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# The Vindication of Magnitude-Based Inference

#### Will G Hopkins, Alan M Batterham

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Institute for Health and Sport, Victoria University, Melbourne, Australia; School of Health and Social Care, Teesside University, Middlesbrough, UK. <u>Email</u>.

Magnitude-based inference (MBI) has again been subjected to detailed scrutiny by an establishment statistician in one of our top journals. Kristin Sainani's critique is on four fronts. First, she claims that the probabilistic statements in MBI, such as the treatment is possibly beneficial, are invalid, because these are Bayesian statements and MBI is not Bayesian. This claim is false, because MBI is a legitimate form of Bayesian inference with a minimally informative dispersed uniform prior, so the probabilities provided by MBI are objective trustworthy estimates of uncertainty in the true value. Sainani supports instead "qualitative judgments" of the lower and upper confidence limits, without realizing that the level of confidence renders such judgments quantitative, and they are in fact MBI. Secondly, she regards as "specious" the logic in MBI that there is no Type-I error when the true effect is trivial and the MBI outcome is likely substantial, because the effect is also unlikely trivial (e.g., with a probability of 0.06). But according to her logic, "specious" would also apply to failure to declare a Type-I error in null-hypothesis significance testing (NHST), when the true effect is zero and the outcome is non-significant (e.g., with a p value of 0.06). She shows that our definitions of error "wildly underestimate" Type-II error rates, but her estimates are based on the null hypothesis, which is no longer a trustworthy approach to inference. Thirdly, she highlights the high Type-I error rates for clinical MBI, yet these are comparable with those of NHST over a range of small sample sizes and trivial effect magnitudes, and they occur mostly with effects presented to the clinician or practitioner as only possibly beneficial. Finally, she claims that unclear outcomes in MBI (when the uncertainty allows for substantial positive and negative effects, or benefit and harm) should be counted as inferential errors. We reject this claim, on the grounds that an error does not occur until a decision is made about the true magnitude. We previously adopted this reasoning even-handedly with conservative NHST and showed the error rates, rates of decisive outcomes, and publication bias were generally superior in MBI. She makes several other crucial errors, including her claim that publications we cited as evidence supporting the theoretical basis of MBI "do not provide such evidence." Her recognition of several possible contributions of MBI to the debate on inference is followed immediately by its dismissal as unsound or demonstrably false, while many other valuable original contributions are simply overlooked. We point out the damage to meta-analyses and young researchers' careers that will ensue, if her critique results in journal editors banning MBI. We conclude that her recommendation that MBI should not be used is itself based on unsound or demonstrably false assertions. Researchers can continue to use MBI in the knowledge that it represents a valuable advance on NHST, with the benefits of Bayesian probabilistic inference and without the drawback of a subjective prior. KEYWORDS: Bayesian statistics, effect, clinical importance, likelihood, null-hypothesis significance test, p value, probability, sample, smallest important difference, statistical significance.

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Authors' note. This article was published as a draft with post-publication peer review. We invited readers to make supportive or critical comments using <u>this</u> <u>template</u> and submit as an attachment in an <u>email to</u> <u>us</u>. We published comments <u>via this page</u> following any minor editing and interaction. This version incorporates points raised in comments to date (24 August 2018). Future comments may be included in a further update. The draft version with tracked changes resulting in this version is available as a docx <u>here</u>.

- The changes from the draft version are as follows...
- From the comments of <u>Little</u> (2018) and <u>Lakens</u> (2018), and <u>our response</u> (Batterham and Hopkins, 2018), MBI can be described as *reference Bayesian inference with a dispersed uniform prior*. Two paragraphs starting <u>here</u> have been augmented.

- The comment of <u>Wilkinson</u> (2018) supports our interpretation of errors and error rates in MBI. We see no need to modify our article in this respect.
- When the editor of *Medicine and Science in Sports and Exercise* announced rejection of manuscripts using MBI, we published <u>a comment</u> (Hopkins and Batterham, 2018) recommending use of the Bayesian description of MBI. We noted that the probability thresholds used by the Intergovernmental Panel on Climate Change are remarkably similar to those of MBI, and we have updated this article accordingly <u>here</u>. We also critiqued an attack on MBI by a journalist who used Sainani's erroneous error rates in a news item. We noted two potentially damaging effects of the news item and of Sainani's critique and include them here as an <u>extra paragraph</u>, followed by a paragraph on avoiding underpowered studies.
- The comment of <u>Buchheit</u> (2018) highlights the

Magnitude-based inference (MBI) is an approach to making a decision about the true or population value of an effect statistic, taking into account the uncertainty in the magnitude of the statistic provided by a sample of the population. In response to concerns about error rates with the decision process (Welsh and Knight, 2015), we recently showed that MBI is superior to the traditional approach to inference, null-hypothesis significance testing (NHST) (Hopkins and Batterham, 2016). Specifically, the error rates are comparable and often lower than those of NHST, the publishability rates with small samples are higher, and the potential for publication bias is negligible.

