The Prevention of Hemorrhagic Stroke

A Review of the Rational and Ethical Principles of Clinical Trials on Unruptured Intracranial Aneurysms and Arteriovenous Malformations

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Summary

There is currently no evidence that preventive treatment of unruptured aneurysms or AVMs is beneficial and randomized trials have been proposed to address this clinical uncertainty. Participation in a trial may necessitate a shift of point of view compared to a certain habitual clinical mentality. A review of the ethical and rational principles governing the design and realization of a trial may help integrate clinical research into expert clinical practices.

The treatment of unruptured aneurysms and AVMs remains controversial, and data from observational studies cannot provide a normative basis for clinical decisions. Prevention targets healthy individuals and hence has an obligation of results. There is no opposition between the search for objective facts using scientific methods and the ethics of medical practice since a good practice cannot forbid physicians the means to define what could be beneficial to patients. Perhaps the most difficult task is to recognize the uncertainty that is crucial to allow resorting to trial methodology. The reasoning that is used in research and analysis differs from the casuistic methods typical of clinical work, but clinical judgement remains the dominant factor that decides both who enters the trial and to whom the results of the trial will apply. Randomization is still perceived as a difficult and strange method to integrate into normal prac-

tice, but in the face of uncertainty it assures the best chances for the best outcome to each participant. Some tension exists between scientific methods and normal practice, but they need to coexist if we are to progress at the same time we care for patients.

*'It is from one's results rather than by reasoning that one ought to show one's art'
Galen, An outline of empiricism'*

Arterial aneurysms and arteriovenous malformations are the most common focal structural lesions that can cause intracranial haemorrhage, a potentially devastating event despite all the advances of modern medical care. Hence they seem to deserve their bad reputation, and preventive actions, if we had the chance to detect them before they rupture, would at first glance seem wise. Unfortunately treatments carry risks, and their efficacy has never been proven. Hence the management of patients with unruptured aneurysms and AVMs remains controversial, and various patterns of practice find their justification solely in expert opinions and preferences.

The clinical dilemma: 'Are patients with unruptured aneurysms or AVMs best managed conservatively or with active treatment' can only find a resolution by resorting to the rigorous methodology of the randomized clinical trial. But this work cannot be delegated to a few

scientists locked into their sophisticated laboratories. Clinical research is a science to be performed inside real-world practices, and its success depends on the dedication of clinicians and the autonomous participation of subjects.

Over decades, physicians have learned to deal with the complexity and diversity of these conditions on a case by case basis, and have developed a unique expertise in approaching most challenging situations. They have formed schools of thoughts and training centres to share this expertise with future generations. But they have failed to provide justification for the preventive treatment of unruptured lesions. If we do not put our acts together and face this clinical dilemma squarely as a unified body, the current clinical dead-end will also be part of our heritage.

The main difficulty with implementation and the main concerns regarding the feasibility of clinical trials have to do with recruitment of the necessary number of collaborators and participants to assure that the trial will provide a meaningful answer to the clinical dilemma. These difficulties are related to a certain clinical mentality, purportedly dedicated to the care of the individual patient, which is sometimes thought to be hardly compatible with trial methodology. This tension finds its source in basic epistemological difficulties that can be traced back to ancient medicine.

That the clinician has no power of divining the future of each individual patient, that some uncertainty will always persist, that clinical judgment is fallible, that some values should be protected (all individuals deserve optimal care, clinicians' and patients' autonomy should be respected for example), and that poor results can follow good intentions are so obvious that we will not discuss them in detail. The present manuscript proposes to review the principles behind trial methodologies. Our goal is to resolve some of the tension and discomfort involved in participating in clinical trials designed to address the present dilemma (ARUBA and TEAM) and to demonstrate that they are based on strong and sound moral and rational intuitions²⁻⁴.

Medical Care and Prevention

Both AVMs and aneurysms frequently remain silent until they rupture (although some aneurysms may present with cranial neu-

ropathies and some AVMs with seizures). With the increasing use of modern non-invasive cerebral imaging, the incidental discovery of these lesions is taking on epidemic proportions, and there is a growing concern that a 'general rule' of treating individuals identified with these lesions may end up doing more harm than good. Risks involved in treating these lesions are not trivial, and reliance on a priori prudential maxims may not suffice to justify risky treatments. In fact there are reasons for requesting more stringent requirements: if medicine in general only has an obligation of means, prevention has an obligation of results. Our duty of beneficence cannot mean that we are forced to offer treatments, no matter the results. We also have a duty of non-maleficence⁵. You can hardly improve the condition of an asymptomatic individual. But no treatment whatsoever, for either condition, has met this ethical requirement. How could 'obligation of results' be translated into clinical practice?

