comment

THE BOTTOM LINE Partha Kar

What will the 2020s hold for diabetes care?

I've been reflecting on how much has changed in diabetes care over the past decade and what changes we may see over the next 10 years. The changes in the 2010s were nothing short of seismic, with fundamental shifts of treatment and approachs, irrespective of type.

Healthcare professionals have struggled to cope with some of the fast paced changes and the shifting evidence base, but the NHS has largely stayed ahead of the curve, although NICE has been criticised for not doing so. And people with diabetes have been even more nimble, innovating themselves when necessary, such as with the DIY artificial pancreas system (APS).

Prevention of type 2 diabetes came to the fore when the NHS launched an ambitious national programme. There was also the roll-out of a national dataset (the National Diabetes Audit), which has proved to be crucial in driving further investment. Over the past decade the whole ethos of treating type 2 diabetes has shifted from seeing it as a progressive condition to one that can, in some cases, be reversed or put into remission. Debate continued as to the perfect diet for people with diabetes, low calorie or low carbohydrate, and this too often ignored the triad of principles on which any diet sits: tolerability, sustainability, and—perhaps most important—affordability.

The world of type 1 diabetes saw an explosion of new technology. There was a move towards non-invasive testing of glucose levels, automated systems, and a movement led by patients who were fed up with a system not moving at the pace they wanted. The development of DIY APS certainly jolted the industry into action, although hurdles remain, such as legality, liability, access, and general acceptance. All of the technology hinged on the simple principle of enhancing self-management while—slowly but surely and encouraged by social media—peer support grew.

The Language Matters movement has also been important. This initiative tried to escape the clutches of "political correctness": as with any such attempts, the question of policing language arises. The aim, however, has been about understanding the nuances and challenges of coping with diabetes as a healthcare professional. There's still some way to go but one thing is clear: a new generation of patients and professionals are showing a willingness to work together to break down barriers.

Yet perhaps the biggest challenge for the NHS over the next 10 years lies in the care of deprived populations. The best drugs and diets will always be those that the person is able to take or use: it's never easy or feasible to consider an avocado for breakfast, or to turn up for a clinic appointment, when you work three zero hour contracts to fund your family.

The challenge will be to see all who are involved in diabetes care working to ensure that advances are available—and evenly for all, not just for the fortunate few.

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The biggest challenge over the next 10 years lies in the care of deprived populations

PERSONAL VIEW Mary Higgins

People deserve safe buffer zones around centres providing abortions

Protests have no place in front of medical sites where many patients —not only those seeking a termination—can be traumatised

On 1 January 2019, abortion care became more widely available in the Republic of Ireland. Before this, abortion was only available when there was a "significant risk to the life of the mother" from either physical or mental health conditions.

Following a public referendum in 2018, abortion is now available under 12 weeks' gestation for any reason, and later if there is significant risk to the life or health of the mother or where the fetus has a condition likely to lead to their death during pregnancy or during the first 28 days of life. Under nine weeks' gestation, care is largely provided by GPs or family planning clinics, unless there is a requirement for hospital care (such as maternal bleeding disorder). Over nine weeks all abortion care takes place in maternity hospitals. Of the Republic's 19 maternity units,10 provide abortion care, including all units in Cork, Dublin, Galway, and Limerick.

The vote in favour of expanding abortion care was passed by a majority of two thirds. Some of those who disagree with the result have been protesting at clinics and hospitals. They have mostly been small and haven't affected patient care, so clinicians have usually stayed silent, not willing to increase the visibility of a small group of people.

The women, couples, and families who attend for abortion care deserve respect and dignity

On 1 January 2020—the first anniversary of the legislation—the largest protest yet was held in front of a maternity hospital in Dublin, a video of which quickly went viral. A group outside the hospital carried placards and crosses, said prayers, and displayed small white coffins. This has raised the matter of safe access zones, or exclusion zones, for clinics and hospitals, similar to those implemented by Ealing Council in London.

Small white coffins

Abortion is only a small part of maternity care. The majority of people using maternity hospitals come for routine or high risk pregnancy care, gynaecology advice and treatment, or they are attending following a pregnancy loss. There are women attending with suspected or confirmed miscarriage, couples attending with stillbirths, and families who have had previous pregnancy losses. For people with these histories, small white coffins are traumatising. A small coffin represents the finality of a pregnancy loss, the sadness of never knowing the personality and potential contained within. For staff, these coffins represent some of the most difficult days of their professional careers.

There are also visitors to the hospital, including siblings of newborns. I saw one child asking her grandmother why there were people outside the hospital holding pictures of babies. The grandmother was silenced by the thought of the conversation that could follow.

The women, couples, and families who attend for abortion care also deserve respect and dignity. The decision to have an abortion can be heart wrenching. To have to walk past people who visibly disagree with your choice must be incredibly difficult. Women report feeling harassed by activists, rather than by their actual activity. Techniques such as "pavement counselling" and "prayerful witnessing" promote an (often religious) ideal where motherhood is sacred and the decision to abort is therefore damaging.

There is no other area in medicine where privacy, respect, and confidentiality are compromised by strangers protesting your

BMJ OPINION Karen E Lasser

A doctor's protest in the era of Twitter

It was a crisp autumn day, and I left my desk at Boston Medical Center and walked through the empty side streets of South End in search of coffee. As I was returning, I caught a glimpse of protesters in front of the hospital. Massachusetts Avenue, a major thoroughfare in the city, had been blocked in preparation for Melania Trump's visit to the centre.

