Usage practices, cautions, and recommendations

(fr *Clinical Trials Dictionary: Terminology and usage Recommendations*; CL Meinert, 1996))

We use different words to mean the same thing. We vary our verbiage to reduce monotony and add zest and color to what we say or write. We expect variation and are taught to deal with it. A child learns that 10:45, quarter to eleven, 15 minutes to eleven, 15 minutes till eleven, and forty-five minutes after ten are the same. As adults, we understand when a radio announcer tells us that the *Yankees trounced the Red Sox, the Athletics pummelled the Angels, the Indians squeaked by the Tigers, and the Orioles were triumphant over the Twins*, though we would have learned as much if the announcer had used *beat* in place of *trounced*, *pummeled*, *squeaked by*, and *were triumphant over*.

We not only tolerate the variation but in some measure are enriched by it. Imagine Mark Twain or Robert Frost with the staid writing style of a scientist.

As in ordinary discourse, we accept minor variations in the discourse of a researcher without difficulty. We accept that an author is using the same basic trick as the sports announcer when discussing the work of others by referring to *Smith's findings and the*

work of Harrison and coworkers, or by indicating that *Jones found*, *Franklin indicates*, and *Green et al concluded*.

However, our tolerance for variation diminishes as we move up the scale of required precision. Lawyers, responsible for drafting wills or contracts, are more interested in producing documents that will stand up to court challenges than in interesting reading. Variation of language in the discourse of research, even if not "fatal" in the same sense as for legal documents, is, nonetheless, undesirable to the extent that it confuses or obscures. For example, a reader is more likely to be confused than entertained by reference in one place to **baseline examinations**, in another to **screening examinations**, and in still another to **eligibility examinations**, when the three terms all refer to the same examinations. The emphasis should be on uniformity and precision, even if to the disadvantage of style and prose.

No self-respecting researcher sets about producing documents that are vague or confusing, although much of what we write is vague and confusing. Why? In part, because of haste and failure to refine, reiterate, and edit, ad nauseam, and in part because the language for a single project, even if carried out over a relatively short period of time, evolves — changes that may go unnoticed in the same way that most other gradual changes escape our notice. Most of the research efforts involving trials, even if followup is of short duration, measured in days or weeks, will extend over a period of months, if not years. Hence, thought must be given at the outset to terminology. Conventions should be established and maintained over the life of the project. The careful worker will establish a glossary of accepted terms and their definitions, including lists of accepted synonyms when applicable, and maintain and update it over the course of the activity.

Recommended and preferred usages

Terms in the table below are classified as follows:

R	Recommended
NR	Not recommended
P	Preferred
NP	Not preferred
A	Avoid
CC	Caution, may be confusing or contradictory in some settings
CR	Caution, may be redundant or unnecessary
CP	Caution, presumptive
CW	Caution, weasel term

Preferred is a weaker categorization than *Recommended* and is used when there are reasons for the preference but when they are not convincing enough to warrant a

Recommended categorization. Most of the categorizations are supported in usage notes for listed terms or their complements (see index heading *usage note* for list). The categorization *Avoid* is used for terms with contradictory definitions or having high potential for confusion in other regards. Terms in the category *Caution, redundant* are likely to be redundant or unnecessary in most usages. The categorization *Caution, presumptive* is used for terms usually implying underlying facts, conditions, or assumptions. Those facts, conditions, or assumptions should be made explicit if terms in this class are used. The category *Caution, weasel* is used for terms used primarily for qualification or **weaseling** (see **weasel term**, page 540, for note).