A statistician from Stanford University, Kristin Sainani, has now attempted to refute our claims about the superiority of MBI to NHST (Sainani, 2018). We acknowledge the effort expended in her detailed scrutiny and welcome the opportunity to discuss the points raised in the spirit of furthering understanding. Sainani argues that MBI should not be used, and that we should instead "adopt a fully Bayesian analysis" or merely interpret the standard confidence interval as a plausible range of effect magnitudes consistent with the data and model. We have no objection to researchers using either of these two approaches, if they so wish. Nevertheless, we have shown before and show here again that MBI is a valid, robust approach that has earned its place in the statistical toolbox.

The title of Sainani's critique refers to "the problem" with magnitude-based inference (MBI), but in the abstract she claims that there plight of a researcher who understands and has opted for MBI, and for whom (in the absence of viable alternatives) a return to p values is unthinkable. His comment represents an endorsement of MBI by an experienced practitioner-researcher who suffered under p values. No update of this article is required.

- Some researchers still need to understand how MBI works and how p values fail to adequately represent uncertainty in effects. One of us (WGH) therefore put together a slideshow and two videos, available via this comment (Hopkins, 2018). One of the slides is included below, with an <u>explanatory paragraph</u>.
- Soon after publication of this version, someone raised the concern that MBI could be viewed as promoting unethically underpowered studies. We have therefore amended the <u>paragraph</u> about small samples.

are several problems with the Type-I and Type-II error rates. In the article itself, she begins her synopsis of MBI with another apparent problem: that the probabilistic statements in MBI about the magnitude of the true effect are invalid. Throughout the critique are numerous inconsistencies and mistakes. We solve here all her perceived problems, highlight her inconsistencies and correct her mistakes.

Should researchers make probabilistic assertions about the true (population) value of effects? Absolutely, especially for clinically important effects, where implementation of a possibly beneficial effect in a clinical or other applied setting carries with it the risk of harm. We use the term risk of harm to refer to the probability that the true or population mean effect has the opposite of the intended benefit, such as an impairment rather than an enhancement of a measure of health or performance. It does not refer to risk of harm in a given individual, which requires consideration of individual differences or responses, nor does it refer to risk of harmful side effects, which requires a different analysis. Magnitude-based inference is up-front with the chances of benefit and the risk of harm for clinical effects, and the chances of trivial and substantial magnitudes for non-clinical effects. This feature is perhaps the greatest strength of MBI.

Sainani states early on that "I completely agree with and applaud" the approach of interpreting the range of magnitudes of an effect represented by its upper and lower confidence limit, when reaching a decision about a clinically important

effect. But, according to Sainani, "where Hopkins and Batterham's method breaks down is when they go beyond simply making qualitative judgments like this and advocate translating confidence intervals into probabilistic statements, such as the effect of the supplement is 'very likely trivial' or 'likely beneficial.' This requires interpreting confidence intervals incorrectly, as if they were Bayesian credible intervals." We have addressed this concern previously (Hopkins and Batterham, 2016). The usual confidence interval is congruent with a Bayesian credibility interval with a minimally informative prior (Burton, 1994; Burton et al., 1998; Spiegelhalter et al., 2004). As such, it is an objective estimate of the likely range of the true value, and the associated probabilistic statements of MBI are Bayesian posterior probabilities with a minimally informative prior. The post-publication comments of Little (2018) and Lakens (2018) further underscore this point.

Unfortunately, full Bayesians disown us, because we prefer not to turn belief into an informative subjective prior. Meanwhile, NHSTtrained statisticians disown us, because we do not test hypotheses. MBI is therefore well placed to be a practical haven between a Bayesian rock and an NHST hard place. (Others have attempted hybrids of Bayes and NHST, albeit with different goals. See the technical notes.) From Bayesians we adapt valid probabilistic statements about the true effect, based on the minimally informative dispersed uniform prior. From frequentists (advocates of NHST) we adapted straightforward computational methods and assumptions, and we computed error rates for decisions based not on the null hypothesis but on sufficiently low or high probabilities for the qualitative magnitude of the true effect. The name magnitude-based inference therefore seems justifiable, but in the Methods sections of manuscripts, authors could or should note that it is a legitimate form of Bayesian inference with the minimally informative dispersed uniform prior, citing the present article. The appropriate reference for the decision probabilities is the progressive statistics article in Medicine and Science in Sports and Exercise (2009). Whether the resulting error rates are acceptable is an issue we will address shortly.

