VALUES IN MEDICAL RESEARCH

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1. Introduction

Medical research is thought to involve the objective or unbiased pursuit of knowledge. This is often expressed by saying that research is, or at least ought to be, value-free. In this chapter, I aim to draw attention to some of the problems with this ideal. I begin by developing a thought experiment aimed at demonstrating the significant challenges of controlling for values in the design, execution, and reporting of medical research. Following this, I outline the implications of pervasive unacknowledged values in medical research, from direct harm to research subjects to the indirect harms that arise as a result of loss of public trust in the research enterprise. Given the undesirability of these potential harms, I clarify what is meant by values in this context and then turn to recent work in philosophy of science, on two questions: “Is value-free medical research possible?” and “Is value-free medical research desirable?” In both cases, the answer is no. In light of these answers, I present a different way of thinking about the role of values in medical research, and trace the practical implications of this approach. Rather than pretending that medical research is more objective than it really is, we ought to improve the social mechanisms that allow for the exposure and critical evaluation of the values that necessarily persist in medical research.

2. Effectivex

Imagine there are two medical researchers: one scrupulous and honest, and the other quite unscrupulous. Each of them is given the same task: design a research trial on a new drug for cholesterol: Effectivex. The good, scrupulous researcher does so diligently, with the sole aim of producing knowledge. The unscrupulous researcher, on the other hand, has a strong desire to obtain positive results in this trial because she stands to benefit, financially and through enhanced reputation, from the success of Effectivex. However, while unscrupulous, she is not willing to go so far as fabricating the results of a study or plagiarizing a study done by someone else, nor is she crude enough to want to falsify the results by directly altering the data once it has been collected. These strategies would be too risky, since she wants to publish the research in a high-impact journal, and the reviewers might notice these more-familiar types of research misconduct. Like the scrupulous researcher, she wants to obtain regulatory approval for the drug, if it works, and this added level of scrutiny provides extra reason for caution. As a more sophisticated breed of unscrupulous researcher, she is keen to rig the trial, through design, to produce the results she wants.
Here’s the challenge, then: none of the tactics the unscrupulous researcher employs can affect the quality of the trial as judged by reviewers and regulators. It will have to be the same design used by the scrupulous researcher, a double-masked, randomized controlled trial (RCT): the gold standard of medical research. This means that selected study participants will be allocated at random to a treatment and control group, and neither the researchers nor the participants will know which group they are in until the trial is complete. There will have to be appropriate follow-up of subjects in the trial and a rigorous statistical analysis. Within these parameters, what tactics might the unscrupulous researcher employ? How might she accomplish her goal?

When I pose this scenario in university classrooms, I am astonished at how many strategies the students are able to come up with. Occasionally the proposed tactics won’t work, because they violate one of the quality conditions, such as by requiring that the researcher knows which group participants have been assigned to during the trial so that she can tamper with the experience of that group (which violates the double-masked condition), but in most cases the tactics abide by the rules and seem like they would work. One such tactic my students often come up with involves giving the treatment to everyone in a set of potential research subjects, before the trial begins, and then eliminating any subjects who are not responding well. Then the real trial (and randomization) can take place, using only the subjects already known to be good responders. (In case this tactic seems too outlandish, I should note here that this strategy is employed regularly in clinical research: it is called a pre-trial run-in period.) I suspect, like my students, by this point you have already thought of one or two strategies the unscrupulous researcher might try.

There is a deeper point to be made here, however: even the scrupulous researcher, in the design of a trial of Effectivex, will have to make decisions during the course of research that make it more or less likely the drug will be shown to be effective. So, for instance, if the scrupulous researcher does not include a pre-trial run-in, this choice has implications for how generalizable the results are and how highly regarded the study will be by other researchers. So even the scrupulous researcher will have to consider the use of such tactics, even if they are ultimately rejected. As we will explore later in this chapter, values guide this assessment all the way through, whether a particular researcher is scrupulous, unscrupulous, or somewhere in between. I will turn now to the empirical evidence on the use of such tactics in actual medical research.

