Evidence Base and Vaccine Policy

David Healy December 13th 2021

When vaccines and drugs are approved, these days, regulators state they have a favourable Benefit-Risk ratio. Regulators have only made statements like this for approximately two decades. Prior to that, treatments were approved on the basis of an established treatment effect with some evidence for a likely acceptable safety profile.

Benefit-Risk ratios are now, according to regulators, established in Randomized Controlled Trials (RCTs), also called clinical trials. RCTs are now, and have been since 1962, essential to approval, but there has been a shift from using them to establish a treatment effect to viewing them as laying the basis for a Benefit-Risk ratio.

Approval is not granted on the basis that this drug acts on the serotonin system or that vaccine produces Spike proteins. These biological effects may be true but the observed effects on people in RCTs in the real world are given primacy. The biology may help explain those observations but is not a basis for approval, other than in exceptional cases.

The approval process requires pharmaceutical companies to run RCTs, the results of which are submitted to regulators (FDA, HealthCanada, EMA, MHRA, and TGA). These bodies may regulate Food and Drugs, as FDA does, or medical drugs and devices but not food (MHRA).

The pivotal (key) RCTs are ordinarily published in medical journals, usually a prestigious journal if the treatment is noteworthy. These publications are the primary means of conveying key details of a drug to doctors who as learned intermediaries are entrusted with responding to queries from patients about their conditions and possible treatment benefits and risks.

For both drugs and vaccines, the RCTs that lead to an approval are viewed as offering a favourable Benefit-Risk ratio on both an individual and population basis. Individuals clearly can opt not to consent when the matter is one that primarily affects them. Regulators believe that across a population the benefits will outweigh the risks and since 1991 they invoke a fear of deterring people from seeking a benefit to explain their caution about warnings about hazards.

Companies rather than regulators decide whether to warn about a hazard. They may do so because the hazard is serious, or because it is one that can be avoided if warned about, or when it is one that induces a frisson that might increase sales. Companies write drug labels. Regulators review these for wording that is not supported by evidence, but do not write them.

RCTs have developed a reputation as a good way to manage all potential sources of bias or confounders that may compromise the evaluation of a treatment. This reputation is misplaced according to Sir Austin Bradford Hill, who developed and ran the first RCTs, and Dr. Louis Lasagna, who introduced RCTs to the regulatory apparatus in 1952 to help establish whether treatments are effective. From the start, companies have been the people encouraging doctors to practice in accordance with evidence that only they have the resources to produce.

RCTs can manage some confounders in very limited settings. This management, however, involves a trade-off. A drug or vaccine can have a hundred or more significant effects. Selective Serotonin Reuptake Inhibiting (SSRIs) antidepressants, for instance, have multiple actions other than just their action on the serotonin system. In addition, they affect every bodily system – eyes, ears, skin, bones, muscle, gut, blood, heart, sperm, hormones, allergic responses, urinary

system, genitals and other aspects of sexual function, as well as the peripheral and central nervous systems, where they affect appetite, sleep, libido, anxiety levels, memory and mood.

Similarly, it was hoped the Spike proteins, that mRNA agents generate, might lead to immunity but in addition they affect most bodily systems in a manner that does not happen with traditional vaccines.

An RCT necessarily focuses on the effect of primary therapeutic interest, called the primary endpoint. Does this drug affect mood? Does this vaccine produce immunity? For the purposes of running a trial, we are not interested in whether it also has antibiotic properties as several SSRIs do or whether an antibiotic inhibits serotonin reuptake and might affect mood.

Most (90%) examinations and measurements in an RCT centre on the primary endpoint, with investigators having little time, or space, to record other effects.

From Model to Mandate?

A model in which companies are required to prove a treatment benefit through an RCT has some utility when the task is one of establishing whether a treatment has an effect of possible therapeutic value, where those effects are uncertain because of natural variation or placebo effects. The intention was to hold companies seeking to make money out of us at our most vulnerable to a higher standard than charlatans.

It was once thought that a positive result in one RCT of a medicine would invariably make for positive results in other RCTs of that medicine, but this has not been borne out.

The model however also has a bureaucratic function. It gives regulators a box to tick. They can approve a drug where there are two positive RCTs, even if the majority of RCTs done have been negative.

The Primary Endpoint Problem

The model when introduced was not viewed as providing a basis for a Benefit-Risk claim. It does not now provide such a basis.