Struck by the sight of my colleagues protesting, I took out my phone, snapped a picture, and posted it on Twitter. Several hours later, a colleague let me know that my name and tweet had been mentioned in coverage of

Physicians who care for immigrant patients feel compelled to speak out

the protest by Newsweek.com.

I have received hate mail in the past, as some of my research has been critical of the insurance, pharmaceutical, and tobacco industries, but these comments were a barrage of hate. A number raise the inflammatory concern that "left wing doctors" will provide inferior care to Republican patients.

Another theme was that doctors should be caring for patients not protesting. These comments recalled the National Rifle Association's message to "anti-gun doctors" that they "stay in their lane" after they published papers about firearm injuries and deaths and recommendations to reduce gun violence. Just as emergency department physicians and surgeons who care for patients with gunshot wounds have been speaking out about gun control, physicians who care for immigrant patients feel compelled to speak out.

Most of my patients are immigrants from Central and South American countries. While they have not discussed with me the effect of immigration policies on their lives,

DAMIEN STORAN/SHUTTERSTOCK

Members of Our Lady of Lourdes Protectors hold a prayer vigil outside the national maternity hospital in Dublin last summer

decisions. I have no problem with peaceful protest. It must be difficult to live in a country that overwhelmingly voted to extend abortion care if this is abhorrent to your morality and ethics. My problem is with protests against the legal right to choose different versions of healthcare in front of those clinical areas that provide it and in plain sight of those who are accessing this care, as well as the many who are not but could still be traumatised.

We have to advocate for those who cannot advocate for themselves—whether they are too upset or angry, or their decision is too recent, or they wish to avail of their legal right to confidentiality and respect. I am one of many physicians who serve as "faithful witnesses to the real world effect of legislative change." Therefore, we welcome the announcement by the Irish health minister that legislation will be brought forward for safe access zones. This is what the people of Ireland deserve.

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colleagues across the US have raised serious concerns. They have observed that immigrants are avoiding medical visits and withdrawing from public benefit programmes out of fear of deportation, in response to increasingly aggressive immigration enforcement.

What did my encounter with the protest teach me? That in times of human rights assaults and so much hate it's important doctors use their voices judiciously, so as not to lose credibility. I realised I had some ambivalence about protesting. Had it been President Trump visiting I would have protested, and not just on Twitter.

Karen E Lasser, professor, Boston University Schools of Medicine and Public Health

ACUTE PERSPECTIVE David Oliver

Discharge is a risky balancing act

On 13 January the BBC reported the contents of an internal email to doctors from the medical director and chief nursing officer at the Royal Cornwall Hospital. In response to "significant pressure," and to free up bed capacity, the email urged doctors to discharge patients "earlier than some clinicians would like." Last month the *Guardian* carried a similar story from Norfolk and Norwich University Hospital.

No doubt, those operational and clinician managers face an almost impossible balancing act. I'm sure you'd find similar emails in dozens of acute hospitals, given they start each day in negative bed equity, with patients queuing in the emergency department.

The Royal Cornwall email went on to say that some patients would be at risk of harm but that this would be "proportionate." You don't often get senior NHS managers being so candid: to that extent, I commend them. But we're entering dangerous territory when the clinical judgment of medics who have assessed patients, and who are accountable for decisions and consequences, is over-ridden, or when they're pressured to act outside their comfort zone.

The profession has been shaken by rare but high profile cases of gross negligence manslaughter, such as that against Hadiza Bawa-Garba. Through fear for our own livelihoods and reputations, our strong sense of a duty of care to patients is challenged. But what's our position when we receive such pressure?

The GMC has issued guidance on formally escalating and documenting concerns whenever staffing, workload, or system failures may put patients at risk. Its guidance suggests doctors must prioritise their primary duty of care and patient safety—but also use resources efficiently and make balanced judgments. I don't find this reassuring, and nor do I see a defence of, "the medical director made me do it."

Another concern is what information patients should be given. Surely, they'll have to be told they're being discharged earlier than their doctor might like, and we should document any safety netting we put in place for ongoing support.

I'd like to see every patient given a letter co-signed by the chief executive, medical director, and chief nurse, making it clear that bed pressures meant they were four square behind clinicians' necessary decisions to free beds. When complaints, inquests, or court cases arise those senior managers should visibly and unequivocally back the decisions of clinicians.

In acute hospital medicine we accept risk, along with competing priorities, daily. But, increasingly, we can't reconcile our professional values, clinical autonomy, and duty of care with our fidelity to employers and the fear of courts, regulators, and harm to our own mental wellbeing.

Ultimately, staff should not be backed into a corner or labelled as a problem when the root cause is a failure to create sufficient capacity in community health and care services and decisions to cut the acute hospital bed base too far.

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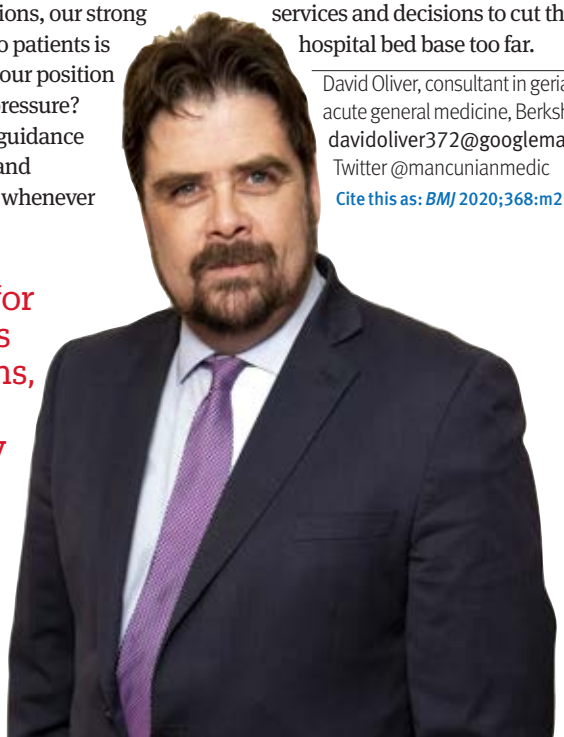