Word or term	**Category**	**Comment**
allocation (defn 2)	NP	Use **assignment**, see **assignment** for usage note (pg 25)
allocation ratio	NP	Use **assignment ratio**
analysis by intention to treat	NP	Use **analysis by treatment assignment**
assignment	R	
arm (defn 2)	NP	Use **group**
average	NP	Use **mean**
baseline	CC	
bi- (meaning twice)	A	Use twice or **semi-**
biannual	A	Dual meaning; twice a year or once every other year
bias	CP	
bimonthly	A	Dual meaning; twice monthly or once every other month
biweekly	A	Dual meaning; twice weekly or once every other week
blind, blinded	NP	Use **mask** or **masked**
careful	CR	See **careful** for usage note (pg 55)
case-comparison study	NP	Use **case-control study**
case-compeer study	NP	Use **case-control study**
case-history study	A	Contradictory meanings
case-referent study	NP	Use **case-control study**
co- (prefix)	CC	co-principal investigator; contradictory meanings in certain usages; see **co-** for usage note
co-principal	CC	See usage note for **co-** and **co-principal**
co-principal investigator	A	Dual meaning; see usage note for **co-** and **co-principal**

Word or term	Category	Comment
collaborative	CR	collaborative trial; not a suitable synonym for multicenter
compeer	NR	case-compeer study; use **case-control study**
confounded	CP	See usage note for **confounded** (pg 96)
cooperative	CR	Not a suitable synonym for multicenter
double-blind, double-blinded	NP	Use **double-mask** or **double-masked**
double-mask, double-masked	P	
drop-in	A	Subject to confusion
early stopping	CP	See usage note for **early** *adj*
endpoint	NR; CC	See usage note for **endpoint**
experimental trial	CR	See usage note **experimental trial** (pg 173)
fraud	CP	See usage note (pg 193)
gold standard	CP	See usage note (pg 202)
informed consent	CP	Use **consent**; see usage note for **informed consent** (pg 235)
intention to treat	CP	Use more informative terminology such as analysis by original treatment assignment; see usage note (pg 239)
intervention	NP	Use treatment; see pg xx
mask, masked	P	
meta-analysis	R	
monthly	CC	See usage note for **month** (pg 292) and **time measure** (pg 495)
multicenter	R	See usage note for **multicenter** (pg 295)
open	CW	Not informative when used as an adjective in relation to trial (eg, open trial) or treatment administration (eg, open label); see usage note for **open** (pg 329)
open label	A	Uninformative and subject to confusion with **open trial**; use **unmasked**
open label trial	NR	Use **unmasked trial**
open trial	A	Subject to confusion; avoid; see usage note for **open trial** (pg 331)
optimum	CP	See usage note for **optimum** (pg 332)
oral consent	R	Use in conjunction with consents obtained without benefit of a written statement; not a synonym for **verbal consent**
outcome	P	See usage note for **endpoint** *n* (pg 160)
overmatch	CW; CP	See usage note for **overmatch** (pg 336)

Word or term	Category	Comment
overrepresent	CP	See usage note for **underrepresent** (pg 522)
overstudy	CP	See usage note for **understudy** (pg 522)
overview analysis	A	Synonym for **meta-analysis**; avoid, use **meta-analysis**
population-based trial	A	See usage note (pg 366)
pre- (prefix)	CC	Use sparingly and with caution; see usage note for **pre-** (pg 371)
preclinical	CC	Meaning dependent on context; use with caution; see usage note (pg 372)
principal investigator	NP	Often not a useful designation, especially in multicenter settings; see usage note for **principal investigator** (pg 379); use only as an administrative label
randomness	CP	See usage note (pg 405)
run-in	NP	Use **lead-in**
semi- (prefix)	P	semiannual, semimonthly, semiweekly; preferred to **bi-**; see usage notes for **semi-** (pg 446) and **bi-** (pg 43)
side effect	CP	See usage notes for **side effect** (pg 451) and **drug reaction** (pg 149)
single-blind, single-blinded	NP	See usage note for **mask**, **masked** *adj* (pg 277)
single-mask, single-masked	P	See **mask**, **masked**
subject	NP	See usage note for **subject** (pg 478) for reasons to avoid or limit use
toxic drug reaction	CP	See usage note for **drug reaction** (pg 149)
toxic side effect	CP	See usage notes for **side effect** (pg 451) and **drug reaction** (pg 149)
treatment	P	Preferred label for the experimental variable in a trial; see usage notes for **treatment** (pg 500) and for **intervention** (pg 245)
treatment arm	NP	Use treatment group or regimen; see usage note for **treatment arm** (pg 501)
treatment failure	CP	See usage note for **treatment failure** (pg 507)
triple-blind, triple-blinded	NP	See defn for **blind** and usage note for **mask**, **masked** *adj* (pg 277)
triple-mask, triple-masked	P	See usage note for **mask**, **masked** *adj* (pg 277)
trohoc study	NR	Jocular; avoid
undermatch	CW; CP	See usage note for **overmatch** (pg 336)
underrepresent	CP	See usage note for **underrepresent** (pg 522)