The basis for a possible claim of a favourable Benefit-Risk hinges on the primary endpoint in a trial offering a significant benefit and being by far the commonest effect of that treatment. Other effects may occur, but they are viewed as rare or events that only appeared after the trial period was over and therefore not missed deliberately.

For instance, in the case of a parachute, saving a life is significant and the life-saving effect is the commonest effect of that device. Limbs might break in the process, but these injuries are less important and less common.

A positive Benefit-Risk balance in other words is obvious. RCTs are not needed. If the primary endpoint in a trial is less common than other effects and less beneficial than the harm these other effects entail, the basis for a positive Benefit-Risk claim disappears. In these cases, RCTs are deployed for their rhetorical value; evidence is used to persuade us something is evident when it's not.

For instance, SSRIs have been licensed for their effect on mood. This effect is marginally more common than the effects of natural variation or response to placebos on mood. About 1 person

in 10 has a benefit from an SSRI that they would not have had from natural variation or placebo factors and this effect may only be apparent after six to eight weeks of treatment.

This might offer the basis for a positive Benefit-Risk claim, provided there were no other more common significant effects. In the case of the SSRIs, there are many more common effects. The most common effect is a numbing of, or irritability effect on, genitals. This happens close to universally (9 out of 10 at least) within 30 minutes of a first pill but was missed in all RCTs of these drugs because of their focus on a primary mood endpoint.

This genital effect can significantly affect sexual functioning. Over time libido falls. These drugs also cause dependence, so a person may be trapped on them unable to make love for years, having to risk withdrawal induced suicidality in order to make love again.

Even if the person stops treatment, the ability to make love and their libido may never return. This is termed post-SSRI sexual dysfunction (PSSD).

These drugs also cause an emotional numbing in about 8 people out of 10. This change can be obvious enough within a day or two of starting treatment to be observable by others – nearly as obvious as the effects of alcohol. This is the effect through which SSRIs mediate the benefit for which they were licensed. But this effect was not detected in RCTs.

The failure to detect this emotional numbing, a ‘chill’ factor, introduces an incoherence into treatment. We give these drugs to treat a mood disorder but do not tell people how they will help bring about this change in mood and so people cannot monitor whether the right things are happening or not. Even if an emotional numbing is present, rather than the irritability or agitation which happens to 1 person in 5, this numbing may be unwelcome to the person on treatment who may opt to stop this treatment and turn to other options and could do so much earlier if properly informed.

SSRIs also cause nausea in up to 1 person in 3, more commonly that is than the hoped-for therapeutic endpoint. In the case of people who stay on treatment, SSRIs double the rates of miscarriage in pregnant women and double the rates of birth defects and behavioural problems in the children born from those pregnancies, and agonisingly for women cause a dependence that can be so severe that women aware of the hazards to a child are unable to stop treatment.

Regulators proclaim these SSRIs have a favourable Benefit-Risk ratio, despite the fact that they can make people suicidal and homicidal, and even though sexual dysfunction, emotional numbing, nausea and other effects are more common than a beneficial mood effect and some of these may be more significant to individuals than even a realized benefit.

Thalidomide offers a striking symbol of the Primary Endpoint problem. It was put into a placebo-controlled RCT, before marketing in the USA, perhaps the first drug to be assessed in this way. It proved efficacious at putting people to sleep and appeared to have fewer side effects than other sleeping pills then available. Regulators and companies, behaving as they do now, would point to the scientific grounds for stating thalidomide has a favourable Benefit-Risk ratio.

mRNA Primary Endpoint

In the case of mRNA vaccines, the primary endpoint of the trial was whether the person caught a Covid infection. If catching significant Covid infections was almost universal and the difference

between being treated or not was clear, this might offer the basis for a positive Benefit-Risk assessment.

The commonest effect following dosing is an action of the mRNA agent on the cells. Apparently, the hope is that this will produce Spike proteins which will generate an antibody response which will bring about immunity and that in turn will prevent death or other serious injury.

MRNA may in its own right act as a drug rather than simply as an agent to generate Spike proteins. If mRNA drug effects could be optimised to produce helpful effects such as tackling Covid pneumonia without producing Spike proteins, such a treatment might have a clear Benefit Risk ratio.

(The effects of mRNA agents are more consistent with a treatment than a vaccine model. These agents do not induce immunity or stop transmission as a vaccine ordinarily would).