Through fear for our livelihoods and reputations, our strong sense of a duty of care to patients is challenged

PRIMARY COLOUR Helen Salisbury

The gaps in our knowledge

At medical school we learn to recognise the patterns of symptoms and physical signs that add up to predefined diagnoses. They appear in the textbooks and again in exam scenarios, but many of the real patients we meet don't fit neatly into diagnostic boxes. Sometimes they're just variants on a theme (the pneumonia without a cough, the painless heart attack), but a sizeable minority of patients in both primary and secondary care have symptoms we can't explain. Estimates vary, but this is said to be a feature of 20-50% of consultations in primary and secondary care.

Patients typically want to know what's wrong, and they can be frustrated by the lack of answers. Doctors are made similarly uncomfortable by their inability to solve a patient's problem. In GP surgeries we frequently say, "I don't know exactly what's causing your symptoms, but I can reassure you that it isn't dangerous." Patients can leave feeling unsatisfied, especially if they don't think they've been believed or that their symptoms have been taken seriously. Doctors often come to dread consultations where their medical toolkit, and by extension they themselves, are found wanting.

As medically unexplained symptoms are so common, it's important to equip our students and junior doctors with the skills to navigate this territory without over-investigation and over-treatment. One of the difficulties is deciding when to teach this: students need to understand the possible explanations and to have a grasp of diagnostic reasoning before we confound them with what can't be explained.

There's also disagreement among doctors about exactly what we should be teaching. Some believe that, if no pathophysiological diagnosis can explain the symptoms, they are by definition a form of somatisation—a physical expression of psychological distress, even when that distress isn't apparent to the patient. On the other hand, there are doctors who, while admitting somatisation is common, also believe that some symptoms are unexplained because our knowledge remains incomplete.

When I was a student in Whitechapel, east London, a common complaint among women, who came originally from Bangladesh, was of pain "all over." This pain was medically unexplained, and theories about cultural difficulties in expressing psychological distress (which could border on racist) were wheeled out to account for this somatisation. Since then we've gained more understanding of vitamin D deficiency, which was likely to explain the pain.

We need to review the learning needs of students and juniors. But we also need to tackle the hubris of our profession and be able to say, "We don't know—yet."

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A sizeable minority of patients have symptoms we can't explain

LATEST PODCASTS

Is it possible to have fair pricing for medicines?

The rising costs of many drugs, and the burden this places on healthcare systems and patients, continues to provoke public backlashes. In this podcast, Suerie Moon, co-director of global health at the Graduate Institute of Geneva, explores what is a fair price for both buyers and sellers of medicines and how it can be achieved:

"I think we need to have a much more robust public debate on how we continue to mobilise funds to invest in innovation, yet at the same time make sure that the new drugs are actually reaching as many people as they possibly can. Ultimately, if a new medicine doesn't reach patients, there's just no point. Most of the scientists that I've spoken to over 20 years of working in this area—the people who are working day in and day out trying to develop new drugs—that's what they want. They want their inventions to reach people and to improve people's lives."

Long term effects of childhood cancer treatment

A new study in *The BMJ* looked at the relationship between exposure to cancer treatment in childhood and the risk of cardiac events among adult survivors. One of the authors of the study, Daniel A Mulrooney, discusses what they found and how the long term effects of cancer treatments have repercussions for how child survivors should be followed through adulthood:

"There are studies out there that show that adult survivors of childhood cancer—while they may know they were exposed to chemotherapy or radiation—don't know the details. Some of these therapies have changed over the years, so it's very difficult for the survivor, and it's not easy for the primary care community seeing these now adult survivors of childhood cancer, to piece that together and understand the specifics of the therapy."

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Edited by Kelly Brendel, deputy digital content editor, *The BMJ*

ANALYSIS

Fool's gold? Why blinded trials are not always better

Blinding is intended to reduce bias but can make studies unnecessarily complex or lead to results that no longer address the clinical question, argue **Rohan Anand and colleagues**

KEY MESSAGES

- Blinding of participants, clinicians, and others avoids bias in clinical trials but can sometimes be detrimental to their integrity
- Some trials without blinding are inappropriately judged as poor quality
- Blinding participants and clinicians can affect recruitment, retention, and applicability to routine practice as well as causing potential harm to patients
- Double blinded designs are not always ideal for providing a reliable answer to the trial's research question
- People using such designs should rationalise their use of blinding
- A more nuanced approach, using blinded outcome assessment and independent blinded adjudication of outcomes, alongside adequate randomisation and objective outcome measures, should reduce the main forms of bias

The essence of blinding is withholding information about treatment assignment from people involved in the trial. Trials in which patients, clinicians, and researchers are blinded to the allocated intervention are usually regarded as the gold standard of clinical research and evidence.[1 2] However, blinding's illustrious reputation brings with it the danger that it is regarded as essential for a trial to be "good," especially if users place an uncritical reliance on hierarchies of evidence in which blinded evaluations are near the top.[3] Given that the number of new trials is increasing every year, with 25 000 registered since the start of 2019, we are concerned that a substantial amount of time, energy, and funding may be going into considering and implementing blinding without a sound rationale for it.[4]

Past, present, and future trials contain vast amounts of important data. If trials without blinding are inappropriately judged to be of lower quality than blinded trials then we may not be making best use of their data to improve healthcare, while blinded trials may be producing results that are more difficult to interpret than they need be. In this article, we seek to stimulate debate by challenging some of the prevailing beliefs on the benefits of blinding.