3. Evidence of Values in Medical Research

Many of the tactics known to have been employed by unscrupulous researchers for the purposes of obtaining positive results have been exposed in recent years (cf. Borgerson 2009). One of the most common ways to meddle with results is to be selective about what ends up in the official record. So, for instance, if the results of a trial were quite positive, researchers have been known to publish them many times, in many different journals (Tramer et al. 1997). This creates the (false) appearance of a preponderance of evidence in favor of the treatment. Conversely, if the results are not what the investigators had hoped for, they might decide not to publish them at all or to publish them in obscure journals in other languages so they won’t be found (Lexchin et al. 2003). Taking this strategy a step further, researchers might publish only the early results of a trial, ignoring the final results, in cases where the trial was looking good for some period of time, but then took a turn for the worse by the end of the study period (the Celebrex scandal arose because of the use of this sort of tactic).

Variations also exist in ways to make the comparison treatment worse (Psaty, Weiss, and Furberg 2006). Specifically, there are studies in which researchers employed what is called
“sub-optimal dosing,” where this involves using too low or too high a dose of the competitor’s drug, in order to make one’s treatment look better by comparison (Rochon et al. 1994). Researchers have also been known to administer comparison treatments in less absorbable forms (e.g., pills rather than intravenous [IV]) for similar reasons (Johansen and Gotzsche 1999).

Another common tactic involves testing treatments for very short periods of time, for instance just a few weeks, even when the researchers know the treatments will be used long term by patients. This makes it less likely they will discover (and then have to reveal) adverse side effects or long-term effects. And there are others: inappropriate surrogate endpoints (Psaty et al. 1999); stopping trials early when the results look favorable (Montori and Guyatt 2007); and perhaps the most common strategy, simply refusing to allow many potential research subjects to enroll in the trial by setting strict inclusion/exclusion criteria (Humphreys et al. 2013). My students’ idea of a pre-trial run-in period is a variation on this last strategy. (Note that some of these tactics have justifiable variations. I discuss this challenge further in section 7.) In addition to these methods, there are dozens more such tactics already in use and no doubt many more that haven’t yet been dreamed up. The authors of one satirical take on this problem, in an article on “how to achieve positive results without actually lying to overcome the truth” identified a handful of very common practices and proposed others (Sackett and Oxman 2003). Drawing on decades of experience in the design and assessment of clinical trials, clinical researchers Alex Jadad and Murray Enkin identified dozens of tactics in their 2007 guide to randomized controlled trials (RCTs) (Jadad and Enkin 2007). Updates to these lists would certainly be required today. For instance, there has been increasing awareness very recently of the tactic of “p-hacking,” which involves selecting and reselecting data or methods of analysis until nonsignificant results appear to be significant; this tactic has been employed not only in medical research but also in many other fields of scientific research (Head et al. 2015).

As this exercise and the supplementary empirical evidence demonstrates, it is possible to introduce various biases into even the highest-quality research designs. That is, even our gold standard highest-quality research trials (RCTs) may not be as unbiased as we might have believed them to be. And because tactics to manipulate trials are extensive, widespread, and always evolving, this is a problem we can’t ignore.

4. Implications of the Widespread Use of These Tactics

The widespread use of these tactics constitutes what Ben Goldacre has referred to as a “cancer at the core of evidence-based medicine” (2012). Physicians who rely upon research evidence to determine how best to treat patients are being misled and misinformed, whether intentionally or not. As a result, they are prescribing treatments to patients that, in some cases, do more harm than good. Many drugs have been withdrawn from the market after these harms came to light: rofecoxib (Vioxx) is a classic example here, since as a result of its popularity it is estimated to have seriously harmed more than 100,000 people in the United States alone. In other cases, the uncertainty about the evidence stalls the process of decision-making and this delays proper treatment, also resulting in harm to patients who suffer without treatment for some period of time.

There are also direct harms to research subjects, who believe they are participating in a socially valuable enterprise, when they are not because the results are too biased to contribute anything meaningful to knowledge. Public awareness of the tactics identified may lead to a loss of trust in the research enterprise. Over time, this would exacerbate the difficulties already encountered by researchers hoping to recruit new research subjects. In addition to these direct and indirect harms, the widespread use of these tactics corrupts our knowledge base, and
because researchers “stand on the shoulders of giants” (i.e., use previous research as the basis for proposed new research), this may have a corrupting effect on future research as well.

A common reaction to this dismal situation is to call for stricter adherence to a value-free ideal of medical research. In what follows, I will outline some of the limitations of this type of solution. Before doing so, I will clarify some key terms and review recent developments in philosophy of science as they relate to this issue.