More speculatively, mRNA agents may change our genetic disposition so that enduring effects occur that may or may not be helpful or that may be transmitted to the next generation of children. Earlier this month an article appeared confirming transgenerational effects for the anticonvulsant valproate. Only time will tell whether such effects are realized but they are a significant possibility and Benefit-Risk ratios that discount such effects are incautious. In addition if these agents provide a treatment rather than a vaccine effect, many people like pregnant women might opt not to be treated.

MRNA agents do produce Spike proteins, in greater amounts and from more bodily locations than expected, with a wider range of actions than just generating an antibody response.

Generating an antibody response moreover is more complex than most of us once thought. The antibodies the Spike protein generates can be neutralising or enhancing antibodies and they are IgG antibodies rather than the IgA antibodies found in the lung in respiratory infections, which would on the face of it be a better bet.

Like SSRI induced emotional numbing, Spike proteins have significant effects, other than a hoped-for immune effect. They cause many deaths, and injuries like myocarditis, pericarditis, thromboses and neurological problems after vaccination. Our focus on a hoped-for immunity means that the full range of effects of these proteins, like the full range of effects of emotional numbing, remains unknown and commonly missed in clinical practice as a result. Because these effects were not reported in the clinical trials, they are not therefore on clinician’s radars.

In summary, there are many more common effects than the apparent benefit on the hoped-for primary endpoint. As with SSRIs, therefore, it is not possible to say that the RCTs for the current Covid vaccines offer a favourable Benefit-Risk ratio. There are grounds for concern that there are more common, or at least as common, serious effects than there are benefits but these have not been and are not being looked for.

There are more deaths in the active treatment arm of these trials than in the placebo arms.

In contrast, Pfizer are claiming an 89% reduction in deaths and hospitalisations for their protease inhibitor nirmatrelvir-ritonavir combination compared to placebo in a trial that only had to recruit 2,246 patients to demonstrate this benefit.

While there may be a treatment rather than a vaccine effect that can be of benefit in cases that develop serious complications, there are also several times more reported deaths from these

vaccines in one year than from all other vaccines combined over a twenty-year period. These are reports to a system that heavily under-reports serious events like death – at best 1 death in 10. No-one is putting these vaccine deaths in a benefit-risk scale to see where the balance lies.

Besides death, the other key index of benefit for a 'vaccine' would be sustained immunity to infection and a greatly reduced risk of transmission to others. Even Messrs Gates and Fauci agree these agents do not give us these outcomes.

The Surrogate Outcome Problem

In SSRI trials, there is a higher death rate in the SSRI arm of trials than in the placebo arm and a higher suicidal event rate on active treatment than on placebo, when one might have expected a licensed treatment with a positive Benefit-Risk ratio to save lives and get people back to work.

The answer to this conundrum is that SSRIs were licensed on the basis of rating scale changes. Rating scale changes are surrogate outcomes, which we expect to reflect processes that will lead to the benefits we hope for such as lives saved, or people restored to functioning.

In similar fashion, we license statins on the basis of lowered cholesterol levels rather than any benefit on mortality. We license hypoglycemic agents on the basis of an ability to lower glucose, even though this commonly leads to more hospitalizations than diabetes. The drugs for osteoporosis are licensed on the basis of an ability to thicken bones rather than reduce fractures with the result that there are now more serious fractures of abnormally thickened bones in the elderly after falls than there ever were before these drugs were introduced.

We have the same situation with the vaccine trials. The ability to reduce infection rates would not ordinarily be thought of as a surrogate marker but reducing the risk of death or of infection severe enough to lead to hospitalization are the hoped-for outcomes. If these do not happen, then reducing apparent infection rates may even be a bad thing. Abolishing symptoms like cough may make infected people more likely to kill their elderly relatives.

The hoped-for outcomes on hard endpoints like death were not measured systematically because they are too rare even for a trial with 40,000 entrants to pick up differences, which is an ironic comment on the severity of the infection. Covid is not Ebola.

Between the primary endpoints and surrogate outcomes that trials need, as Bradford-Hill recognised RCTs are almost by definition not a good way to evaluate a drug or vaccine. They can establish that there is a potential for benefit. They do not provide a basis to establish a Benefit-Risk ratio. When there is a benefit in terms of lives saved as clear as there is with parachutes, there is no need to run RCTs.