Blinded trials may be producing results that are more difficult to interpret than they need be

Purpose of blinding

Blinding is used in trials to reduce bias by ensuring that knowledge of which intervention a given trial participant received does not influence the judgments of trial participants or investigators. This allows the identification of the "true effect" of the new intervention, as distinct from any effect arising simply from the participant's knowledge or expectation of receiving an intervention. In placebo controlled trials, any placebo effect of the new treatment would be discounted when comparing the intervention and control group to determine the effect of the active properties.

Blinding is also used to reduce bias in which the measured effect is not the true effect.[6] Blinding aims to minimise response and observer bias. Response bias occurs when participants respond inaccurately, either intentionally or unintentionally. Observer bias occurs when researchers assessing the effects of the interventions have presumptions about them and so may inaccurately measure outcomes, leading to different effect estimates. Blinding also aims to minimise co-intervention bias, in which non-trial interventions may be taken differently by the groups being compared if participants know what they have been allocated.

Evidence on the ability of blinding to minimise the "placebo effect" (which can occur regardless of whether an actual placebo is used) and reduce bias comes from comparisons between selected trials[7] and from systematic reviews of methodology research,[8-12] with lack of blinding leading to an exaggerated treatment effect of up to 68%. However, there are several negative consequences that can arise from blinding.

Blinding's negative aspects

The substantial challenges of recruitment and retention in clinical trials have been highlighted as priorities for research.[13 14] Poor recruitment leads to prolonged study times and underpowered results. These challenges are made worse by blinding, especially in trials using a placebo control.

Trials with nested components that were blinded and unblinded found that blinded designs discouraged people from participating.[15-17] Key reasons given by patients for not wanting to enrol in these trials were that they wanted a named medication or wanted to know what was in the tablets. This suggests that achieving blinding and using a non-active comparator discourages people from joining a trial. In another study about 25% of patients expressed concerns about receiving placebos.[18]

Successful retention of patients is equally important,[19] and the use of a placebo might be damaging if

Box 1 | Problems associated with blinding

Emergency unblinding

If an individual's allocation has to be unblinded for clinical reasons, there is the potential for this to cascade and unblind others in the trial. A simple example would be an adverse event needing treatment that is reported by blinded trial staff, who then code break to identify which intervention the patient received.

Although the trial staff are officially unblinded to only this single case, they might now associate this event or related symptoms with the specific intervention. Even worse, if all the interventions had been coded in the same way (such as "drug A" and "drug B") those who unblind themselves to one patient, effectively unblind themselves to all patients. Even in the absence of such coding, unblinding of patients in a trial using blocked randomisation might reveal the allocations of patients from the same block or strata.[31]

Testing for blinding

Testing for the success of blinding in trials has been reported in about 2% of trials,[32] usually by asking those blinded to guess treatment allocation.[33-36] In theory, any significant difference over chance suggests that blinding was compromised. However, measuring blinding is highly challenging.

Asking people to say which treatment was allocated after outcomes have been accumulated makes them likely to base their answer on assumptions related to the effects of the intervention. This was observed in a 2x2 factorial trial of aspirin and sulfinpyrazone for stroke prevention in which blinded clinicians were asked to guess treatment groups and did significantly worse than chance.[37] Their guesses seemed to be influenced by their prior assumptions that sulfinpyrazone was more effective than aspirin and that patients who did well must have been on sulfinpyrazone, when in fact the trial showed the opposite.[38]

This essentially confounds testing for the success of blinding with expectations about treatment efficacy.

In theory, any significant difference over chance suggests blinding was compromised

patients who suspect that they have been allocated to receive it withdraw from the study.

A meta-analysis investigating retention in trials of antipsychotic interventions concluded that a placebo controlled design significantly increased dropout.[20] Patient preference or resentful demoralisation can be a problem if patients in a placebo group lose motivation when they suspect or discover they are not receiving an active treatment. This could result in bias from differential loss to follow-up between groups.[21] Patients may feel frustrated because they believe they are receiving inadequate treatment and so exaggerate negative answers on questionnaires or even withdraw from the trial.[22]

The production and packaging of interventions in ways that will ensure their identity is blinded to participants, including use of placebo controls, can also cause difficulties. Not only do control interventions need to look identical to the intervention, any characteristic taste, texture, smell, colour, or viscosity of the intervention needs to be matched as well, which can be expensive.[23]

Money spent on blinding has opportunity costs if it reduces funding to optimise other features that would have more influence on the trial's robustness such as the training of trial staff, boosting the sample size, and comprehensively measuring outcomes.[24] Even if the blinded control is designed to be physically identical to the intervention, any signature side effects associated with the intervention(s) may lead to unblinding.[25]

Examples come from the IMOP trial of isosorbide mononitrate for cervical ripening[26] and the IMAGES trial of magnesium for acute stroke,[27] both of which had high rates of specific side effects in the intervention arms; even though no formal unblinding of researchers and patients occurred, those involved in such trials may have had a good idea about the groups that patients were in.

In addition to this passive association, others might actively look for signs that they believe to be linked to the interventions.