Word or term	Category	Comment
understudy	CP	See usage note for **understudy** (pg 522)
verbal consent	NP	Use **oral consent** or **written consent**
withdrawal	CP	See usage note for **withdrawal** (pg 542)

Comparative and relative terms

Clinical trials, by definition, are comparative and concerned with ascertaining relative truth. As a consequence, the language of trials is laden with the language of relativity and comparison.

Comparative terms such as *large*, *early*, or *long* have meaning only in relation to explicitly defined or implied standards. The tendencies in everyday discourse to use such terms as if they have intrinsic meanings of their own is not acceptable in discourse when those terms are used or intended to have an explicit meaning. The careful user in such settings will take care to be explicit as to the meaning of comparative terms used in relation to some method, process, or result in which meanings are important.

Words such as *more* or *less* are in and of themselves comparative terms. They should not be used in relation to states or conditions not amenable to such quantification. For example, one is either pregnant or not pregnant there are no other states. Similarly, it is pointless to think of or characterize one position or stand as *more* ethical than another. If one is ethical, there is no way to be *more* ethical.

For the most part, the language of comparison is symmetrical and should be thought of and used in that way. Hence, one should not use *early*, as in *early stopping*, unless there is a notion of what it means to stop on time or to be *late* in stopping. Similarly, the notion of *big* or *bigger* should have counterparts related to *small* or *smaller*, and the notion of *easy* has meaning only in contrast with *difficult* or *hard*.

Our everyday usage abounds in the use of relative terms as absolutes. To be convinced one need only count the number of times one is expected to make a decision or choice without the information needed for doing so. For example, at the fast food lunch counter, one is expected to answer the question: *Small, medium, or large?* without any idea of the sizes involved. Merchants are adept at wooing us into their stores by notice of *sale* or *discount* or by announcing *Everything 30% off*. We rush to spend to "save".

Often the norm or standard for comparison is implicit, as in *tall* or *short, fat* or *thin*, and *early* or *late*. We usually know what is meant when somebody tells us that *Johnny*

is tall, Darlene is fat, or *Henry is late*. The standard implied for Johnny is the average height of other boys about the same age and general heritage as Johnny.

Our everyday language is laced with terms indicative of change, such as *more* or *less, up* or *down, high* or *low*, and *better* or *worse*. To make an assessment of change, one has to have observations of the condition or variable of interest at two or more points in time. Ordinarily, one is careful to indicate the point of comparison, eg, *We are better off financially now than we were a year ago*. Exceptions arise when the previous time point is implied, eg, *the patient is worse today*, or where there is a desire or value to being vague as to the actual point of comparison, eg, advertising claims such as *better than ever, new and improved, save more than ever*, or *Now, more than ever* (NBC television voiceover boast following their evening news show).