There is a logical inconsistency in Sainani's "qualitative judgment" of confidence intervals. In her view, it is not appropriate to make a probabilistic assertion about the true magnitude of the effect, but it is appropriate to interpret the magnitude of the lower and upper confidence limits. The problem with this approach is that it all depends on the level of the confidence interval, so she is in fact making a quantitative judgment. Indeed, such judgments are actually nothing more or less than magnitude-based inference, the only difference being the width of the confidence interval. Towards the end of her critique she cites "an excellent reference on how to interpret confidence intervals (Curran-Everett, 2009)." Here is a quote from that article: "A confidence interval is a range that we expect, with some level of confidence, to include the true value of a population parameter... a confidence interval focuses our attention on the scientific importance of some experimental result." In the three examples he gives, Curran-Everett states that the true effect is "probably" within the confidence interval or "could range" from the lower to the upper confidence limit. Again, this interpretation is quantitative, with probably and *could* defined by the level of confidence of the confidence interval.

There is a further inconsistency with Sainani's applause for qualitative judgments based on the confidence interval: the fact that her concerns about error rates in MBI would apply to such judgments. Consider, for example, a confidence interval that overlaps trivial and substantial magnitudes. What is her qualitative judgment? The effect could be trivial or substantial, of course. Where is the error in that pronouncement? If the true effect is trivial, we say there is none, but she says there is an unacceptable ill-defined Type-I error rate. The only way she can keep a well-defined NHST Type-I error rate is to make a qualitative judgment only if the effect is significant. In other words, if the confidence interval does not overlap the null, she can say that the effect could be trivial or substantial, but if it does overlap the null, however slightly, she cannot say that it could be trivial. Presumably she will instead call the magnitude unclear. If that is the process of qualitative judgment she has in mind, it is obviously unrealistic.

Sainani is also inconsistent when she makes the following statement: "Hopkins and Batterham's logic is that as long as you acknowledge even a small chance (5-25%) that the effect might be trivial when it is [truly trivial], then you haven't made a Type I error... But this seems specious. Is concluding that an effect is 'likely' positive really an error-free conclusion when the effect is in fact trivial?" Consider the confidence-interval equivalent of Sainani's statement. A small chance that the effect could be trivial corresponds to a confidence interval covering mostly substantial values, with a slight overlap into trivial values, such that the probability of a trivial true effect is only 6%, for example. Hence we say the effect could be trivial, so no Type-I error occurs (Figure 1). Now consider what happens in NHST. If the 95% confidence interval overlaps the null only slightly, with p=0.06, then a Type-I error has not occurred (Figure 1). In other words, it's the same kind of decision process as for MBI, except that in MBI the null is replaced with the smallest important effect. The same argument could be mounted for Type-II errors: Sainani does not specifically call our logic here specious, but she does show later that our definitions "wildly underestimate" the traditional Type-II error rates. We will not be held accountable for error rates based on the null hypothesis.

Figure 1. Examples of confidence intervals and associated inferences to illustrate marginal Type-I errors in non-clinical magnitude-based inference (MBI) and null-hypothesis significance testing (NHST). In the MBI examples, the true value is trivial, and the coverage of the 90% confidence intervals is sufficient to produce a trivial true-effect probability of 0.04 (very unlikely trivial, a Type-I error) and 0.06 (unlikely trivial, no Type-I error). In the NHST examples, the true value is null, and the coverage of the 95% confidence intervals is sufficient to produce a p value of 0.04 (statistically significant, a Type-I error) and 0.06 (statistically non-significant, no Type-I error). These examples demonstrate that, by analogy with NHST, there is nothing illogical or specious in declaring no Type-I error in MBI when the true effect is trivial and the probability for a trivial true magnitude is 0.05-0.25 (chances of 5-25%, unlikely).