The online community group PatientsLikeMe was set up to enable people to share information on their illnesses. Members who were enrolled in blinded clinical trials shared their outcomes, including side effects, on online platforms outside of the official protocol or any trial regulations, even before the trial's completion.[28] Their aim was to help each other deduce their allocated intervention, showing their frustration in the blinded approach. This highlights that maintaining blinding may be increasingly difficult in the age of social media and online networks.[29]

Researchers have also been found to break blinding by comparing pills and searching through the restricted notes of patients.[30]Box 1 describes other problems that can arise.

Patient safety risks

When blinding might compromise patient safety, it is paramount to consider whether it is necessary. For example, a placebo controlled trial of fibrinogen for postpartum haemorrhage required a moratorium on the use of any new treatments for 15 minutes after the randomly allocated treatment was given, with the sole purpose of maintaining the blind, potentially creating an unacceptable risk for the women.[39]

Similarly, adjusting doses creates problems in blinded trials and in such situations, using a fixed dose of a drug with a narrow and volatile therapeutic range could compromise patient safety. Clinical trials with anticoagulants[40] and antipsychotics have been historically difficult to blind because of the need for dose adjustments.[25]

Use of a placebo or other sham therapy might lead to adverse effects that would not have happened if an open control group had been used. These could be direct harms from the procedures intended to ensure blinding, such as infection from piercing the skin to give a placebo injection or muscular problems from sham physiotherapy.

In considering these concerns about patient safety, Franklin G Miller outlined key questions that

might help when deciding whether to use placebos in surgical trials.[41 42] It seems reasonable to apply a similar but expanded set of questions, as listed in box 2, when considering using blinding in all clinical trials.

These questions are context dependent and would be determined by those designing the trial; if the disadvantages outweigh the benefits in one of the questions then a blinded trial might not be appropriate.

Pragmatism and the real world

At its simplest, a randomised trial is a comparative effectiveness study that aims to obtain as unbiased an estimate as possible of the difference in the outcomes for patients in the treatment group compared with those in the control group. Beyond this, the ultimate aim is to generate evidence that can be used to make assumptions about what will happen to future patients who receive the treatment after the trial.

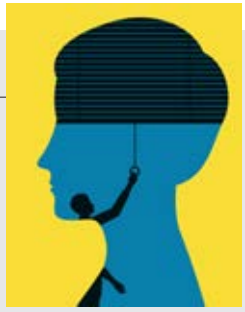
Blinding might help to reduce bias but hamper the evidence generated. Minimising biases with blinding might weaken the ability to predict the future accurately, because blinding is unlikely to be used in routine practice. There is a continuum from explanatory to pragmatic trials, and blinding influences where a trial is on this continuum.[43]

Some of the types of blinding that would be contemplated only in a research setting are inconsistent with the desire for pragmatism in large, phase III pragmatic effectiveness trials. Pragmatic trials strive to generate situations that are as close as possible to routine practice, when patients and clinicians will not be blinded to the intervention.

Outside trial settings the intervention is known and this will have a legitimate effect on behaviour, including use of co-interventions, concerns about side effects, and decisions about continuing or stopping the therapy. Some interventions will be marketed for over-the-counter and prescription use, and both patients and clinicians will be susceptible to brand psychology, meaning choices will be determined by facets surrounding brand loyalty.[44]

Clinicians might pay particular attention to assessing patients for side effects and act if they observe them. Both patients and clinicians might choose to continue with a therapy they believe to be active and beneficial and stop taking therapies they believe to have completed their action, or switch from those that do not seem to be working. Box 3 (on bmj.com) gives some hypothetical examples.

Box 2 | Questions to consider before using blinding



- Is blinding needed for a scientifically sound result? (Will the intervention have a placebo effect which needs to be separated from its true effect?)
- How likely is it that patients or clinicians will behave differently if they know the intervention and would this change in behaviour bias the results?
- Are the potential harms to patients of using blinding excessive?
- Does the anticipated social value of the study results justify any potential harms of blinding?
- Does the financial cost of blinding compromise spending on other methodological aspects of trial integrity?

Increasing trial integrity

The prospective randomised open blinded endpoint evaluation (PROBE) is an established method for trials.[45-47] It emphasises randomisation (with secure concealment until the allocation is revealed) and blinded outcome assessment, two facets that protect against bias. The blinding is implemented while evaluating defined endpoints during a trial. Trials using PROBE are regarded as open label with respect to patients and clinicians but implement the blinding of outcome assessors or the blinded evaluation of the trial's endpoints.

This approach of keeping outcome assessors blind to the random allocation can be used in most trials, including pragmatic effectiveness trials in which outcomes are either subjective or objective. Blinding the outcome assessors throughout a trial or using blinded evaluation of endpoints by a committee at set points, reduces the effect of observer and response bias, which can cause substantial reported differences between treatments.

Such methods would increase rigour when double blinding of patients and clinicians is dropped, might be simpler to deliver, and can avoid the many challenges we have outlined. For example, although the outcome assessor is blinded, the study replicates routine practice in that patients and clinicians know which intervention is being used for a particular participant.

If blinded outcome assessment cannot be used in a trial, bias can still be substantially reduced by using objective (eg, death) rather than subjective (eg, quality of life) outcomes. This is supported by a large meta-epidemiological study that found little evidence of bias in unblinded trials that used objective outcomes for both drug and non-drug interventions.[48] Another option to reduce bias is to modify the outcome to make it less subjective. This can include avoiding surrogate markers and limiting the size of any effect on a given clinical measure (eg, using a 5 point Likert scale rather than 10 point Likert scale).[49]

Blinding can increase the reliability of a trial's results but has consequences for the practicality, safety, and results of some trials. We suggest that the key elements for clinical trials seeking to minimise bias when comparing the effects of interventions should be adequate randomisation, allocation concealment, use of objective outcomes, independent blinded adjudication of outcomes, and, when possible, blinded assessment of outcomes.

