

A practice or group of practices with, say, 20 000 patients could readily monitor data on fatal and non-fatal outcomes. With information on population characteristics and the ability to compare data with similar practices, data on local outcomes could be used to inform local policies. Perhaps patients could use the data to help them assess the balance of benefits and harms for their own treatment decisions.

Richard Baker, professor emeritus, Leicester

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individuals, taking into account the complexity of organising, delivering, and monitoring care across multiple conditions.

One way to achieve this is with a person centred framework including experiences and outcomes, with practitioner experiences and tools to support self management and wellbeing.

The primary goal should be baseline assurances and internal intelligence for quality

improvements, with freedom for practices to conduct their own audits and peer-to-peer learning. The system should use simple, easily understood metrics that provide clear warning signals and should avoid tunnel vision, gaming, and perverse incentives.

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HEALTH AND SOCIAL CARE

Will STPs lead to further cuts?

Sutaria et al outline the cuts made to health and social care by local authorities, but they fail to make the case that sustainability and transformation partnerships (STPs) will lead to further cuts (Analysis, 30 September).

Their argument amounts to the fact that they “expect the distinction between [health and social care services] to blur over time and some health services to fall out of commissioning and out of NHS funding altogether.”

Most commentators have long called for greater integration of health and social care. The expectation that this will lead to services losing funding stems less from rational argument and more from a prejudice against any health service reorganisation.

The primary purpose of STPs is to promote collaboration between healthcare organisations, eliminating the purchaser-provider split, the internal market, and all associated costs. Without STPs the cuts to health services would be much greater than if they are successful.

Jeremy P Wight, public health physician, Hope

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PUBLIC HEALTH POLICY

STPs are based on flawed financial assumptions

Oliver says that STPs could “in theory” deliver benefits (Acute Perspective, 28 October). But STPs have fundamental problems.

As the mechanism for delivering the new models of care envisaged in the *Five Year Forward View*, STPs are based on flawed financial assumptions, including the availability of sufficient capital to transform NHS services; a fall in the rate of growth of healthcare in acute hospitals; investment in public health and education to

rapidly reduce patient demand; and adequate investment in social care.

Worse still, the *Five Year Forward View* reproduces the World Economic Forum's prescription for supply side change and the various levers available to policy makers. This is reform in the interests of big business and not for patients.

STPs could “in theory” deliver benefits through empowering local teams and integrating care, but their cost saving imperatives mean they are not actually designed for this purpose.

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OVERPRESCRIBING

Opioids: not just an American problem

The rise in opioid prescriptions and mortality in the US has brought to light similar concerns in the UK (Editorial, 21 October). Opioid prescriptions and the number of deaths related to opioid misuse have risen in the UK. The factors contributing to the rise in prescribing are likely to be different from those in the US and perhaps secondary to the lack of effective alternatives for non-cancer chronic pain.

New evidence indicates that some traditional analgesics are ineffective in musculoskeletal pain, which is one of the most common indications for opioids. We need high quality evidence about the comparative benefits and harms of analgesics.

Rather than assigning opioids an “American problem,” we advise ongoing vigilance in the UK. Large scale population health studies using electronic health records will allow quantification of individual benefits and risks of opioids. This would enable prescription of the safest drugs to those most likely to benefit.

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Political change is needed

Makary et al acknowledge that doctors' habits have contributed to the opioid crisis (Editorial, 21 October). We must be careful that, in raising awareness of this matter, people who have a clear medical need are not denied these drugs; over-reacting would be as bad as letting the situation go unchecked.

We have insufficient data on the scale of misuse. We must move beyond crude indicators, such as the number of prescriptions issued, to gain an understanding of those most at risk and to offer a more targeted prevention approach.

We need interventions that support patients physically and psychologically. Treatment needs to be individually tailored allowing sufficient time, an optimum dose of a drug such as methadone, and a more assertive outreach approach, all of which increase the chance of recovery and minimise mortality.

Policy makers continue to ignore the role of evidence based treatment. Without political change people will keep dying.

Ian Hamilton, lecturer, York

Cite this as: *BMJ* 2017;359:j5519

STRATIFYING SUICIDE RISK

Risk tools protect doctors and institutions

Large et al advocate individualised assessments rather than over-reliance on instruments that have little evidence of effectiveness

(Uncertainties, 4 November). However, risk instruments also serve to protect individual clinicians and institutions.

After suicide, the NHS holds a detailed investigation, which usually concludes that trust or hospital policies were not followed and formal risk assessments were not carried out. Trusts' insurance premiums are decreased if they can show that systematic risk assessments are used by clinical staff. Commissioners often stipulate use of such instruments in their contracts.

There is consensus that these instruments add little to patient care and can act as a distraction, causing vital clinical cues to be overlooked. But we cannot underestimate the importance of form filling rituals in decreasing institutional anxiety. I call for more honesty about the process.

Frederick P Souza-Faria, consultant psychiatrist, Kidderminster

Cite this as: *BMJ* 2017;359:j5531

NEW MODELS OF CARE

Community development is not so new

It was refreshing to see the St Paul's Way transformation project covered in *The BMJ* (New Models of Care, 14 October). But there are several things worth pointing out.