Trials can be run for two reasons. One is to demonstrate that we know what we are doing, in which case, as with parachutes, we would expect to get the same result every time. There is no treatment that regulators approve that meets this criterion.

The other reason to run trials is when we do not know what we were doing. In this case, even with 40,000 patients recruited and trial designs that enable a lot of deaths to vanish, we still ended up with more dead bodies in the vaccine arm of these trials than in the placebo arm.

Not knowing what we are doing, and not getting a clearly favourable result, we nevertheless mandated the administration of these agents because of their favourable Benefit-Risk ratio.

The Conduct and Publication of Trials

As of the 1980s, companies began to outsource the running of their clinical trials to Contract Research Organizations (CROs) and the medical writing of reports of what those trials showed to medical writing companies. The medical writing side of the business is regularly called ghostwriting because the authorship line of these papers will list academic physicians but not the writers who wrote the drafts and even wrote the cover letter for the submission of the paper to a medical journal.

The upshot of this outsourcing was that in the interests of speedy completions CROs took trials to Eastern Europe, India, Africa and South America. The pressure to get trials done quickly meant that the patients didn't always exist. North American academics nevertheless remained the named authors on these trials although they had never collected a scrap of data or met a single patient.

Trials also became larger and multinational. Larger does not mean better. Weaker medicines need larger trials to demonstrate an effect. It only takes a trial of 12 people to show that the genital numbing SSRIs cause can make them a treatment for premature ejaculation, whereas it takes several hundred people to have a hope of finding an antidepressant effect. Even snake oil can demonstrate a benefit with large enough numbers and the right outcome measures.

Because the CRO operatives were shuttling between centres there was a natural drift to having the master copy of all records in one location. An academic investigator, who was increasingly unlikely to have seen the patients anyway, no longer had the records from the whole trial that s/he could analyse. At best s/he had copies of a small subset of files.

The CRO transcribes the data from records into spreadsheets. For instance, in Study 329, where paroxetine (Paxil) was compared to placebo in depressed adolescents, there were 77,000 pages of records, Clinical Report Forms (CRFs), with each subject in the trial having 300 or so pages of trial records. The data from CRFs, along with various protocols took up 5000 pages of appendices, accompanying an 800 page Clinical Study Report (CSR). In many instances, data goes missing in the transcription process. Particular problems can end up effectively concealed under esoteric coding rubrics, such as emotional lability for suicidality.

The 800-page CSR gives a company view of what this trial has shown. The final medical journal publication from this trial may then amount to 10 pages.

Company submissions to regulators centre primarily on the Clinical Study Report. The 5000 pages of appendices will almost certainly accompany these but are rarely looked at by regulators. The 77,000 pages of Clinical Report Forms may be notionally available to regulators but are never looked at by them.

If a problem blows up about a drug, regulators will ask the company to review their material and report back to them. They will not go to their own archive and see what they make of what is there. Even if the 77,000 pages were there all names are redacted so the regulators can never contact the person behind the record to find out what in fact actually happened – or even establish if they actually existed.

Regulators never see the bedrock data from RCTs. They do not have access to either the figures in the CRFs behind the figures appearing in the appendices or the people from whom those figures come. The regulators of medicines have for three decades depended on the

integrity of company submissions. The apparent success of this practice may underpin the recent turn of air safety regulators to depending on Boeing's submissions on its planes as the sole basis for approval.

Prior to the 1980s, clinical trials of medicines had usually been run in a small number of university hospitals, and the clinicians involved knew the patients and had access to and analysed the data. When an RCT was brought into a legal setting as evidence, the Court could bring an expert into the proceeding to answer questions about the effects of a drug on real patients who could potentially also be called to testify. This understanding made it sensible to grant the evidence from RCTs a Hearsay exemption. It no longer makes sense.

The changes that were taking place from 1990 onwards led New York State to lodge a fraud charge against GlaxoSmithKline in respect of an RCT of paroxetine done in depressed teenagers. This trial, Study 329 was carried out in the mid-1990s and published in 2001. It claimed the drug worked well and was safe. Documents emerged that made it clear that GSK knew the drug did not work but the company intended to pick out the good bits of the study and publish them. This laid the basis for a fraud charge and later a $3 billion fine from the Department of Justice.