5. What Are Values?

Before going any further, it is important to clarify what is meant by values in this discussion, since we have been using the term very loosely thus far. Values are often contrasted with facts or empirical evidence. It can be useful to keep this sort of contrast in mind when we are talking about values in the sciences, since scientific inquiry may aim to produce facts but draw on values along the way: “Values are statements of norms, goals, and desires; evidence consists of descriptive statements about the world” (Douglas 2007: 126). We are all familiar with facts, or descriptive statements, such as “the earth is round” and “the sky is blue.” Value statements may contain terms like “ought” and “should” or otherwise signify that they are meant as norms or rules. So, when we say that simplicity is a value in the sciences, we mean that scientists operate with a norm, or rule, such as “the simplest explanation is often the best one” or, put more directly, “when all else is equal, choose the simplest explanation.” (This may or may not be a good rule.)

A distinction is sometimes drawn between epistemic values, such as truth or accuracy, and non-epistemic (moral or political) values, such as equality or freedom. This distinction is also contested; we will stick with it for now because it will help to clarify a key position in the debate over the role of values in science.

The unscrupulous researcher described above aimed to design research studies in such a way that they would produce only positive results. In doing so, she might be said to have valued her own financial interests more than accuracy or truth. Sometimes people talk about negative values as those that compete with the standard positive epistemic values like truth. These values lead us away from knowledge. Because one of the core scientific values is accuracy in our descriptions of the world, one of the most common forms of negative value are biases. Biases are any factors that interfere with our ability to obtain accurate results; in other words, they are the negative value that contrasts with the positive value of accuracy. A bathroom scale may be biased if it systematically displays a higher or lower weight than is accurate, and dice at a gambling table can be biased if they have been weighted to turn up lucky 7’s more, or less, frequently than balanced dice. Determining whether a value is positive or negative can sometimes be tricky and requires close attention to the particular context. For instance, there is nothing inherently wrong with valuing financial gain. But it can become a negative value, or disvalue, in the context of medical research.

6. What Does It Mean for Someone to Claim That “Science Is Value-Free”?

Philosophers and historians of science have written extensively on value-freedom as an ideal in the sciences. A systematic overview of this literature can be found in a collection of essays entitled Value-Free Science? Ideals and Illusions (Kincaid et al. 2007). Many of the case studies and examples used in the collection stem from areas such as biology, archaeology, evolutionary psychology, and economics. The lessons, though, are readily applicable—perhaps even more immediately applicable—in the practically oriented domain of medicine, where the stakes, and the interests, are very high. The value-free ideal maintains that whereas moral and political
decisions often depend on interests, values, and preferences, scientific claims are dependent only on empirical evidence. Kincaid and colleagues characterize this view as follows: “The job of science is to tell us the facts” (2007: 4).

The first thing to realize about the claim that “ideal science is value-free” is that, in its strongest form, it is obviously false. This is not simply because there are so many cases of biased science (as in the examples of medical research described above). It is for two deeper reasons. First, epistemic values seem to be a necessary component of all elements of scientific research. Insofar as scientists value truth or accuracy (and we hope they do), these epistemic values (and others) ought to permeate and guide all elements of scientific research. Second, non-epistemic values are a necessary component of scientific research at key stages. In the earliest stages of scientific research, scientists must decide what topic or area to study, what specific question to ask, and what study population to use, and so on. These choices will be interest-driven and thus value-laden. They will respond to things like pressing health needs in the world or a desire for financial gain. For instance, choosing a homogenous and healthy study population limits the generalizability of results but arguably gives the treatment the “best shot” at success because it limits confounding factors. Which matters more, in a particular case, comes down to values: for instance, the value of increased knowledge for its own sake versus the value of results directly relevant to clinical care. And when the research is complete, the scientists may have to decide whether to make the results public, whether to patent the discovery, and so on. Again, these decisions depend on commitments to different values.