The traditional double blinding of participants and clinicians should not be regarded as a gold standard to strive for and should be used only if the negative effects are considered carefully and are outweighed by the potential benefits.

Maintaining blinding may be increasingly difficult in the age of social media and online networks

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RESEARCH, p 104

LETTERS Selected from rapid responses on bmj.com

LETTER OF THE WEEK

True candour means full disclosure of system failures

I agree with Maskell that we should be honest and volunteer all information to people harmed by provision of services (Personal View, 7 December). But why should we stop at doctors' honesty about mishaps during patient care? Why shouldn't we make the public aware of the shortages nearly all hospitals face and the stress and unrealistic demands that these place on staff?

Hospitals should have a board outside the entrance, like those outside car parks, stating the number of staff shortages, vacant beds, and patients waiting on trolleys in the emergency department. And the number of scanners that aren't working and the delay in discharge because of the shortage of community care and nursing home beds. And the number of staff who are absent because of stress or involved in appraisals and revalidation.

Then, some people might decide that their hospital visit could wait for another day or might even decide to have the investigation done elsewhere. Others might decide to take their loved one home and bridge the gap before care starts. This would make the public more appreciative of the care provided under difficult conditions in a constantly overstretched system. They would also be more understanding when unintentional errors are made.

Above all, staff should feel supported and their sacrifices appreciated. The public should realise that the NHS is the envy of the world but is giving way at its seams. If we don't support NHS staff—the service's greatest asset—we are in danger of losing our national treasure.

Rajaratnam Jeyarajah, consultant physician, Carshalton

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VOTING TO END HOME VISITS

Have GPs gone mad?

GPs voting to cease home visits—has the profession gone mad? (Helen Salisbury, 30 November). I am a GP in my 60s, close to retirement and even closer to burnout. I have observed changes in general practice over the decades and recognise that our profession is toiling under major stresses.

Sitting with a patient that you have come to know as a friend over the years in their house with its family possessions, while listening to them as a friend and doctor, is one of the things that has made family medicine worth while. We should think long and hard before electing to lose this privileged aspect of primary care.

Something has to change, but it is not ditching home visits. Traditional family medicine would be gone, and the profession would have lost a lot in the eyes of the public.

Cornelius Brodbin, GP, Birkenhead

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UNDERSTANDING DEMENTIA

Hearing loss mistaken for dementia

Cook and colleagues summarise deficiencies in the care of people with dementia but do not mention hearing loss (NIHR Signals, 9 November). How can I follow instructions if I can't hear what you are saying? Healthcare professionals have a duty to work out why, to ensure the necessary environment and equipment are optimised, and to convert communication into conversation.

Obstructing ear wax must always be excluded, then simple measures such as facing the patient, lowering the pitch of the voice, and avoiding shouting might enable conversations.

Perhaps the best preventive measure is to ensure that all adults take up and use hearing aids as soon as hearing loss is identified. Regular use should mean that patients are more likely to continue with it as their mental ability deteriorates. Hearing aid use is also associated with reduced incidence of dementia, and hearing loss can also be easily mistaken for the condition.

Ted Leverton, retired GP, Bere Alston

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MATERNITY CARE FAILINGS

When unusual circumstances become accepted as normal

It seems extraordinary that it has taken so long for an investigation into the serious problems with maternity services at the Royal Shrewsbury Hospital and the Princess Royal Hospital in Telford (News Analysis, 30 November).

The Royal Shrewsbury was held up as a beacon of excellence on account of its unusually low caesarean section rate, which was actually a contributing factor to the deaths of 42 babies and to 51 being left with brain damage and cerebral palsy. What was recognised as being unusual became accepted as normal.

England and Wales are short of at least 2500 midwives. Rising maternal obesity and a trend towards older motherhood are making childbirth more complicated. There is no obvious solution, so the unusual situation of midwife shortages has become accepted as normal.

We need an inquiry into the safety of the current state of unusually low midwife numbers, before it is too late.

Malcolm John Dickson, consultant obstetrician and gynaecologist; Maheshie Obeysekera, specialty trainee year 4 in obstetrics and gynaecology, Oldham

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Living without water, with HIV: a dangerous cycle

WaterAid helps empower regions with world's highest prevalance of the virus. Please give generously

For the nearly 28 million people in sub-Saharan Africa living with HIV, a lack of clean water, decent sanitation, and good hygiene could be life threatening. They constantly face an increased risk of diseases and infections, including pneumonia and diarrhoea.

WHO recommends a minimum of 20 litres of water per person a day to cover consumption, food preparation, cleaning, and hygiene. For someone living with HIV this can rise to more than 100 litres a day because of the need for extra cleaning and the consumption of medication.

Yet populations worst hit by HIV are often also those with the poorest access to clean water. The kingdom of eSwatini (Swaziland) has the world's highest adult prevalence of HIV, with 27% of people aged between 15 and 49 living with the virus. Alongside this, a third of people lack close access to clean water and two in five have no decent toilet.

WATERAID/NYANI QUARMYNE/PANOS

Minky Sithole (right) with members of the HIV support group she set up

People living with HIV must take antiretroviral drugs daily. Many, however, have no choice but to take them with dirty water that can cause sickness and diarrhoea. This raises the risk of food and drugs not being absorbed in the right quantity to keep the virus under control—a dangerous cycle.