It transpired that the entire literature on the results of the use of antidepressants in RCTs for depressed children at that point was ghostwritten,

There was a complete mismatch between what the ghostwritten articles said and what the data showed when accessed.

It turned out that FDA and other regulators were willing to license drugs on the back of negative trials and also willing to avoid mentioning this to anyone.

Study 329 was not a bad study. It was conducted to a higher standard than the recent vaccine trials. What this points to is that, quite aside from the limitations of RCTs, fraud is the de facto company modus operandi when it comes to their RCTs.

(What companies have been doing is not fraud in terms of business processes, but nobody would think that faced with a wide range of jeans or cars to choose from we could be mandated to buy a particular brand of jeans or car and would lose our jobs if we refused. In terms of the norms of science, however, the company trials are fraudulent. The practices adopted are designed to maximise commercial advantage rather then adhere to scientific norms, but the marketing is in terms of following the science and even more worrying politicians supporting these treatment options claim to be following the science).

In the case of the RCTs for the Pfizer mRNA agent, this was run by a CRO - ICON. There is a published BMJ article on how shoddy some of the recruiting centres were. There is every chance this shoddiness, already put on the record in the BMJ, and uncontested, is nothing compared to what has happened in other centres in which this trial was run that have not yet been looked at.

The published articles reporting the trials of mRNA and related agents were ghostwritten. These published reports are patently misleading in terms of the conduct and findings of these trials. The harms that occurred in these trials have been egregiously written out of the script.

As things stand these agents cannot be given or taken with informed consent.

Mandates vitiate consent. If mandated to take a treatment we have to trust the authorities. In this case, the authorities never had the data and never will have it. In terms of what has been submitted to FDA and other regulators (company reports of what their trial has shown and correspondence between regulators and companies in respect of the trial), FDA have blocked access to this for 55 years and are trying to have that period extended.

Were the material that FDA is blocking from release available we still would not have the raw data. The bedrock information on which consent should be based is not available to anyone. The authorities have not been able to review this material before instituting mandates.

They have not mandated a recording of or assessment of the hazards of treatment following the requirement for all of us to be treated.

Consent can be given on the basis of trust but with a track record of fraud and regulatory willingness to turn a blind eye to that fraud, there are no grounds for trust either.

Pre-Vaccine Summary

1. Clinicians do not have access to clinical trial data on medicines or vaccines.
2. Close to all of the medical literature reporting trial results for on-patent drugs and vaccines is ghostwritten, hyping the benefits and hiding the harms.
3. Clinical trials of these treatments that are negative on their primary or their most common outcomes are often published in prestigious journals as positive.
4. Clinical trials have their harms airbrushed out of ghostwritten publications.
5. Regulators (FDA, Health Canada, MHRA, EMA) do not get to see the full trial data.
6. Regulators approve treatments as working even when more people die on active treatment than on placebo.
7. Regulators approve medicines on the basis of negative studies and agree not to let the wider world know about this.
8. Regulators say nothing when companies publish negative studies as positive and make adverse effects of treatment, including death, vanish.
9. For many trials there are more deaths on active treatment than on placebo, but this does not lead regulators to warn about hazards as to do so would in their stated view deter people from seeking a benefit (even when the benefit is better characterized as a commercial benefit to a company rather than a benefit to the individual in terms of a life saved or a restoration of function).

Rules of Evidence

In 1962, when the current regulatory system was put in place, the regulators of medicines were viewed as bureaucrats, primarily concerned with establishing a paperwork trail to support the licensing of a drug. A license permits a medicine to be prescribed and certain claims to be made.

The role of a regulator is to ensure that drugs, just like butter or other foodstuffs, and words like organic or artisanal, meet certain criteria. They do not offer views on whether drugs or butter

are good for us or whether this vaccine or that chocolate is a good vaccine or good chocolate, or the use of the word organic meets general understandings of what that word means.

Regulators are not scientists, clinicians, investigators, or public health officials. It is not their role to think, other than to decide if something conforms to a previously established template.

Around 1962 and for three decades afterwards, while regulators licensed medicines, physicians, not regulators, evaluated them in practice and established what other effects these medicines might have. Physicians were still viewed as the most important part of a broader regulatory apparatus for these unique products that were available on prescription-only.

Regulators followed a developing consensus among clinicians in respect of evaluative methods or harms, embodying them in rules. They did not tell clinicians how to do their job.