Change measures are the result of differencing operations and, hence, are signed. The direction of the comparison must be made explicit for proper interpretation of the measure. Typically, changes are measured relative to baseline or relative to a specified study treatment (usually a control treatment) in the case of trials. Changes relative to baseline are presented as a signed difference (eg, *the mean weight loss after 6 months of treatment was + 8.9 lbs*) or with sufficient information to allow the reader to do the differencing (eg, *the mean body weight was 156.5 lbs at baseline and 147.6 lbs after 6 months of treatment*). Changes relative to a specified treatment are presented in similar fashion (eg, *the 6 month mortality rates were 17.6% and 22.8%, for the test and control treatment groups, respectively*, or *the test-control difference in mortality was - 5.2%*).

Some changes will involve changes of changes (eg, *laser treatment produced a net intraocular pressure (IOP) drop of 3.1 mmHg relative to baseline and the control treatment as measured at the 6-month followup visit*). Net changes (defn 2) are differences of differences. The value, in the example, 3.1 mmHg, is in fact the result of two different differencing operations. The first one involves deriving the net IOP change for the two treatment groups being compared, done by subtracting the 6-month value for a patient from the patient's baseline value and deriving the mean of those differences for the eyes represented in the two treatment groups. The value for the laser-treated eyes is then subtracted from the corresponding value for control-treated eyes to yield the net laser treatment effect, (16.5 - 22.1) - (19.4 - 21.9) = - 5.6 - (- 2.5) = - 3.1.

The potential for confusion is great in all differencing operations. Confusion as to the way in which the differences were obtained, when they are large, has the potential of causing readers to indicate the wrong treatment. Hence, signed differences, such as the + 8.9 or - 3.1 in the paragraphs above should be accompanied by sufficient detail (via example or definitional verbiage) to minimize the chance of readers being confused about meaning of the sign in relation to the treatment favored or disfavored.

Redundancies, repetitions, and unnecessary words

The habit of repeating what we say for emphasis or "clarity" carries into what we write. In case of doubt, delete every other sentence in a prized draft. Most of the message survives with half the words. Early drafts of most things are long and wordy because of repetition and poor organization. The amount of redundant and repetitious material provided may go unnoticed until one is faced with the need to shorten or edit by edict of editors. It is sobering, at such times, to note the number of awkward or wordy parses or sentences that can be "fixed" simply by deleting them. Usually the editor's requirement to cut the length, sometimes by as much as 50%, though painful, results in a better, more informative paper.

Our spoken language, by the same token, is wordy, repetitious, and redundant. We repeat because we seemingly abhor silence and because we want to make certain we are "getting through". We use throwaway declaratives such as, *you know* in place of pauses, and we ask for reassurance in the form of questions such as *OK*? or *Understand*? — questions we ask repeatedly and usually without even pausing for an answer. Though our written word is devoid of such annoying fillers, it is certainly not free of redundancies and needless repetition.

The emphasis in scientific writing should be on conciseness and on word economy. Saying the same thing with different words in different places in the manuscript can cause a careful reader to assume that difference in language is purposeful and intended to convey difference. Consider the following sentences, intended by the writer to be equivalent: *Baseline information was collected at baseline visits* and *Entry data were collected during screening examinations*. The only way they will be recognized as being equivalent is if the reader is clever enough to equate *baseline information* and *entry data* and *baseline visits* and *screening examinations*.

Ralph Waldo Emerson reminds us that *A foolish consistency is the hobgoblin of little minds*, and indeed it may be so. However, the consistency of nomenclature and terminology within a manuscript and across related manuscripts is neither foolish nor is it likely to be the product of small minds.

Redundant words or phases should be avoided, if for no other reason than for word economy. Some words are unnecessary simply because they are obvious or implied in the context of usage, eg, *human* in *human subject*, *prospective* in *prospective followup*, and often *clinical* in *clinical trial*. Other examples are *primary* in *primary purpose* and *overall* in *overall aim*.

Other words, though technically unnecessary, are nonetheless required, for example, *female* in *pregnant female*.