We will claim that rationality necessitates the proof of experience to justify the preventive treatment of healthy individuals and that this proof can only be supplied by the clinical trial armamentarium. In other words, good intentions and elementary *a priori* truths (such as 'it would be better not to have an aneurysm') do not suffice. Modern medicine, as a science of what should be done to promote health and decrease suffering, requires the proof that actions, to be qualified as appropriate, lead to better outcomes compared to inappropriate actions (the group of patients treated in fashion A do better than the group treated in fashion B, and the difference is solely due to treatment, not to extraneous factors or bias).

In Search of the Elusive Natural History

The realization of a trial is so difficult that perhaps we could first attempt to judge more critically how dangerous these lesions really are, through observational studies. Unfortunately, reliable information on the 'natural history' of these lesions is scant or absent, but this may not be surprising if one considers that they are often incidentally discovered by imaging and that the frequency of their discovery will depend on the development, availability and utilization of imaging technologies. Patients harbouring these lesions are frequently referred to specialized centres, where they will be

selected to be treated or observed according to local dominant opinions. Even if numbers could be found that would represent a reasonably accurate picture of the risks of harbouring unruptured lesions, they would still have to be compared with the complications that occurred in different groups of treated patients, an invalid procedure, no matter how powerful our computers or how large the case series. We end up comparing 'apples and oranges' and to sort out of statistics what is in the nature of the disease and what is man-made becomes an impossible task. Hence the situation calls for a different approach: the direct prospective comparison between two options.

To rely on the statistics of observational studies to feed homemade algorithms designed to compute the individual lifetime risks tailored to each patient is asking for too much precision where only vagueness and generalizations can be found.

The error that is built into the data will be multiplied in an uncontrollable fashion. Unfortunately the use of such pseudo-precision is commonplace in individual practices and contributes to an unwarranted certitude about management that prevents many physicians from facing squarely the clinical dilemma that confronts many more patients than they are willing to believe. 'Surely I cannot recruit this patient because the calculated life-time risks entailed by the lesion are so and so, and it would be unethical not to treat'. But how could a calculation based on approximate, if not erroneous numbers and dubious methodology provide such a certainty that confrontation with reality for the sake of prudence could qualify as 'unethical'?

Confusion Regarding Ethics and Science

The context of the therapeutic relationship between alerted patients and experts is not, on first impression, favourable to the expert's uncertainty regarding the 'best thing to do'. 'The last thing my patients want to hear', we are often told, 'is 'I don't know''. Moreover, the patient-clinician teamwork essential to clinical research is not characteristic of the conventional therapeutic relationship. Hence it is hardly surprising that some physicians may feel uneasy at sharing the current medical uncertainty with their patients.

Nevertheless the tension between scientific methods and ethics of practice that seems to be

common in clinical medicine is on reflection, inappropriate. A 'good' medical practice cannot force us to use unproven methods, or prevent us from finding what could be 'good'. 'As my study and thinking progressed', wrote J. Dewey, 'I became more and more troubled by the intellectual scandal involved in the current dualism between something called 'science' on the one hand and something called 'morals' on the other...'⁶.

This dualism is also a heritage from authoritative Commissions, created in the horror of historical scandals from World War II and the indignation of some early human experiments⁷. They were mandated to formalize the conditions and rulings that would allow experimentation of new therapeutic avenues in a clinical context candidly presumed to be well established. Commissioners assumed that a mature and stable body of medical knowledge was the invariant context that they were in no right to question, while scientific experimentation, potentially depriving individuals of the 'benefits' of standard care, was the extraneous practice they had the responsibility to control. One important but paradoxical result is that any trial is scrutinized in a much more thorough manner than clinical practice, and at multiple levels by a wide variety of experts versed in all scientific and ethical aspects of medicine.

Standard medical practice can be defined by guidelines from expert groups, expert opinions, dogmatic but unproven assertions, custom and habits, but none of these definitions will accommodate the fact that while medicine is fallible and perfectible, and human suffering still exists, we need to progress at the same time we are caring for patients.