Firstly, the concept of community development has been around for a century or so and is undoubtedly an essential part of any robust effort



The St Paul's Way community project has its peers across the UK

to improve wellbeing. Many stakeholders have been funding or delivering this type of work for decades. The Bromley By Bow Centre is pioneering, but similar pioneers exist in every town. Similarly, social prescribing and health champions are not new concepts.

Finally, assuming it was a direct quote, saying that “liberal *Guardian* readers writing reports rather than getting things done” is demeaning, factually inaccurate, and insulting to those who have been working in this space for decades. An article discussing the Hull Settlement in Chicago—a similar model to Bromley by Bow—was published in 1899.

Greg Fell, director of public health, Sheffield

Cite this as: *BMJ* 2017;359:j5509

PATIENT CENTRED DIAGNOSIS

In dementia we must listen to patients' wishes

Berger et al discuss shared decision making (Analysis, 4 November). Patient centred diagnosis in old age psychiatry covers not only which investigations to do but also what to conclude from the results. Patients are increasingly referred to memory services at earlier stages of cognitive decline, which adds to the dilemma of the degree of cognitive and functional impairment necessary for a diagnosis of dementia.

This is an inexact science, and patient wishes have a role in breaking bad news and making management decisions. Some have their eyes wide open and demand treatment at the earliest opportunity. Others are anxious and don't want the psychological burden of a terminal illness. We must also listen to patients' wishes and be prepared for decisions to be staged through a period of observation, collaboration, and discussion. Watchful waiting can aid the diagnosis and the therapeutic relationship.

Mike Devine, consultant in old age psychiatry, Dagenham

Cite this as: *BMJ* 2017;359:j5524

Gian Franco Bottazzo

Pioneering researcher into type 1 diabetes and impressive lecturer

Gian Franco Bottazzo (b 1946; q University of Padua, Italy, 1971), died after a short illness in his hometown of Venice on 15 September 2017

In 1969, at the age of 23, Gian Franco Bottazzo—a medical student at the University of Padua in Italy—travelled to London on a quest for knowledge. The young Italian was fascinated by immunology and spent countless hours in a university laboratory. To advance in the specialism, he wanted to learn the latest laboratory techniques.

In London, Bottazzo visited Middlesex Hospital and appeared before Deborah Doniach, an acclaimed researcher of autoimmune diseases (read obituary: <http://www.bmj.com/content/328/7435/351.1>), who had not met the charming young man before.

“I would like to learn immunopathology,” Bottazzo said.

With no hesitation, the world famous researcher replied: “Come tomorrow morning, nine o’clock.”

After learning the techniques used in Doniach’s laboratory, Bottazzo went back to Padua to finish his medical studies. He returned to London in the autumn of 1973 to work with Doniach as a research fellow.

Landmark discovery

A year later Bottazzo was the lead author, and Doniach a co-author, of a landmark paper published in the *Lancet*, which showed for the first time that type 1 diabetes is associated with the development of antibodies directed against insulin producing β cells. In simpler terms, Bottazzo showed that type 1 diabetes was an autoimmune disease. The paper, according to PubMed, was only the second in Bottazzo’s research career and his first in English. In 1972 he had published a paper in an Italian journal.

The discovery shown in Bottazzo’s study opened the door for countless investigations of autoimmunity as

a basic cause of failure not only of islet cells of the pancreas, leading to type 1 diabetes mellitus, but also the loss of other endocrine producing cells, such as those in the thyroid and pituitary glands.

“Homicide or suicide?”

Bottazzo was an extraordinary orator with an actor’s sense of the dramatic. He dazzled audience members during a lecture at Oxford University in March 1985, when he was honoured with the RD Lawrence lecture award of the British Diabetic Association (now Diabetes UK). The title of the lecture was *Death of a Beta Cell: Homicide or Suicide?*

He repeated the lecture later the same year at the XII Congress of the International Diabetes Federation in Madrid. In 2011 some 11 diabetes experts in the US published a paper in the journal *Diabetes* that largely focused on the conceptualisations presented 26 years before by Bottazzo.

Early life and career

Bottazzo was born in Venice. As a teenager he loved to play football, recalls Corrado Betterle, a lifelong friend who grew up in the same neighbourhood and is now a professor of clinical immunology at the University of Padua. Betterle says Bottazzo came close to joining Venezia FC, which at the time was playing in Italy’s top league Serie A. “He wisely decided to continue his studies instead,” says Betterle. Bottazzo was mentored at Padua by Mario Austoni, an internist who encouraged him in 1969 to travel to London for the meeting with Doniach.

In 1977 Bottazzo was appointed lecturer in clinical immunology at Middlesex Hospital. The next year he began a fruitful collaboration with Andrew Gordon Cudworth of St Bartholomew’s Hospital Medical College and founder of the Bart’s-Windsor Family Study of diabetes. Their first joint paper was published in 1978 in *The BMJ* and was followed



Bottazzo was an extraordinary orator with an actor's sense of the dramatic

during the next five years by 16 additional joint papers. Bottazzo’s most important HLA papers independent of Cudworth include two that were published simultaneously in the *Lancet* in 1983 and another in the *New England Journal of Medicine* in 1985.