Minky Sithole, a 40 year old mother in the Lubombo region of eSwatini, says, "Sometimes, when you have to take the pills, you don't even have a sip of water in the house."

Sithole, who was diagnosed with HIV in 2006, set up a local support group that is a haven for people coping with the virus. The community has endured three years of low rainfall and now, after a long dry season, face dire conditions. "I feel hurt, every day. In the morning I go crazy because I'm not sure where we're going to find water," she says.

The burden and strain of fetching water from distant sources is higher for people living with HIV who often have lower energy levels or side effects from drugs and symptoms of opportunistic infections.

Sithole and her family travel a significant distance to a dirty water source every day in the dry season. In the rainy season, they collect rainwater from the roof, which although contaminated with dust and insects, is cleaner than the river water.

"Where we fetch water in the river it is not clean. Sometimes, because you are weak, you can't even go and fetch the water. You have to wait for the school kids to come home," she says.

WaterAid is working in Sithole's community to ensure there is sustainable access to water, by rehabilitating and installing 10 water systems, specifically targeting drought affected communities. They are also collaborating to build and run water kiosks and toilets. The charity also works at international level to highlight the need for water and sanitation to be integrated into HIV programmes.

We all need to do more to strengthen efforts towards universal access to water and sanitation. It is essential that there be continuous empowerment of people living with HIV to demand their right to water and sanitation.

Chilufya Chileshe, Regional Advocacy Manager for Southern Africa , Wateraid

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19/MAB/01B

David Christopher MacDonald Burns

Consultant genitourinary medicine physician (b 1937; q King's College Hospital, London, 1964; FRCOG), died from complications of Parkinson's disease on 25 January 2019

David Christopher MacDonald Burns trained originally as a gynaecologist but chose to move into genitourinary medicine—a decision he never regretted. He was appointed consultant at the Royal Free Hospital, London, in 1973, where he stayed for the rest of his career and saw patients from the earliest challenging days of HIV infection through to the advent of effective therapies. For a decade he was also consultant to Holloway prison. David was an active member of the BMA's Hampstead division and president of the London Harveian Society in 1996. Outside medicine he was a knowledgeable and eclectic collector of antiques and loved pre-war cars. He leaves his second wife, Jean; two children from his first marriage to Janet; two stepchildren; and six grandchildren.

Jean MacDonald Burns

Cite this as: *BMJ* 2019;367:l7018

Robert Dick

Consultant radiologist (b 1937; q Sydney 1960; FRCR, FRACR), died from multiple system atrophy on 26 April 2019

Robert Dick ("Bob") moved to the UK from his native Australia in 1966, to take up a radiological registrar post for Commonwealth graduates at the Middlesex Hospital. During this placement he met and married Diana Fairclough (a graduate of Guy's medical school). After posts in Athens and at King's College London, Bob was appointed consultant radiologist at the Royal Free Hospital in 1971. He was a pioneer in hepatobiliary interventional procedures and excelled at embolisation, angioplasty, stent insertion, stone removal, and percutaneous biopsy. He published numerous articles and in 1987 he co-edited and contributed to the book *Imaging in Hepatobiliary Disease*. He retired from the Royal Free Hospital at 60 but continued to work at King George Hospital, Ilford, and the Central Middlesex Hospital into his 70s. He leaves Diana, four children, and 11 grandchildren.

Diana Dick, Antonia Fletcher, Elizabeth Dick, David Allison, James Dooley

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John Robin Munro Gibson

Consultant obstetrician and gynaecologist St Richard's Hospital, Chichester, west Sussex (b 1930; q Royal Free Hospital Medical School 1956; FRCOG), died from pneumonia, left ventricular failure, frailty, and dementia on 30 October 2019

John Robin Munro Gibson was appointed consultant to the Chichester Hospital Group in 1968. During his first four years, he was involved with the building and establishment of a new maternity and gynaecological department at Chichester Hospital. Although not academic by nature, John enjoyed student and other teaching sessions and was also responsible for the introduction of laparoscopic techniques to the department in the very early 1970s. He was self taught from a textbook, a practice that would not be condoned in modern medical education. A large garden kept him occupied in retirement; he also enjoyed watercolour painting and playing the piano. His wife, Jennifer, predeceased him, and he leaves four children, eight grandchildren, and five great grandchildren.

John Robin Munro Gibson

Cite this as: *BMJ* 2019;367:l7016

John Anthony Lynn

Consultant endocrine surgeon (b 1941; q King's College Hospital Medical School, London, 1964; FRCS, MS), died from metastatic renal carcinoma on 16 September 2019

After house jobs, John Anthony Lynn worked in general practice for a year, during which he began studying for a surgical career. In 1967 he was employed by Cable and Wireless as medical officer on Ascension Island in the South Atlantic. He resumed hospital work in Chester and spent time in Boston, USA. As consultant endocrine surgeon at the Hammersmith Hospital for some 29 years, he developed at the hospital and Royal Postgraduate Medical School what was to become the largest endocrine surgery unit in the UK. John retired from NHS work in 2006 and continued in private practice until shortly before his death. He leaves his wife, Ann Drury.

Paul David Lewis

Cite this as: *BMJ* 2019;367:l7020

Gamal Mahdi

Consultant paediatric gastroenterologist Aberdeen (b 1949; q Ain Shams University, Cairo, Egypt, 1973), died from pancreatic cancer on 30 April 2019

Gamal Mahdi moved from his native Egypt to the UK with his family in 1984. He worked in Chester, Bath, Bristol, Hull, West Sussex, and most recently Scotland. His career also took him to Saudi Arabia, Cairo, and Canada. Gamal had a particular affinity for the care of young babies with reflux, never forgetting their stressed and anxious parents. After retiring from full time work in Canada in 2015, Gamal returned to locum practice in the UK and became the first consultant to work in all three Scottish paediatric gastroenterology networks based in Aberdeen, Edinburgh, and Glasgow. He leaves his wife, Naglaa Massoud; four children; and a grandson.