A medicine has two parts, one chemical and the other information on how to use that chemical. Chemicals are not organic. All medical and regulatory systems explicitly view the chemicals used in medical practice as inherently and unavoidably hazardous.

The dominant medical wisdom was that giving these chemicals necessarily entailed risks. Even if the intention was to bring good out of the use of a chemical, giving such chemicals was an act of therapeutic poisoning and the patient might well be poisoned. The information component of a medicine aimed at managing those risks as best as possible.

Anesthetics, for instance, regularly kill people going for surgery. We give them in the hope that while using them we can effect other changes that will be of benefit – and the patient is informed of the risk of death.

Two hundred years ago, Philippe Pinel said that it is a great art to be able to use medicines to good effect, but an even greater art lies in knowing when not to use them.

Phrases like the art of medicine now conjure up a contrast between soft clinical interviews and a hard science which for many lies in the turn of medicine to controlled trials (RCTs).

RCTs hinge on quantification and algorithmic processes and these can give an appearance of objectivity in contrast to which a clinical interview with a patient reporting an adverse event on treatment might appear subjective. Good interviews might look like an art rather than a science.

After interviewing patients and investigating their report of a harm, clinicians routinely wrote up their observations and conclusions in articles which were published in medical journals in the form of case reports. These came with the names of the clinicians attached and today may often have the patient’s name also.

When a crisis blew up in 1991 about SSRIs causing suicide, the company response to compelling case reports that these drugs could cause suicide was that these unfortunate cases were anecdotes (today’s misinformation) not science.

Companies produced the appearances of analysing their RCTs and on this basis claimed that the science showed there was no problem. Companies challenged the public, politicians and the legal system to decide whether they were Going to Believe the Science or the Misinformation.

It is now established that this 1991 clash was not between Hard Science in the form of RCTs and a Soft Art that gave rise to Misinformation. It was a clash between Fraud and what I am calling here a Judicial Process. This choice of words will be explained now in detail.

As outlined above company RCTs are close to fraudulent. The fraud is not readily checked as there is no easy way to establish what actually happened to people in these trials. When the records are accessed, it turns out that there were people in the RCTs to whom exactly the same hazards such as suicidal events or sexual dysfunction happened as doctors later reported in the Case Reports. More trial subjects had these events than were prevented from having such events by treatment.

The scale of the problem happening in these RCTs was obscured by egregious company manoeuvres, several of which breached FDA regulations. FDA noted but turned a blind eye to these breaches.

Words like fraud are emotive. The key point is that RCTs are not ipso facto science and case reports are not ipso facto non-science.

Science is often bedecked with the appearances of quantification and processes that are untouched by potentially biased human hands – algorithmic processes. But quantification and algorithms are not the hallmarks of science.

Science has rules of evidence and requires judgements, verdicts, diagnoses. They are ordinarily provisional and come with a requirement to be reviewed should new evidence emerge.

When it developed in the 17th century, science distinguished itself from philosophy and theology on the basis of a requirement to explain observable events in front of individuals, without appealing to matters that could not be settled by experiment. The beliefs or biases of Christians, Muslims, Jews and Atheists had to be left outside and there was no leaving the room until a consensus was reached – other than to do further experiments.

A few years before these ground rules laid the basis for the Royal Society and science, the British legal system reached a similar conclusion as regards Rules of Evidence for legal trials following the execution of Walter Raleigh. Raleigh had been convicted on the basis of hearsay. After his execution, the new Rules meant that cases could only be decided on the basis of the testimony of witnesses who came into the court to be examined and cross-examined. A verdict as to what the observable testimony supported required unanimity among 12 people with differing backgrounds.

This approach to Rules of Evidence is shared by Science and Judicial Systems. It better characterizes Science than any adherence to quantification and algorithms.

The term judicial process here means a process of interrogating observable data that culminated in a judgement. The processes of science are judicial in this sense. For sure, some legal cases will call for input on technical matters, but most science is supported by input on technical matters, from statistics to machinery, and there is specialist knowledge on both legal and scientific sides.

When done properly the construction of a case report about a hazard or other novel effect revealed by the use of a medicine is similarly judicial (in the sense of weighing evidence and

coming to a verdict/diagnosis) in its approach and as rigorously Evidence based as anything in medicine's ancillary sciences.