The enterprise of proposing clinical research is a modern formalized answer to the problem of how to harvest reliable medical knowledge from observation. Without attempting to resolve these issues fully, our stance is that pertinent facts should be collected within the context of our practices, in line with the goals of our interventions, the treatment of the 'next patient'. Hence we designed 'pragmatic studies' or 'management trials' that may stray away from 'pure science' and its search for 'natural truths', but will assure, if it is possible, that we are dealing with the reality of day-to-day practice. We believe that most debates on the ethics of clinical trials, opposing the therapeutic obligation to the duty of advancing medical knowl-

edge, have elaborated responses that are skewed because they have addressed the wrong horn of the dilemma. The question is not whether trials (read science) are acceptable according to the 'ethics of clinical care', but rather how is it possible to offer the best clinical care without the means to determine what is 'best'. Hence clinical trials should be an integral part of the 'best clinical practice', and the more fundamental problem is how to define clinical practice in such a way as not to prevent determination of what is best for our patient.

What is peculiar about a trial is that clinical care has to be provided in a context of uncertainty, and the collection of valid data is done simultaneously with care. But this simply reflects the fact that we need 'to repair the boat while it is at sea'⁸. Unfortunately this is a frequent situation in clinical medicine, and what is needed first and foremost is an account of the ethics of clinical practice that can acknowledge uncertainty and accommodate the means to work within this realistic framework and to progress simultaneously: the clinical trial. The clinical trials we are proposing do not address artificial and theoretical questions for the sake of advancing medical science. They are, from ethical and scientific points of view, the answer to a significant clinical dilemma that concerns the particular patient encountered in the physician's office, for whom no action has proven beneficial, or one better than another. In other words the patient is not a tool in a scientific enterprise; science is a tool to promote the patient's well-being.

Individualized Care and Participation in a Trial

The individual, confronted with a health problem, seeks the opinion of a knowledgeable expert. Where is this expert supposed to have found this knowledge, if not from other patients, and 'general information' from schools, 'training', and clinical trials?

We will assume that a fundamental principle of medicine is individualized care, and that it is the duty of the physician to promote the well-being of each patient. We will also adopt a conventional form of the 'therapeutic obligation': 'always treat each patient in a way that will optimize his or her outcome'. This rule is silent about the scientific nature of medical knowledge. Unqualified knowledge of the individual and good will cannot suffice to provide medical

care. Individualized care can be provided by mothers and friends, confessors and quacks. What is specific about medical care is that physicians possess unique skills and knowledge: what is unique about medical knowledge is that proposed treatments have proved beneficial (or can be submitted to such a test) in a number of previous patients. The clinician facing the individual patient for the first time cannot know anything about him. Whatever he knows comes from previous experience, and extrapolations from previous patients. Even the most casuistic clinician must admit that his concern for this patient is based on vague generalizations: the discovery of this unruptured aneurysm or AVM is worrisome because other aneurysms and AVMs have on occasions bled in the past. The key question is how often they bleed. The answer to this question will always be uncertain and probabilistic. If the patient or clinician is repulsed by the uncertainty, he may opt for systematic treatment: I do not know if and when this could rupture, but if it is eradicated, I will know for sure (of course this is also a naïve oversimplification since treated patients may not be immune from future hemorrhages). But the same problem with uncertainty reappears when treatment is considered. The clinician has no expertise whatsoever in treating this patient whom he encounters for the first time. He may have a tremendous experience in treating this sort of patient (patients with aneurysms or AVMs). Now most of us cannot treat patients without potential complications and failures, and we cannot foresee when they will occur (otherwise we would simply refrain from treating 'dangerous cases' and achieve 100% success in others). Again, the key question is how often complications occur. An autonomous and individualized decision by the patient is impossible without reliable and realistic information regarding the risks of the condition and the risks of treatment in general, but in the same population. This problem is an ancient medical problem in new guises.

Experience and Ancient Empiricists

The theory that medical knowledge is acquired only through experience can be attributed to the early empiricists, dating back to as early as the second half of the third century BC. They were opposed to other doctors, designated as 'rationalists' or 'dogmatists', who elaborated

theories capable of inferring, from what was visible, the existence of unobservable entities.