Richard Hansen, Johan Van Limbergen, Yasmin Mahdi

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Thelma M Phelps

Specialist in community medicine Nottinghamshire (b 1922; q 1945; MFCM, DPH), died from a stroke on 26 October 2019

After house jobs in east London, Thelma M Phelps married and moved to Nottingham. She worked as a dental anaesthetist for 17 years and then moved into public health. She worked as a specialist in community medicine in Nottinghamshire until she retired in 1987. She had responsibility for working with social services and spent most of her time as a reference point for councillors, senior managers, and anyone who had a query about healthcare in Nottinghamshire. Her work in adoption and fostering, services for older people, and young people in the criminal justice system was much valued. Thelma was a member of the Medical Women's Federation for 65 years. She leaves two children; four grandchildren; and five great grandchildren.

Rachel Angus, Christine Hopton

Cite this as: *BMJ* 2019;367:l7015

Iain MacLaren

Surgeon, examiner, and vice president of the Royal College of Surgeons of Edinburgh

Iain Ferguson MacLaren (b 27 September 1927; q 1949; FRCSEd, FRCSEng, FRCPEd), died from Parkinson's disease on 3 October 2019

In 1956 Iain MacLaren agreed to get his chest x rayed. He later said this was done to please his GP father. He was working as a surgical registrar at the Royal Hospital for Sick Children in Edinburgh at the time and had to step down when he was diagnosed with tuberculosis.

Fortunately, he was in the right place. He became an early recipient of John Crofton's triple drug approach—the "Edinburgh method," which transformed the treatment of the disease—and he made a full recovery.

Proud Scot and surgeon

MacLaren was born in Edinburgh in 1927 to Gaelic speaking parents. He was proud of his heritage and in 1970 became chairman of Clan MacLaren. At the age of 9 he learnt to play the pipes and went on to judge piping. A medical colleague recalled how he liked to play the pipes at key events, often afterwards offering guests a fine single malt whisky.

MacLaren attended Edinburgh Academy in 1932 and then moved to Fettes College on a scholarship in 1939. As the second world war drew to a close, he said it "seemed natural to drift towards medicine." He trained at Edinburgh University, qualified in 1949, and became a house surgeon to James Learmonth, the surgeon awarded the Royal Victorian Order for performing a lumbar sympathectomy on George VI in Buckingham Palace in 1949.

In 1950 national service interrupted his medical career, and MacLaren joined the army. On Christmas Day 1951 he arrived in the Suez Canal to provide cover for the medical officer of the First Battalion of the Lancashire Fusiliers. He said he enjoyed his time so much he almost signed up permanently, but instead he returned to Edinburgh in 1952 and became a demonstrator in the university anatomy department while studying for the fellowship exam of the Royal College of Surgeons.

MacLaren felt torn. He had spent a year assisting his father, a singlehanded GP in Edinburgh, and was excited by the possibilities of general practice in the new NHS. He decided, however, to continue pursuing his surgical career and took a registrar job, first with James Learmonth and then at the Royal Hospital for Sick Children. He also spent a year at the Hahnemann Medical College in Philadelphia in the US, working for John M Howard, a leading figure in pancreatic surgery.

Consultant and examiner

In 1967, MacLaren was appointed consultant general surgeon at the Deaconess Hospital in Edinburgh and in the same year married Fiona Heptonstall, whom he had met when they worked on adjacent wards. They had two children, Catriona and Patrick, and hosted many convivial gatherings of friends and clan members at their home in Minto Street.

In 1974 MacLaren was appointed consultant surgeon at Edinburgh Royal Infirmary, where he stayed until he retired from the NHS in 1992.

He took a wide ranging interest in the profession and in 1972 became the secretary of the Royal Society of Surgeons of Edinburgh and then its vice president between 1983 and 1986. He was an examiner for the FRCSEd and travelled widely to places such as Iraq, Libya, Sudan, and Zimbabwe. He also examined candidates from Scotland's three extramural medical schools who were taking the Scottish triple qualification. This led to him becoming involved with the General Medical Council's tests for foreign doctors seeking to practise in the UK. He chaired the Professional and Linguistic Assessments Board from 1984 to 1999, where he established the objective structured clinical examination (OSCE), which measures candidates' clinical competence.

MacLaren liked to play the pipes at important events, often afterwards offering guests a fine single malt whisky

Surgical museum founder

MacLaren was interested in history and, as well as helping set up the surgical museum at the Royal College of Surgeons of Edinburgh, he co-wrote *Surgeons' Lives: An Anthology of College Fellows over 500 Years*. In 2017 the MacLaren Research Centre opened at the college. It is a space for the study of surgical history and was funded by a former student of MacLaren, the urologist Andrew Chan.

In later years MacLaren was able to spend more time pursuing his other interests, such as music, the Clan MacLaren Society, military history, and keeping up with his wide circle of friends. In 1991 he was invested as a chieftain of the Clan MacLaren in a ceremony at the Lochearnhead Highland Games, in honour of his outstanding contribution.

Although very fit all his life, he latterly developed Parkinson's disease and died aged 92. He leaves his wife, Fiona; their two children; and four grandchildren.

Penny Warren, London
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