In judicial settings (whether legal or clinical), a rigorous approach to Rules of Evidence, which shape the observables that jurors, judges and clinicians face, does not mean that the right answer is supposed to arise magically from the observable data. Clearly there is a need for insights that grasp the possible relations between the observables and judgements as to which of the possible relations is the most probable. These judgements are called verdicts in legal settings and diagnoses in medical settings.

In both legal and clinical settings, verdicts can be shaped by the credibility of experts and witnesses, which might appear problematic from a scientific point of view, but this potential bias is as nothing compared to the systematic bias that stems from abandoning judgement altogether, leading as it does to an effectively fraudulent academic literature.

The Abandonment of Verdicts

Without verdicts and diagnoses, we know nothing. Algorithmic processes, ratings scales for behaviour that preclude judgement calls as to whether a disease or its treatment has led to suicidality, and statistical processes are inherently meaningless.

The crisis with the SSRIs and suicide however led to an abandonment of verdicts. Lilly appeared to prevail in the case of Prozac and suicide in 1991, and while the company's success on the issue of Prozac and suicide has been completely overturned, its legacy is a widespread belief that the only form of knowledge in medicine that counts comes from controlled trials. In legal settings, this is the central plank of company presentations to Daubert hearings in cases involving treatment induced injury or death.

After 1991, medical journals became scared to publish case reports of treatment induced hazards in part because they were uncertain as to their validity but also, with the changed landscape, they worried about being sued by pharmaceutical companies for publishing something companies could claim was misinformation. In addition, journals made far more money from publishing RCTs and analyses of these trials, which were bought by companies for marketing purposes, than they did from case reports.

Given the difficulties in getting published, the only place for doctors to report was to regulators. This made little sense in that regulators have no experience in or training in determining whether a drug or vaccine might have caused a problem. The regulators of drugs are concerned with the wording of adverts only. They turn a blind eye to fraudulent scientific publications but quibble over claims made in adverts.

In respect of harms reported to them, regulators do three things. First, they remove any identifying details and in so doing they convert these reports into hearsay. They generate the phenomenon of misinformation, as these reports then accumulate without anyone making a connection between a drug and a problem creating the impression that there are a lot of fake reports. Reporting that there have been 5000 reports to the regulator of deaths immediately after taking a vaccine is labelled as misinformation by mainstream media and social media fact checkers, unless it is accompanied by a rider than none of these deaths have been determined to have been caused by the vaccine.

Second, regulators file these reports.

Third, regulators devote considerable resources and time to telling politicians and others that they spend considerable resources and time working out if there is a needle in the haystack of reports. Faced with a needle-stack, they are unable to spot the needle. Without interviewing the patient and tracking the event that is possibly related to treatment, they cannot come to a verdict.

This is striking in the case of Covid-vaccine related death reports which outnumber reports of deaths from all other vaccines over several decades twenty-fold. These deaths congregate in the first two weeks after a vaccine is administered, many in very healthy people.

If a wife shoots a husband, it is possible that in one case out of a hundred he died from a heart attack just beforehand. An autopsy might help us with this, but doctors at present seem inhibited in coming to a verdict in cases like this that even a 12-year-old could diagnose. Given their diagnostic faculties in respect of harms have remained unused for three decades, doctors may have lost this ability, but in failing to make their diagnoses public, doctors have abandoned their birth right, as much as any judge would were s/he to advocate abandoning trials in favour of algorithmic processes.

The vaccine or drug-related harms that doctors witness in their clinics can be investigated in a scientifically appropriate manner. A doctor's investigation and diagnosis, especially when replicated by others, is better evidence about how best to practice than anything that comes from trials run by CROs whose data is concealed by force majeure and ghostwritten publications that hype the benefits and conceal the harms of treatments. This latter material, that today parades under the banner of Evidence Based Medicine, should not get in the way of a doctor being a scientist and following the only evidence they or anyone else can follow.

While doctors continue to fail in their duty to establish the harms of treatment and communicate information about these hazards, they further compromise the ability of any of us to give informed consent to treatment. They have lost their salt as doctors and the profession risks going out of business unless this changes.

A medicine is a chemical with that comes with information. Drugs and vaccines are chemicals and, as that word connotes, they are hazardous to put into the human body. The information that comes with these chemicals is what makes them medicines. The chemicals will always be hazardous. In recent decades the information has been degraded and now poses an increasing threat to any of us who take any on-patent medicine.