For empiricists, medicine was a collection of direct personal observations of whatever proved beneficial or harmful to sick people not just once, but repeatedly. These observations were for the most part casual and one could not raise in advance the issue of the relevance of what was to be observed⁹. But the observations of one individual were not on their own enough to constitute medical experience; it took the accumulated experience of numerous individuals over the course of time. The reliability of these accounts was a problem, which was partially countered using the criteria of agreement among however many people had written about a particular thing⁹. A third ingredient to the art of medicine was 'the transition to the similar', a conscious extension of experience already acquired to cases not yet studied.

In antiquity empirical medicine and sceptical philosophy were often put on a par because both contended that one should suspend judgment about the things that are obscure. The rationalists formulated sceptical arguments against the theory of experience, by asking how it was possible to know that one illness is always the same as another, or by claiming that it was impossible to determine the number of observations necessary to make a medical practice acceptable. 'Do you have any means of telling us, Ô Empiricists, how many times are 'many times'?'¹⁰.

But empiricists countered by cruelly attacking dogmatists on the dangers of unproven assumptions, on their appeal to authority, claiming that they entertained a vicious relation with 'duped patients that they ended-up killing'^{11,12}. Galen, in a less dichotomous conception of medicine, proposed that certain things are known by experience, others by reasoning¹⁰. If experience can provide evidence that treatment could benefit the majority of patients in the past, reasoning and judgment will inevitably have to be reintroduced, in applying knowledge to the future individual patient.

This ancient debate almost seems contemporary, and these preoccupations feature concepts crucial to trial methodology: the unique value of observation, its pitfalls and potential biases from irrelevant confounders; the necessity for suspension of judgment in the presence of uncertainty; the concept of agreement and its modern corporative vests, the guidelines,

and perhaps the notion of community equipoise; the difficult reconciliation of individual care with notions of diversity, aggregation, and generalizability; the meaning of statistics and their normative thresholds of 'significance', to name a few. But some progress has really been achieved. Although imperfect, there are some modern responses to these ancient problems. Preoccupations regarding the relevance of facts of observation and the prevention of bias are the fundamental principles behind clinical trials, while statistical sciences were developed to deal with the problem of 'how many times are many times'. However, the main difficulty today is not at what frequency the repetition of an event becomes evidence rather than a chance finding, but what are the conditions necessary to perform this 'transition to the similar' to collect the reliable knowledge that allows the projection of past observations to future patients we will encounter with a similar dilemma. The modern method of addressing this crucial problem is randomization.

Before we examine the ethics of randomization we will first consider the essential components of the form of reasoning deeply entrenched in the tradition of 'clinical judgement'. Far from underestimating the importance of analogical reasoning and particular emphasis on individual cases involved in everyday clinical judgement, which can be contrasted with the formalized approach of the trial, we rather wish to emphasize that they play divergent but complementary and equally essential roles in achieving the knowledge necessary to offer the best possible care.

Medicine is Casuistry

Medicine has often been used to illustrate the contrast between theory, its universal, atemporal, and idealized truth, and practice, with its emphasis on the particular context and circumstances, its timely and local approximations. In a sense clinical medicine has no taste for eternal natural laws which constitute the primary goal of 'pure' sciences. The clinician has too much respect for the individual, his practical wisdom is too sensitive to the complexity of the details of each personal history, to be attracted by the supposed truth of blunt generalizations or of statistical means. He never wants to see his patient submitted to the tyranny of numbers. The contrast has been overemphasized, in a sense

creating two different worlds, one theoretical, pure and abstract, the other practical, dirty and real, with diverging principles that resort to opposing thinking processes. Science calls for exact numbers, deductive logic, impersonal repetitions, while medicine needs vague predicates, analogical reasoning, and humanized singular decisions. The same contrast has been evoked in the evolution of moral, religious and legal history, and can be traced at least as far back as Aristotle with his distinction between episteme and phronesis.

The divorce of theory from practice is of course a caricature.