Sainani offers a novel solution to her perceived problem with the definition of MBI Type-I error: allow for "degrees of error", which inevitably makes higher Type-I error rates. But a similar inflation of error rates would occur with NHST, if degrees of error were assigned to p values that approach significance. We doubt if her solution would solve the problems of the p value that are increasingly voiced in the literature; in any case, we do not see the need for it with MBI. When an effect is possibly trivial and possibly substantially positive, that is what the researcher has found: it's on the way to being substantially positive. Furthermore, for effects with true values that are close to the smallest important effect, the outcome with even very large sample sizes will usually be possibly trivial and possibly substantial. Importantly, a Bayesian analysis with any reasonable prior would reach this same conclusion, because the prior is inconsequential

with a sufficiently large sample size (Gelman et al., 2014). Now, should such a finding be published? Of course, but we advise against making inferences with the p value alone, because it will be <0.0001 and leave the reader convinced that there is a substantial effect. It follows that such outcomes with more modest sample sizes should also be published. By making a clear possible outcome a publishable quantum, you also avoid substantial publication bias, because researchers get more of their previously underpowered studies into print with MBI. Adoption of MBI by the research community would not result in a chaos of publication bias. On the contrary, there would be negligible publication bias, and the farcical binary division of results into statistically significant and non-significant at some arbitrary bright-line p-value threshold would be consigned, along with the null hypothesis, to the dustbin of failed paradigms.

For researchers, reviewers and journal editors who are still undecided about using MBI in preference to p values, see Figure 2, which is taken from the slideshow and second video, available via <u>this comment</u>. The figure shows outcomes with small samples where the interpretation of the magnitude of the confidence limits–that is, MBI–provides a succinct and accurate description of the uncertainty in the magnitude of the true effect, whereas p values fail. For the two outcomes where the conclusion with non-clinical MBI is *could be* +*ive or trivial*, one is significant and the researcher would conclude *there is an effect*, while the other is non-significant and the researcher would conclude *there is no effect*. Both conclusions based on the p value are obviously wrong; the conclusion with MBI properly describes the uncertainty. For the outcome where the MBI conclusion is unclear, the p value again fails, because non-significance would be interpreted as *no effect*, which does not represent the fact that the true value could be substantially negative, trivial or substantially positive. We have given the *conventional* NHST interpretations of significance and non-significance here; the interpretations of what we called *conservative* NHST, according to which the magnitude only of significant effects can be interpreted (Hopkins and Batterham, 2016), fare little better.



Turning now to the problem of error rates in MBI, we find some agreement and some disagreement with Sainani about the definitions of error. We consider that we made a breakthrough with our definitions, because they focus on trivial and substantial magnitudes rather than the null. As we stated in our Sports Medicine article (Hopkins and Batterham, 2016), a valid head-tohead comparison of NHST and MBI requires definitions of Type-I (false-positive) and Type-II (false-negative) error rates that can be applied to both approaches. In the traditional definition of a Type-I error, a truly null effect turns out to be statistically significant. Sample-size estimation in NHST is all about getting significance for substantial effects, so we argued that a Type-I error must also occur when any truly trivial effect is declared significant. It was then a logical step to declare a Type-I error in any system of

inference when a truly trivial effect is declared *substantial*. Sainani appears to have accepted this definition. However, she seems unable to accept our definition of a Type-II error. In our definition, a Type-II error occurs when a true substantial effect is declared either trivial or substantial of opposite sign. It's a false-negative error, in the sense that you have failed to infer the effect's true substantial magnitude and sign. This definition makes good sense, especially when you consider a figure showing error rates on the Y axis and true effects on the X axis (Figure 3).

In her opening statement on definitions of error, Sainani states that "Hopkins and Batterham are confused about what to call cases in which there is a true non-trivial effect, but an inference is made in the wrong direction (i.e., inferring that a beneficial effect is harmful or that a harmful

effect is beneficial). In the text, they switch between calling these Type I and Type II errors." Yes, we may have caused confusion with the following statement: "...implementation of a harmful effect represents a more serious error than failure to implement a beneficial effect. Although these two kinds of error are both falsenegative type II errors, they are analogous to the statistical type I and II errors of NHST, so they are denoted as clinical type I and type II errors, respectively." They are denoted as clinical Type-I and Type-II errors in the spreadsheet for sample-size estimation at the Sportscience site, but they are correctly identified as Type-II errors in our figure defining the errors, in the text earlier in the article, and in the figures summarizing error rates. Sainani goes on to state that "in their calculations, they treat them both as Type II errors (Table 1a). But they can't both be Type II errors at the same time." We do not understand this assertion, or her justification of it involving one-tailed tests (but see the technical notes). She concludes with "inferring that a beneficial effect is harmful is a Type II error," with which we agree, "whereas inferring that a harmful effect is beneficial is a Type I error," with which we disagree. When a true harmful effect is inferred not to be harmful, it is a Type-II error. Sainani also notes that a true substantial effect inferred to be substantial of opposite sign can be called a Type-III error, but we see no need for this additional complication. That said, we do see the need to control the error rate when truly harmful effects are inferred to be potentially beneficial.