So when people claim that science is value-free, they really mean something much less dramatic than their statement suggests (at least, if they have thought through the position). They allow for epistemic values throughout the process of scientific inquiry, and they allow that non-epistemic values affect science “before and after” the crucial experimental phase of research (where that includes the interpretation of results). What they mean to deny is that non-epistemic values play a role in the middle stage: during hypothesis testing. The reason they might want to maintain some “pure” domain within science is because they are concerned that the intrusion of non-epistemic values into the core of science will compromise the focus on obtaining knowledge. The worry is that researchers might simply manipulate (or “torture”) any data they gather in order to obtain the results they’d like, and there will be a free-for-all that loses all purchase on the truth. It is important to keep this worry in mind, and to ask whether proposed middle-ground positions, which allow a role for non-epistemic values throughout scientific inquiry, avoid the dangers just described.

7. Is Value-Free Medical Research Possible?

I will assume for the sake of this discussion that even if medical practice is a blend of art and science, as is often claimed, medical research is, or aims to be, scientific. We can then approach the question of whether the core of scientific inquiry is value-free (in the limited sense clarified above) through the case of medical research.

Someone faced with evidence of the widespread use of the tactics used to bias medical research outlined above may well call for stricter adherence to a value-free ideal in the hopes that it will provide resources for eliminating bias in the sciences. To someone with this position, stricter adherence to, for instance, methodological rules in medical research, is needed to solve the problems outlined above. I will show that this approach, while sometimes helpful, cannot fully resolve the problem, and I will do so by returning to the case of research on Effectivex.

Some of the biasing tactics employed by medical researchers seem like they might be prevented through clearer rules for researchers. So, for instance, researchers who refuse to publish
unfavorable results could be made to do so by funding agencies or could be tracked through registration systems designed to publicly track all clinical trials. In fact, these solutions have been implemented in recent years, though they are not wildly successful as yet. However, other biasing tactics seem to be not only challenging to eliminate through rules imposed from outside, but actually so like the decisions necessarily made in the course of research that they could not be imposed from outside without serious harm to inquiry.

Take, for example, inclusion and exclusion criteria for trial participation. In the design of a trial, researchers will have to decide which potential research subjects to include and which to exclude. There is no option to just not decide this or to have an independent committee decide it, though we could require that a burden of justification be placed on researchers to defend any exclusions if we were worried about heavy-handed use of exclusion criteria (as has been common). However, if researchers are committed to a certain type of causal or explanatory trial, with the fewest number of participants possible, and this is key to their research question, then a strict rule prohibiting this choice seems misguided. What rule, then, would prevent the sorts of abuses outlined above? However many safeguards we put in place, researchers will always have some degree of autonomy, and to that extent values will continue to shape research. This effect can be limited, and constrained, but not eliminated.

Consider also the practice of stopping a trial early due to dramatic effects. Surely there are some cases where this is appropriate, even if there are others where researchers are stopping trials early because they are afraid that the dramatically positive effects will fade with time (as is common). These sorts of judgment calls will have to be made, and while rules can help guide these decisions, and some regulatory mechanisms exist for checking on these decisions (such as Data and Safety Monitoring Boards), there will always be room for individual judgment.

A third example concerns the choice of comparison treatment in a controlled trial. Again, some rules can be put in place to ensure roughly appropriate comparison treatments (for instance, ethical prohibitions on the use of placebo comparisons when other treatments have been approved for the condition, with oversight by Research Ethics Committees). But there will still be room for judgment about what the best comparison is, and what the appropriate dose of that control treatment ought to be. Where judgment calls are needed, biased intervention is possible, yet we cannot eliminate these moments of judgment.

Hopefully these examples from recent medical research help to illustrate why philosophers of science have come to believe that the value-free ideal is not achievable. Philosophers such as Helen Longino have arrived at similar conclusions using case studies from biology and the behavioral sciences, and investigations into other domains have turned up similar conclusions (Longino 1990, 2002, 2013; Kincaid et al. 2007). But philosophers, including Longino, have also gone beyond the claim that value-free science is unachievable to consider whether the ideal might actually be undesirable. In the next section, I will review Heather Douglas's argument that we ought to reject the value-free ideal entirely.