If in practice the clinician does pay much attention to the details of the individual stories, he has some knowledge of what to do because in his analysis of the single case, he perceives similarities and differences with prototypical cases, uses a taxonomy of symptoms and causes, looks for extreme circumstances (as opposed to 'normal' situations), deviations from standards, or exceptions to maxims, and an implicit generalization is hidden in each and every one of these steps. If nothing truly general can be said, if there is nothing left to be considered apart from particular cases and situations at the right time and opportune moment, as Georgias maintained, we risk falling into sophistry¹³. Where is the clinician supposed to find this 'general' truth, this 'normal evolution', this 'standard' case, without which he cannot form a judgement about the single case at hand? There remain many obscurities in this simplified picture of his thinking process, that intuitively seems to fit our understanding of the concept of analogical reasoning from one case to the other, the 'transition to the similar' of ancient empiricists. And one can certainly imagine that if this process is supple enough to accommodate individual case stories, it also shares many pitfalls and drawbacks with medieval casuistry. It does heavily rely on heuristics that are liable to be misleading, and leaves ample room for extraneous influences, motivational and emotional biases that may distort judgement, as well as the risks of corporate consensual thinking and peer pressure in the control of clinical behaviour¹⁴. As specialists, we are trained to think and act in a certain way.

If this 'transition to the similar' seems appropriate when one is dealing with an irregular succession of typical disorders, one wonders how this thinking process could provide knowl-

edge on the frequency of rare events, such as intracranial hemorrhages, that lies way beyond the perception possible by single individual physicians, and how he could reliably inform his patients of the relative merits of therapeutic options designed to neutralize a certain risk.

This is where the science of clinical trials finds its crucial role. But resorting to the machinery of the clinical trial to collect reliable knowledge from multiple institutions, and to analyze results in such a fashion as to minimize bias and error, does not mean that the clinician must abandon his clinical judgement, which will remain essential at both ends of the clinical trial process.

First the decision to propose participation in a trial remains his prerogative, and patients, society as well as trial investigators trust the clinical judgement of clinicians that the inclusion of the particular patient is appropriate and in his interest. Finally, at the end of the trial, once analysis provides a general answer to the clinical dilemma, it will be up to the clinician to decide, using his judgemental expertise, to whom the answer applies and what particular circumstances and features of the case should be taken into account to tailor the new medical knowledge to the individual so that he can be offered the best possible option. Medicine must cater to individualized care. We must emphasize however that this application of the knowledge observed in previous instances to future instances is permissible only because results of the trial are reliable, thanks to the randomization process that assures that the differences in outcome are solely effects of the different merits of treatments.

The Ethics of Randomization

We cannot reliably compare the outcome following two treatment options without resorting to randomization. This does not mean that we are bending the therapeutic obligation to current individuals to meet the scientific requirements that will provide knowledge to guide the treatment of future individuals. The research question concerns first and foremost our current patients, for whom no action has yet been proven beneficial. Thus randomization is not only a scientific solution to the problem of bias; it is also a practical way of assuring the best possible outcome for each individual patient.

A common mistake is to create two worlds, the world of clinical patients, and the world of trial subjects, with different rules and values. There is only one world of patients, inside or outside participation in trials. In the absence of evidence, by treating patients to prevent ruptures we could cause more harm than by not treating them.

The best option for each individual is currently unknown. Until it can be asserted with confidence that patients need to be treated, because they do better with treatment than without, the 'best' we can offer to our patient is a chance to be treated and thus to be protected from rupture of the aneurysm or AVM, and an equal chance not to be treated, and hence to be exempted from immediate complications. Hence, when the uncertainty dominates, we offer randomization until the uncertainty can be replaced by reliable evidence. How and when the reliability of evidence will be determined is a crucial question. We will simply mention here that this cannot be asserted by individual clinicians facing individual patients, and that determination of the acquisition of reliable knowledge necessitates a pool of data from multiple individuals, and a judgement to be delegated to an impartial and independent group of persons, the DSMC¹⁵.

A final point is in order. The ethical requirements that have been articulated to ensure that the therapeutic obligation is not violated for the benefits of science have been schematically summarized into three concepts: equipoise, indifference and uncertainty regarding the treatment options that are allocated at random.