Figure 3. Inferential error rates with five methods of inference for sample sizes of 10+10, 50+50 and 144+144. The top panel is reproduced from Hopkins and Batterham (2016); the bottom panel shows the Type-I region enlarged (and with Type-II error rates shown as solitary symbols for standardized effects of  $\pm 0.20$ ). The dashed horizontal lines indicate an error rate of 5%.



Our rebuttal of Sainani's assertions about error rates might not satisfy fundamentalist adherents of NHST. Figure 3 shows our original figure from the Sports Medicine article and an enlargement of the Type-I rates. We did not misrepresent these rates in the text, but arguably we presented them in a manner that favored MBI: "For null and positive trivial values, the type I rates for clinical MBI exceeded those for NHST for a sample size of 50+50 (~15–70 % versus ~5–40 %), while for the largest sample size, the type I rates for clinical MBI (~2–75 %) were intermediate between those of conservative NHST (~0.5–50 %) and conventional NHST (5–80 %)." These error rates are consistent with those presented by Sainani, but the changes of scale for the different true-effect magnitudes in her figure gives an unfavorable impression of the MBI rates.

We gave an honest account of the higher Type-I error rates with odds-ratio MBI, which Sainani did not address. Our justification for keeping this version of MBI in the statistical toolbox along with clinical MBI seems reasonable. From the Sports Medicine article: "The Type-I rates for clinical MBI were substantially higher than those for NHST for null and positive true values with a sample size of 50+50. The probabilistic inferences for the majority of these errors were only possibly beneficial, so a clinician would make the decision to use a treatment based on the effect, knowing that there was not a high probability of benefit. Type-I error rates for odds-ratio MBI were the largest of all the inferential methods for null and positive trivial effects, but for the most part these rates were due to outcomes where the chance of benefit was rated unlikely or very unlikely, but the risk of harm was so much lower that the odds ratio was >66. Inspection of the confidence intervals for such effects would leave the clinician with little expectation of benefit if the effect were implemented, so the high Type-I error rates should not be regarded as a failing of this approach."

In her discussion, Sainani asserts: "Whereas standard hypothesis testing has predictable Type I error rates, MBI has Type I error rates that vary greatly depending on the sample size and choice of thresholds for harm/benefit. This is problematic because unless researchers calculate and report the Type I error for every application, this will always be hidden to readers." But the "welldefined" Type-I rate for NHST is only for the null; for trivial true effects it also varies widely with sample size and choice of magnitude thresholds, and this variation is also hidden from readers. The fact that the Type-I error rate for MBI peaks at the optimum sample size (the minimum sample size for practically all outcomes to be clear) is no cause for concern, because sample-size estimation in MBI is based on controlling the Type-II rates. She goes on with this particularly galling assertion: "Furthermore, the dependence on the thresholds for harm/benefit makes it easy to game the system. A researcher

could tweak these values until they get an inference they like." This is a fatuous charge to level against MBI. Any system of inference is open to abuse, if researchers are so minded. A researcher who assesses the importance of a statistically significant or non-significant outcome can choose the value of the smallest important effect at that stage to suit the outcome obtained with the sample. Researchers also game the NHST system by providing a justification for sample size based on moderate effects. Sainani presumably has the same concerns about full (subjective) Bayesians gaming not only the smallest important effect but also the prior to get the most pleasing or publishable outcome.

Sainani's only remaining substantial concern about our definition of error rates is not so easily dismissed. MBI provides a new category of inferential outcome: unclear, which is synonymous with unacceptably uncertain, inadequately precise, or perhaps most importantly, indecisive. In our definition of Type-I and Type-II errors, you can't make an error until you make a decision about the magnitude. The spreadsheets at the Sportscience site (sportsci.org) state: "unclear; get more data." Hence we do not include unclear as a Type-II error when the true effect is substantial, or indeed as a Type-I error when the true effect is trivial, a point that Sainani did not make. We applied this definition even-handedly to what we call conservative NHST, where researchers do not make a decision about an effect unless it is statistically significant. A major outcome of our study of the various kinds of inference is that the rates of decisive (and therefore publishable) effects for small sample sizes with MBI are surpassed only by those with conventional NHST, which is 100% decisive but pays for it with huge Type-II error rates. The other major outcome is the trivial publication bias with MBI, whereas the bias is substantial with NHST in both its forms. If the error rates with MBI are as high as Sainani asserts, they obviously do not have implications for publication bias. We have no hesitation about keeping indecisive outcomes out of the rates of making wrong decisions, but if writing off MBI is on your agenda, you will continue to assert that unclear outcomes are inferential errors.