### 8. Is Value-Free Medical Research Desirable?

Douglas argues that, in many areas of science, the value-free ideal is actually detrimental to good scientific practice (2007). The areas of science she focuses on include all those in which the knowledge produced is used to inform decisions, guide actions, and solve problems in the real world. Medical research is a paradigm case of this sort of science. Douglas focuses on the choices made by scientists during the course of research, and in particular on the internal or core stages of hypothesis testing where proponents of the value-free ideal
would hope to eliminate all non-epistemic values. Throughout scientific inquiry, including this internal stage, Douglas reminds us that scientists must make choices. Any choice they make has the possibility of being wrong: they may choose the wrong methodology, the wrong study sample or sample size, or the wrong form of statistical analysis. There will be some uncertainty about what the right thing to do is in any particular case. If the scientists know that the results of their research will be used to inform decisions in the world, they will have to choose what level of error they are prepared to accept in their own decisions throughout the study. These choices will be affected by things like how much harm would result if the wrong results were applied in practice. It seems, then, that these are value-laden choices (Douglas 2007).

Douglas illustrates this point using a study that involved the liver tissue of rats that had been exposed to dioxin, a type of organic compound thought to be harmful to humans, at three different dose levels, plus one control group (2007: 124). The slides of the liver tissue were analyzed initially and classified as either free from tumors or containing tumors, whether benign or malignant. Over the next 14 years, “those slides were reevaluated by three different groups, producing different conclusions about the liver cancer rates in those rats” (2007: 124). This exposes the uncertainty around what counts as liver cancer in rats. Douglas stresses this point: all scientific inquiry contains some degree of uncertainty and some possibility of error in decisions made to manage that uncertainty.

Which errors should be more carefully avoided? Too many false negatives are likely to make dioxin appear to be a less potent carcinogen, leading to weaker regulations. This is precisely what resulted from the 1990s industry-sponsored reevaluation . . . that was used to weaken Maine water-quality standards. Too many false positives, on the other hand, are likely to make dioxin appear to be more potent and dangerous, leading to burdensome and unnecessary overregulation. Which consequence is worse? Which error should be more scrupulously avoided?

(2007: 125)

There is no way for scientists doing this kind of research to avoid making decisions about the trade-off between, for instance, human health and economic efficiency. They will have to decide which type of error is appropriate. These value-laden decisions are, as Douglas points out, “at the heart of doing science,” not at the periphery as advocates of the value-free ideal might hope (p. 125).

Douglas responds to an obvious objection to this argument: why not require that scientists estimate the uncertainty involved in any judgment and report it rather than take a position? There are two problems with this position. First, it is extremely difficult to estimate, with any precision, the effect of any and all methodological choices on the outcome of a study. This is particularly clear in cases where methodological choices made very early in the study have an effect on the outcome. Douglas offers another medical example to make this point. Medical researchers sometimes rely on the cause of death reported on death certificates to track outcome measures in an experiment, but death certificates are sometimes wrong about the cause of death, for instance in cases involving soft-tissue sarcoma. Nobody knows what the error rates are, but they exist. Medical researchers would be hard-pressed to produce a precise estimate of the effect of this possible error on their results. Now consider that many other such decisions will be made during the course of research, each with some imprecise level of uncertainty. Because research has to proceed on the basis of some decision, these uncertainties will come along for the ride.
Second, and even more fundamentally, even the estimate of error has its own chance of error. That is, it too is imprecise and might be wrong, and so can be assigned some probability of error. It seems researchers are stuck in a regress, in which the task required (e.g., estimating error) itself requires an estimate of error, and that estimate also requires a further estimate of its error, and so on. (A version of this argument was first made by Richard Rudner in 1953, in an admirably clear paper: “The scientist qua scientists makes value judgments.”) While the value judgment might, in some cases, be pushed back one level, or set by convention, it can never be eliminated (Douglas 2007).

9. What Are We Left with, Once We Reject the Value-Free Ideal in Medicine?

Recall how entrenched the commitment to a value-free ideal is in the sciences: “when the value freedom of science is questioned, a fundamental institution in our lives is being challenged” (Kincaid et al. 2007: 4). It is likely that many of you reading this chapter will have been taught, whether in elementary school, through the media, or even at university, that the sciences produce objective knowledge through a trustworthy and reliable scientific method, which has been carefully designed to eliminate biases. The alternative, it seems, is quite frightening: if we reject the view that the sciences are value-free, we seem to be left only with the view that scientific inquiry is so thoroughly value-laden that it is merely a reflection of our own prejudices (whether individual or social). This is clearly an undesirable position!