Bottazzo was promoted to senior lecturer at Middlesex in 1980 and appointed as reader in clinical immunology in 1984. In 1991 he moved to what was then the London Hospital Medical College as professor and chair of the department of immunology. He also served as honorary consultant at the Middlesex Hospital Medical School from 1980 to 1991, and at the Royal London Hospital from 1991 to 1998.

He returned to Italy in 1998 as scientific director of the Bambino Gesù Children’s Hospital in Rome. However, he retained a London apartment and served as scientific director of the Autoimmune Diseases Charitable Trust in London from 1992 to 2002.

Bottazzo was author of nearly 350 research papers and more than 200 reviews and book chapters during his career, and his list of honours is long. He leaves his wife, Lamyia, a native of Kuwait, whom he met in London when she was a young immunologist; and a daughter.

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FROM THE ARCHIVE

The Doctors' Trial: medical experiments in Nazi concentration camps

On this date in 1946 an American military tribunal in Nuremberg opened criminal proceedings against 23 German physicians and administrators accused of war crimes and crimes against humanity in what became

known as the Doctors' Trial. *The BMJ* reported on the trial (*Br Med J* 1947;1:148) as having "drawn public attention to the vast number of human experiments, many of which proved fatal to the victims, which

were carried out on prisoners in concentration camps."

The author observes that "some people in this country have suggested that the accounts which they have read of these experiments, and of conditions in concentration camps generally, have been wilfully distorted as propaganda in order to intensify hatred against Germany. It has even been suggested that few or even no experiments of an objectionable nature ever took place. The fact of the experiments was clearly proved by the International Military Tribunal, which tried Goering and his colleagues."

The report describes how it is under the charge of war crimes that the various medical experiments are cited, which include: toleration of high altitudes, resistance to freezing, malaria infection, mustard gas,

treatment with sulphonamides and other substances of artificially inflicted wounds, the potability of seawater, methods of sterilisation, epidemic typhus, effects of poison, and the treatment of burns by incendiary bombs.

The journal notes that "the prosecution has used the word 'thanatology,' which they define as 'the science of producing death,' to describe the experiments. They allege that the object of the majority of the experimenters was not to advance medical science but to produce methods of speedy extermination. This seems to be true of some investigations... The work on the effects of poison gas would seem to have been so mixed with the programme of extermination of Jews and others deemed 'undesirable' that it is difficult to distinguish experimentation from wholesale killing."

WHAT YOU'RE TWEETING ABOUT

Doctors denigrating other doctors

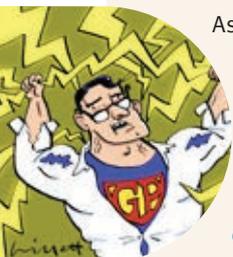
Last week *The BMJ* reported on a survey that found 70% of medical students had come across negativity towards general practice in clinical settings. Many of our readers on Twitter responded to share their own perspectives:

When will this end? Such attitudes harm general practice, the #NHS, and ultimately patients
 Prof Maureen Baker @Maureenprsb

This unfortunately goes both ways, and it undermines the care given by specialists and GPs
 Katie Lines @katielines1

This sort of tribal behaviour contributes to a culture of division, discrimination, and bullying. Medicine is not a competition... it's a collaboration
 Simon Judkins @JudkinsSimon

As part of their training all doctors should have a rotation in #generalpractice just like #GPs undergo hospital training. This will lead to a better understanding of the pressures in both
 Lamah El-Sharkawi @SharkawiLamah



Have heard lots of people say this goes both ways, really don't think it does. (Lost count of the number of my peers who say to good foundation year doctors that they would be "wasted as GPs")
 Dan Thomas @dan26wales

A little over 20 years ago I was told I lacked ambition because I wanted to be a GP. It's sad that it persists
 Gregor Smith @DrGregorSmith

Orthopods, radiologists, pathologists, ED docs, etc etc all have their own version of this denigration, perhaps not yet borne out in a college survey
 Kartik Logishetty @karlog43

I enjoy an excellent working relationship with hospital based colleagues. Mutual #respect makes for good patient care = which is the whole point
 Richard Weekes @rdmweekes

Fostering mutual respect is key. We are trained differently, have complimentary roles, and this is our strength
 Saliha Mahmood Ahmed @salihafoods

You can follow *The BMJ* on Twitter @bmj_latest and join in the latest discussions there

MOST READ ONLINE

Back to blame: the Bawa-Garba case and the patient safety agenda

BMJ 2017;359:j5534

Coffee consumption and health

BMJ 2017;359:j5024



Secondary care doctors denigrate general practice in front of medical students, study finds

BMJ 2017;359:j5517

Oral anticoagulants for prevention of stroke in atrial fibrillation

BMJ 2017;359:j5058

Mother is awarded £9m for "wrongful birth" after GP error

BMJ 2017;359:j5493