Sainani concludes her critique with the following solution to fix what she regards as the MBI Type-I error problem: "...a one-sided null hypothesis test for benefit–interpreted alongside the corresponding confidence interval–would achieve most of the objectives of clinical MBI while properly controlling Type I error." We disagree. First, we do not wish to conduct "tests" of any kind; we embrace uncertainty and prefer estimation to "testimation", to borrow from Ziliak and McCloskey (2008). Secondly, the p value from her proposed one-sided test against the non-zero null given by the minimum clinically important difference is precisely equivalent to 1 minus the probability of benefit from MBI. If the one-sided test is conducted at a conventional 5% alpha level, the implication is that Sainani requires >95% chance of benefit to declare a treatment effective-equivalent to our very likely threshold. Elsewhere in her article, however, she suggests that "...clinical MBI should revert to a one-sided null hypothesis test with a significance level of 0.005." This test implies a requirement for a minimum probability of benefit of 0.995equivalent to our most likely or almost certainly threshold. We regard both of these thresholdsand one-sided tests at 2.5% alpha favored in regulatory settings-as too conservative, particularly as clinicians and practitioners we have worked with over many years tell us that a 75% chance of benefit-or odds of 3:1 in favor of an intervention-is a cognitive tipping point for decisionmaking in the absence of substantial risk of harm. We also acknowledge that caution is warranted in making definitive inferences or decisions on the basis of a single study, but this is perhaps less of a problem, if the single study is a large definitive trial with a resulting precise estimate of treatment effect (Glasziou et al., 2010).

Before we leave the issue of error rates, it is important to note that the theoretical basis of NHST is now held to be untrustworthy by some highly cited establishment statisticians. Consider, for example, the following comments of two contributors to the American Statistical Association's policy statement on p values (Wasserstein and Lazar, 2016; see the supplement): "we should advise today's students of statistics that they should avoid statistical significance testing (Ken Rothman)" and "hypothesis testing as a concept is perhaps the root cause of the problem (Roderick Little)." If they are right, it follows that the traditional definitions of Type-I and Type-II errors, both of which are based on the null hypothesis, are themselves unrealistic and untrustworthy. Our definitions deserve more recognition as a possible way forward.

In her criticisms of the theory of MBI, Sainani

claims that the three references we cited in our Sports Medicine article to support the sound theoretical basis of MBI "do not provide such evidence." We will now show that her claim is misleading or incorrect for all three references.

The first reference is Gurrin et al. (2000), from which she quotes correctly: "Although the use of a uniform prior probability distribution provides a neat introduction to the Bayesian process, there are a number of reasons why the uniform prior distribution does not provide the foundation on which to base a bold new theory of statistical analysis!" However, she neglects to point out that later in the same article Gurrin et al. make this statement: "One of the problems with Bayesian analysis is that it is often a non-trivial problem to combine the prior information and the current data to produce the posterior distribution... The congruence between conventional confidence intervals and Bayesian credible intervals generated using a uniform prior distribution does, however, provide a simple way to obtain inferences in Bayesian form which can be implemented using standard software based on the results and output of a conventional statistical analysis... Our approach [effectively MBI] is straightforward to implement, offers the potential to describe the results of conventional analyses in a manner that is more easily understood, and leads naturally to rational decisions [our italics]." Her claim about this reference is therefore misleading and by omission, wrong.

The second reference supporting MBI is Shakespeare et al. (2001). Sainani states that this article "just provides general information on confidence intervals, and does not address anything directly related to MBI." On this point she is also wrong. The method presented by Shakespeare et al. to derive what they refer to as "confidence levels" uses precisely the same methods as MBI to derive the probability of benefit beyond a threshold for the minimum clinically important difference. For example, the authors present the following re-analysis of a previously published study using their method: "The study found a survival benefit of 28% favoring immediate nodal dissection (hazard ratio 0.72, 95% CI 0.49-1.04). There is a... 94% level of confidence [i.e., chance of benefit] that the survival benefit is clinically relevant (improvement in survival of 3% or more). The information contained in confidence levels is clearly far more useful than CIs alone to clinicians in applying results to daily practice [our italics]." This method is very obviously MBI in all but name. Shakespeare et al. also calculated the risk of harm, but it was the risk of harmful *side effects*, not the risk of the opposite of a beneficial outcome.