The word equipoise places perhaps too much emphasis on a responsibility of fine tuning a delicate balance, disturbed by the most feeble hunch, or implicitly encourages an unwarranted confidence in the power of divination of the clinician. Most human beings confronted with the unknown are desperately tempted to fall on either side of a dilemma while we wish participating clinicians to suspend judgment whenever evidence is lacking. In contrast, indifference has a ring of apathy, almost a misnomer considering what is at stake, and may inadvertently favor a passive and unjustified choice: why bother with this, if there is no difference? Both of these options also seem to contradict the formulation of a research hypothesis which will be tested during and at the end of the trial. We prefer the notion of uncertainty because its

vagueness is in keeping with the reality of what is possible regarding clinical knowledge, and the fact that despite heated debates and raging controversies before the initiation of a trial, the outcome for the majority of participants of both groups will be equivalent at the end of the trial (differing for only a small percentage of patients recruited). Thus it seems that for the majority of cases we were right in being uncertain. It also emphasizes that one must be humble and prudent before adopting a risky treatment destined to healthy individuals, and this concept imposes the burden of proof on action and sufficiently strong evidence to lift the current uncertainty.

Randomization is not giving the decision up to chance. It is to opt for a rational, responsible choice, to suspend judgment until there is evidence, to maximize the chances of a benefit for each individual patient while we remain uncertain, and to act in a context that will promote knowledge and progress, in respect for patient autonomy.

The Autonomy of Patients

In line with modern liberalism, and confronted with uncertainty, why not offer various choices and let individuals decide? There are at least two important difficulties with this approach. First, autonomy or self-determination necessitates competence, rational desires, and reliable knowledge¹⁶.

The individual confronted with the diagnosis of an aneurysm or an AVM will naturally wish to see the problem 'taken care of', even though this could qualify as irrational in the current context of ignorance regarding what should be done about it. He will delegate competence to the expert physician he will consult, but as we have seen there is currently no such expert who could offer this reliable knowledge. Thus an autonomous decision is hardly conceivable if one is not willing to accept the current uncertainty.

Second, to conceive medical care as just another product in a market where consumer satisfaction is what matters may appear somewhat strange, as if there were no truth to the matter regarding the best approach to ensure the best possible outcome. Of course the facts of the trial may focus on 'hard' outcomes, while individuals may take into account other values in their decision analysis. But there are reasons to wor-

ry about apparent paradoxes that can occur with other outcome measures such as quality of life (QOL). For example, one author reporting the results of a trial on asymptomatic aortic aneurysms, perplexed by a significant increase in QOL scores 12 months after major surgery for asymptomatic diseases, proposed that this observation ‘may provide an empiric demonstration of Churchill’s observation that “nothing in life is so exhilarating as to be shot at without result”^{17,18}.

Uncertainty is felt by patients and physicians as painful and sterile, especially if it is a repeated confrontation with no perspective of resolution. Thus most clinicians look for the local circumstances that will weigh in favour of one option or the other, and many will color their explanations to the patient according to the option they have selected. However our responsibilities include the need to accompany patients in the difficult decisional contexts brought about by our own technologies, help them understand that the uncertainty regarding what to do cannot be simply resolved, and the professional requirement that we should not act as if we knew¹⁹.

The randomized trial methodology forces more objective explanations as part of the consent procedure, and at the same time provides hope for resolution of the dilemma. Thus we believe that our obligations of honesty and veracity, as well as respect for patient autonomy, three crucial aspects of the relation of trust between the patient and his physician, are well preserved within the context of clinical trials.

Just Another Conflict between Dogmatic Scientists and Pragmatic Clinicians?

Medicine is still imperfect today, and human beings continue to suffer and die. Hence medicine can and should progress. How can this be done? Perhaps the expert clinician honestly believes that he does good, but in the absence of a reliable method to assess the results of his actions, what are the basis of his beliefs? A medical world divided into clinicians dedicated to the care of individuals, impelled to act in the face of uncertainty, and laboratory scientists looking for abstract truths is unlikely to make progress possible. Given the differences between their respective world-views and value systems, we should not be surprised that pure clinicians and pure scientists end up talking past each other. A reconciliation is in order. The clinical trials we propose were designed by and for clinicians to better the outcome of their patients. The world of neurovascular specialists is too small to afford delegating progress to a scientific elite, while the majority of clinicians resist and continue to practice ‘standard care’ based on opinions and custom. As a community of experts, we cannot wait for others to confront us with facts, since they cannot possibly come from outside our practices. The main difference between medicine and other means to palliate human sufferings is the requirement for self-imposed rigorous evidence that our actions do lead to better outcomes. Hence whenever proof of benefits remains unavailable, clinical trials should be an integral part of standard practice.

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