This degradation has underpinned a pandemic of overtreatment that has led to falls in life expectancy in Western countries even before Covid struck.

It is important for the common good, even more than for individual liberties, to question vaccine mandates, which risk entrenching the very factors, the fraud, that has led to this pandemic of overtreatment.

We might board a spacecraft and leave earth to escape a deadly virus if we were confident it would take off and land safely. In this case, the Pfizer and Astra-Zeneca vaccines have a track-record of blowing up on lift-off and we still don't know if they can land. In these circumstances many reasonable people might prefer their chances with the virus.

A Miscarriage of Clinico-Judicial Process

Patients with a problem that might have stemmed from a vaccine or drug come to a doctor for help. The first step in helping is a diagnosis/verdict.

The ability of a patient to get a fair hearing has been severely compromised since 1991. For instance, although the commonest effect of SSRIs is on genitals and sexual function, and even before these drugs were launched companies had healthy volunteer and other evidence that sexual dysfunction might endure after treatment stopped, the RCTs that brought these drugs to market indicated that enduring problems were non-existent and other problems were rare and would clear when treatment stopped.

As a result, clinicians dismissed patients who brought them problems of enduring sexual effects – post SSRI sexual dysfunction (PSSD). It took close to two decades before reports of these problems reached the medical literature and this only happened because some clinicians reported their own PSSD, albeit without making this clear.

If a problem, like PSSD, does not appear in the supposed Evidence Base, patients are told their difficulties are in their mind rather than stemming from a prior medicine – how could a drug that has been out of your body for months still be causing this? Ridiculed and dismissed like this, some have committed suicide because of this miscarriage of the clinical judicial process, which strongly suggests to them that nobody is doing any research on PSSD or possible cures for it.

These miscarriages continue to happen even though PSSD has now been written into the label of these drugs. The 'recognition' appears in a part of the drug label that nudges most clinicians to translate this mention as 'we have also had reports from flat-earthers and anti-vaxxers – make of them what you will'. In fact, mentions like this only happen when companies have cases that even they can only explain in terms of the effect of their drug – or when they hope to phase out their drug in favour of another more lucrative product.

It is little exaggeration to say that a Nobel Prize awaits someone who can establish how SSRIs bring about this effect. A cure would both save lives and open up ways to engineer new treatments which taken in short courses could have enduring beneficial effects.

PSSD is a dramatic example of what is now the norm. Death and disability from medical treatments is now our commonest cause of death and disability. This stems in part from a failure to recognise that treatment can harm, a failure to recognise that having people on multiple treatments is even more likely to harm and a failure to appreciate that this is an inevitable consequence of tolerating a ghostwritten literature with lack of access to trial data and entrusting bureaucrats to keep us safe rather than doctors.

For this to change, doctors need to realise that the judicial processes they conduct, and the verdicts they come to, are more important to justice for their patients than any steer from a government or regulatory apparatus.

In the case of vaccines, it is very clear that healthy people, many of them enthusiastically pro-vaccine, as well as others driven by fear of the virus or losing a job, are being killed and seriously injured by these agents. When injured they meet medical systems and personnel who ridicule them and tell them their problems are in their mind or the pain in their chest is a sign that the vaccine is working.

Doctors and nurses have lost jobs for linking injuries and vaccines. This inhibits others from doing so and blocks the possibility of early diagnoses that might encourage research on the injuries and lead to treatments that minimize disability and prevent deaths.

It now appears to be the norm for doctors facing a patient with thrombosis, myocarditis, peripheral neuropathy or other problems following a first dose of a Covid vaccine to refuse to endorse an application for a medical exemption from the second dose. In this case, the doctor is de facto denying a causal link to treatment.

If a doctor writes a letter supporting an exemption, this will ordinarily be turned down by another person in the system, commonly working in public health, who has never met and will never meet the injured person and will almost certainly have less medical expertise in managing that injury than the person supporting the exemption.

Over the past three decades, the encroachment of a fake literature paraded as gold standard evidence has produced soft mandates that have eroded the likelihood that patients will get justice in clinical settings.

The addition of hard mandates for vaccines can only make things worse.

The argument outlined here is not based on the rights of individuals to bodily autonomy. It speaks to the wider rights of all of us to the benefits that stem from all of us operating in accordance with the jointly held values that are embodied in what we call science and justice.