The third reference that she claims does not provide evidence supporting MBI is our letter to the editor (Batterham and Hopkins, 2015) in response to the article by Welsh and Knight (2015). By her account, this reference "is a short letter in which they point to empirical evidence from a simulation that I believe is a preliminary version of the simulations reported in Sports Science [sic]." But the issue here is the theoretical basis of MBI, which indeed we had argued succinctly in the letter. Hence this claim also is wrong.

Finally, the overarching negative tone of Sainani's critique deserves attention. We counted three occasions in the article where she gives any credit to our achievement with MBI, but each is immediately followed by an assertion that we were misguided or mistaken. She is the one who is misguided or mistaken. It is deeply disappointing and discouraging when someone in her position of influence fails to notice or acknowledge the following *novel* contributions that we have made to the theory and practice of inference: the definitions of inferential error that go beyond the null (nil) hypothesis and statistical significance; sample-size estimation based on controlling these errors, especially the risk of declaring a harmful effect potentially implementable; the higher publishability rates and negligible publication bias with MBI compared with NHST; quantitative ranges for qualitative measures of probability; smallest and other magnitude thresholds for the full range of effect statistics in the sports-medicine and exercise-science disciplines; procedures for estimating and assessing the magnitude of the standard deviation representing individual responses with continuous outcomes and of the moderators explaining them; the need for a distinction between clinical and non-clinical inference; the concept of *clear* effects with the two kinds of inference, and the associated decision rules based on adequate precision or acceptable uncertainty; and easily the most valuable of all, the notion of accounting for the risk of harm-the probability that the true effect represents impairment rather than enhancement of health or performance-with clinically important effects.

in improvements in MBI. The most obvious debatable feature are the rules we have devised for deciding when effects are clear in clinical and non-clinical settings-in other words, the rules for acceptable uncertainty in the two settings. These rules in turn depend on the threshold probabilities that define the terms *most unlikely*, very unlikely, unlikely, possible, likely, very likely and most likely, because it is only with these or similar qualitative terms that researchers, clinicians and practitioners can make informed decisions as stakeholders. The decision must not be left solely with the statisticians. Some will argue that these thresholds are as arbitrary as the p value of 0.05 defining significance. Our rejoinder is that our thresholds are for real-world probabilities based on experience with clinicians and practitioners. They are also similar to, and a little more conservative than, those used by the Intergov-Panel Climate ernmental on Change (Mastrandrea et al., 2010), another group of scientists who are concerned about communicating decisions based on plain-language probabilities of outcomes. Furthermore, our simulations showed that they provide realistic publication rates and negligible publication bias for smallsample research. Anyone wishing to define *clear* more conservatively will inevitably reduce publication rates and increase publication bias.

We have demonstrated that the error rates in MBI are acceptable overall. However, those wishing to use MBI, but who remain concerned with error rates, could present an additional statistic with excellent error control, the secondgeneration p-value (SGPV) (Blume et al., 2018). Briefly, this statistic is based on an interval null hypothesis equivalent to the trivial region in MBI. The SGPV is not a probability; rather it is the proportion of hypotheses supported by the data and model that are trivial. If the SGPV=0, then the data support only clinically meaningful hypotheses. If the SGPV=1, then the data support only trivial hypotheses. Values between 0 and 1 reflect the degree of support for clinically meaningful or trivial hypotheses, with a SGPV of 0.5 indicating that the data are strictly inconclusive.

If the attack on MBI results in journal editors banning the use of MBI in submitted manuscripts, and if the editors do not accept MBI as *reference Bayesian analysis with a dispersed uniform prior*, what is the alternative? We have shown that simple presentation of the confidence interval is effectively MBI, and that hypothesis tests against the smallest important effect are far too conservative. Researchers may therefore have to make the choice between Bayesian analysis with informative priors and a return to p values. We have argued in a comment (Hopkins and Batterham, 2018) that full Bayesian analyses are generally unrealistic and challenging for most researchers, which leaves p values as Hobson's choice for researchers and a stop-gap choice for reviewers and editors. In the same comment, we pointed out the following two unfortunate consequences. First, many small-scale studies with clear outcomes in MBI will no longer be publishable, because the outcomes will not be significant. These effects, which do not suffer from substantial bias, will no longer contribute to meta-analyses, where they would have helped push the overall sample size up to something that gives definitive outcomes. Meta-analyses based on a large number of small studies rather than a few large studies also give better estimates of the modifying effects of study and subject characteristics and thereby better generalizability to more settings. Secondly, it will be harder for research students to get publications, because they will need larger sample sizes to get significance, often impractically large when the subjects are competitive athletes. Their careers will therefore suffer needlessly.