The choice of positions is, happily, not as stark as this. Philosophers of science have, since the 1980s, explored the conceptual territory between these extremes, and many middle-ground positions have been constructed and defended. This is good news, since many important practical decisions are made on the basis of scientific research, including decisions about the care of individual patients, and these decisions can have tremendous importance for the lives of individuals. Health insurance organizations, whether public or private, also need evidence to decide which treatments to cover, and governments (at least ideally) use evidence to guide allocation decisions at the highest level, so having trustworthy evidence is vitally important.

The most promising class of proposals for how to proceed with our new value-laden understanding of scientific inquiry emphasize the importance of transparency and critical engagement within scientific communities (Longino 1990, 2002, 2013). The central idea is this: since values are ineliminable in the sciences, we must identify and acknowledge the values and background assumptions guiding decisions and subject them to critical scrutiny. That critical scrutiny should come from as many diverse perspectives as possible. Elizabeth Anderson nicely draws out the contrast between this approach and the one currently preferred under the value-free ideal:

Insistence on the value-neutrality of scientists is self-deceptive and unrealistic. . . . Indeed, it is self-defeating: when scientists represent themselves as neutral, this blocks their recognition of the ways their values have shaped their inquiry, and thereby prevents the exposure of these values to critical scrutiny.

(2012, np)

Instead of allowing scientists to hide value-laden choices under the guise of neutrality, they ought to be required to acknowledge and critically discuss those choices with other community members. Douglas sums this up nicely:
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Giving up on the ideal of value-free science allows a clearer discussion of scientific disagreements that already exist and may lead to a speedier and more transparent resolution of these ongoing disputes [over public policy issues].

(2007: 136)

The “open science” movement of recent years provides specific recommendations for ensuring the transparency and publicity of scientific research. In other words, it provides recommendations for ensuring recognized avenues for criticism and for ensuring that community members use these avenues. These include: disclosure of competing interests in publications, prohibitions on ghost authorships, a mandatory clinical trials registry, open peer-review, open-access journals, and more comprehensive analytic training for health professionals.

Of these, the latter is perhaps the least developed but most important. All the transparency in the world won’t solve anything unless educated and informed community members engage critically with the identified value-laden assumptions. The analytic training could, for instance, take the form of education in philosophy, which tends to be focused on developing critical thinking skills through the examination of taken-for-granted assumptions. It is also vitally important that critics represent different perspectives and viewpoints, since these diverse perspectives are most likely to expose common assumptions to scrutiny and provide new ideas on how to proceed. Finally, it is worth pointing out that certain values may turn out, through this critical evaluation, to be bad for medical research. (Financial interests, for instance, may well interfere with a commitment to knowledge. We saw this in the Effectivex case, and the problem may be widespread.) If we have reason to believe this is true, then the medical research community will need to organize itself, or advocate for policy makers, to limit or prohibit the influence of such values. Although some values might require a lot of debate, and policies might thus be subject to revision over time, others, such as the value of truth or accuracy, will be more settled.

10. Conclusion

Consider a medical researcher who is making a decision about which disease to investigate in her research. She is not value-free if she chooses to investigate ovarian cancer rather than pancreatic cancer because that disease affected, or even killed, a friend or loved one. She is not value-free if she chooses to investigate a disease affecting impoverished people in developing nations, such as malaria, on the basis of concerns about social justice and maximum benefit. And she is not value-free when she chooses to conduct research on prostate cancer because there is funding dedicated specifically for research on prostate cancer by the national research institute in her home country.

The difficulty in characterizing a process of value-free reasoning persists in cases where we examine choices of research method, of outcomes, of which journal to publish in (or whether to publish), and so on. That is, it persists at every stage from the very first to the very last choice made in the research process. It is no less a value-laden choice when the researcher aims to do the right thing and choose the most judicious topic, method, outcome, or journal, than when she aims to act self-interestedly and chooses the topic, method, outcome, or journal based on personal gain. Some of these choices are laudable and others are not, and we have good reasons for making these assessments, but they are all underpinned by values. It is not clear that we can make any sense out of the claim that scientists can learn to reason in a wholly value-free manner. Values pervade all aspects of knowledge production. If we are to avoid losing sight of the truth, these values should be carefully and critically evaluated by a diverse set of people,
but in order to do that, they will first have to be acknowledged. However counterintuitive it might seem, giving up the value-free ideal is a good place to start.

References


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Further Reading