Most adverbs (*ly* words) are unnecessary. Many can be deleted simply because they are implied in the context of usage, for example, *carefully* in *carefully measure*. One assumes care on the part of the researcher hence, there is nothing to be gained by its use in this context. If the writer believes it is important for the reader to know how something was done then details should be provided and the writer should leave the characterization to the reader. Other examples include *extremely* as in *extremely high* (use *high*), *highly* as in *highly important* (use *important*) or as in *highly significant* (use *significant* and state the p-value), *really* as in *really low* (use *low*), or *actually* as in *actually determined* (use *determined*).

Words expressing desire, such as *want* or *like*, are also unnecessary. For example, rather than writing *we want to point out* write *we point out*. Similarly, rather than writing *we would like to thank*, write *we thank*. As a reader one is more interested in what authors do than in what they would like to or want to do.

Many of the words or phrases of transition, deduction, conclusion, or exception, such as *however*, *generally*, *moreover*, *therefore*, *in general*, *in summary*, or *nonetheless*, can be eliminated from the finished written product. Use should be limited to places where they are needed to warn of breaks in flow, of exceptions to what is being said, or of a conclusion or deduction. Avoid redundant usage, as in *therefore, we conclude ...* (use *therefore* or *conclude*) or as in *In general, usually ...* (*usually* serves the same function as *in general*; use *usually* — one word and fewer letters than for *in general*).

Various other excesses are:

actively reinforce (use *reinforce*)
careful monitoring (use *monitoring*)
careful review (use *review*, one assumes all reviews are carefully done)
comprehensive system (use *system*; let the reader judge as to comprehensiveness)
effective solution (use *solution*, all solutions are effective in the literal sense of that term)
formal system (use *system*, one assumes a system has structure and hence is formal in that sense)
further clarification (use *clarification*, let the reader decide if it is “further”)
overcomplier (jargon; avoid; it is not possible to “*overcomply*”)
planned schedule (use *schedule*, the term implies *planned*)
quite good (jargon; avoid; describe and let the reader judge as to “goodness”)
regularly review (use *review* and indicate the schedule of review)
strict method (use *method* and let the reader decide if it is “strict”)

Not saying what we mean

Often we do not mean what we say or ask. The practice arises from our desire not to offend and from carelessness in the way we talk and write. Often the questions we are asked are not to be interpreted as questions at all, such as the *May I help you*? question of a building sentry (usually better interpreted as *Halt, who goes there*? or *What do you want*?). The proper answer to *May I bother you for the time*? is *yes* (assuming one is willing to be bothered) or *no*.

As a literalist, I find that there is a certain mischievous satisfaction in answering the question asked rather than the one intended. My usual answer to sentries at my institution is *Yes* to *Do you have an ID*? Depending on the sentry, I am from two to a half dozen strides beyond the sentry post before I am actually asked to produce my ID. On the phone, the proper response to *May I ask who is calling*? is *yes* (or *no*) and wait in silence for the proper question such as *Who may I say is calling*?, a less polite *Who is calling*?, or a curt *Who is this*?

One need merely read such childhood favorites as *Amelia Bedelia* to appreciate that what we say is not what we mean, especially when it comes to instruction. The adage *when everything else fails read the instructions* is as much a reflection of the usefulness of most instructions as of our own impatience in dealing with them. Surely any parent who has had to assemble a child's toy can attest to the "usefulness" of written instruction. Often, it is after one has managed to assemble the toy, largely by trial and error, that one manages to understand the instructions — an understanding most assuredly not enhanced by the desire of manufacturers to make one set of instructions work for 17 versions of the toy and by the fact that your version is "new and improved" and is not mentioned in the instructions.

Amelia Bedelia's only "failing" was that she followed Mrs. Rogers' instructions to a T. So when she was told to dust the furniture she did — with powder — and when she was told to change the towels in the bathroom she did — by cutting them in half. The problem was in the instruction not with Amelia. Nevertheless, it was Amelia who suffered the embarrassment of "her" mistakes, not Mrs. Rogers for hers.