The lack of substantial bias with MBI should not be used as an excuse for performing underpowered studies. In the simulations of controlled trials where the MBI-optimal sample size was 50 in each group, a sample size of 10 in each group resulted in ~55-65% unclear non-clinical effects and ~20-65% unclear clinical effects over the range of true trivial effects (Hopkins and Batterham, 2016). It is unethical to undertake research when the expectation of a decisive outcome for trivial effects is determined by a coin toss, but when an optimal sample size for trivial effects is not possible, should the research should still be performed? Yes, if there is a genuine expectation that the effect will have sufficient magnitude to be clear, or if another cohort of participants can be recruited eventually to make the sample size adequate (although the bias with a group-sequential design in MBI has yet to be investigated). The smaller sample sizes for publishability with MBI reduce the risk of unethically underpowered studies compared with NHST.

In conclusion, MBI represents a trustworthy mechanism for representing the uncertainty in

effects with well-defined qualitative categories of probability. It beggars belief that any journal reviewer or editor could take exception to publication of an effect as being harmful, trivial, beneficial, substantial increase, or substantial decrease prefaced by possibly, likely, very likely, or most likely. Such outcomes, along with unclear, should be welcomed as a sunny spring following a long dark winter of p-value discontent. Instead, MBI has now experienced two onesided negative critiques. The current critique turns largely on the assertion that possibly beneficial outcomes in clinical MBI and unlikely trivial and possibly trivial outcomes in non-clinical MBI have unacceptably high Type-I error rates. We have shown that the error rates are generally lower than those of NHST, and where any are high, they are comparable with those of NHST. By communicating the uncertainty in the magnitude of effects in plain language, by increasing the rates of publishability, and by eliminating the potential for publication bias, MBI has provided a valuable service to the research community. A return to hypothesis testing, p values and statistical significance is unthinkable. MBI should be used.

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### **Technical notes**

Throughout this article, null means nil or zero, rather than Fisher's generic conception of the hypothesis to be nullified (Cohen, 1994). We make this point, because some have argued that, instead of MBI or full Bayesian inference, one could perform a hypothesis test against the minimum important difference, rather than against the nil hypothesis, and present a p value for that test (e.g., Greenland et al., 2016). Sainani may have had this in mind when she wrote: "In addition, a one-sided null hypothesis test for benefitinterpreted alongside the corresponding confidence interval-would achieve most of the objectives of clinical MBI while properly controlling Type I error." Here, by *null* she presumably means the *hypothesis* to be nullified: the smallest important beneficial effect.

Some full Bayesians have previously taken exception to the non-informative or "flat" prior of MBI, by invoking two arguments. First, representing such a prior mathematically is an intractable problem (Barker and Schofield, 2008). We delighted in parodying this argument by calling the flat prior an imaginary Bayesian monster (Hopkins and Batterham, 2010): the argument is easily dismissed simply by making the prior minimally informative, which makes the prior tractable but makes no substantial difference to the posterior. The second argument is that a uniform flat or minimally informative prior must become non-uniform, if the dependent variable is transformed, for example using logarithms or any of the transformations in generalized linear modeling (e.g., Gurrin et al., 2000). Again, this argument is easily dismissed: the flat or minimally informative prior is applied to the transformation of the dependent variable in a model that makes least non-uniformity of the effect and error compared with any other transformations (including non-transformation) and models. What happens to the prior with these other transformations and models is irrelevant.

Interestingly, if we were full Bayesians, we might not be expected to concern ourselves with error control, as some full Bayesians distinguish "beliefs" from estimates of "true" values; for them, frequentist notions such as Type-I errors do not exist (Ventz and Trippa, 2015). A full Bayesian-with the caveat that more than 30 years ago there were already 46,656 kinds (Good, 1982)-might say, for example, that "75% of the credible values exceed the minimum clinically important threshold for benefit", whereas the MBI exponent would claim that "the probability that the true value of the treatment exceeds the threshold for benefit is 75%; that is, the treatment is likely beneficial." In MBI, adopting a least-informative prior and making decisions based on a posterior distribution equivalent to the likelihood arguably requires us to give due consideration to error control, which we have done. The general notion of Bayesian inference with a model chosen to yield inferences with good frequency properties has been described as "Calibrated Bayes" (Little, 2011; Little, 2006). Other attempts at reconciling Bayesian and frequentist paradigms include "Constrained Optimal Bayesian" designs (Ventz and Trippa, 2015). Meanwhile, to make probabilistic statements, Sainani recommends we adopt a full Bayesian analysis, in which there is no apparent

requirement for error control, while lambasting MBI for having higher error rates in some scenarios. Her position once again is inconsistent.

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