One need merely read the instructions in the manuals we write to discover that we are not necessarily any better at instructing than Mrs. Rogers. Similarly, we have the same potential as the sentry or the person on the other end of the phone for asking the wrong question when it comes to designing our data collection forms. It is certain that our instructions and data forms will be vague, confusing, and even misleading unless they are written and rewritten and tested and retested before being put to use.

Humanizing the inanimate

We learn as children to attribute human qualities to inanimate objects. Children's stories such as the *Little Engine That Could*, and TV shows such as *Sesame Street* are filled with objects that have human qualities. As children we are thrilled by fantasies of dancing sugarplums, steam engines with personalities, and scarecrows that come alive. As adults we come to realize that there are no talking scarecrows or engines that can, while at the same time offering encouragement to Betsy, the family car, as she struggles up a hill or cursing our computer for being so obstinate. We speak of Mother Nature, Father Time, Old Man River, winds that are calm or restless, stock markets that react, and economies that recover.

Some of the attributions are useful. It is more efficient (and colorful) to say that the *wind is calm* than to say that the *wind velocity is 0* or that the *computer tells us* instead of *our analysis indicates*.

We are likely to write that *the trial found*, *the study concluded*, and *the results tell us*. It is people who find, conclude, and tell us, not trials, studies, and results. Those processes are distinctly human and should not be attributed to the object of interest in what we write.

Pre- and post- words

The prefixes *pre-* and *post-* are used as modifiers to denote order or sequence in relation to some event or action, eg, pre- or post-war. Of the two, *pre-* is the more common and more objectionable. There is no doubt that if the Big Dictionary Writer in the Sky suddenly banned all *pre-* words a few would be missed, such as *preview* and *preamble*, but overall there would be more celebrations than wakes. Would anyone miss those vacuous congratulatory salutations of letters from credit card companies notifying us that our applications — applications never made or desired — have been *pre-approved*? Would anyone be upset if the airlines simply offered early boarding instead of the opportunity to *preboard*? Would we care if cooks suddenly stopped *pre-heating* their ovens and were content to simply heat them?

The creation of a *pre-* or *post-* word by affixing the prefix to a verb creates some of the most objectionable uses, for example, *preboarding* a plane or a *prerecorded* show. How is it possible? What is the state of being *preboarded*? Does it involve being beamed aboard in the "Star Trek" sense? Or does it involve boarding the plane on the tarmac before it has arrived at the gate? Similarly, what are we to make of the claim *prerecorded before a live audience*? How does a TV network manage to do that? Does it mean they recorded the show before the audience arrived? Does it mean that they did the recording before the audience died?

The best practice is to avoid all *pre-* and *post-* words, except those found in ordinary desk dictionaries. Use beyond the ordinary should be limited to instances in which such terms are used as forms of shorthand expressions for more complicated phrases, if at all. The finished written product should be scanned for jargonistic usages, undefined uses, and usages in which the terms can be avoided by use of other words or modifying phrases. In fact, most uses can be avoided with *before* or *after* as in *before randomization*, *after randomization*, *before screening*, *after screening* (instead of *pre-randomization*, *post-randomization*, *pre-screening*, and *post-screening*).

Small troublesome words

Prepositions such as *by*, *for*, *from*, *on*, *to*, and *through* are often used in relation to measurements or time designations. Hence, we may read that all patients were seen ***by*** *the middle of the year*, *measurements cover a range of values* ***from*** *42* ***to*** *89*, *all patients are to be seen* ***on*** *the 1st of the month*, *the last interval includes values* ***through*** *423*, or *patients were instructed to take their medication* ***for*** *a period of 10 days*. All of the words have varied usages, as is readily seen by the number of definitions and the length of the entries for those terms in any standard desk dictionary.

By in relation to time means up to, up to and beyond, close to, past, in the period of, not later than. *On* in the same context means occurrence at a given time or at an exact moment in time. Hence, the two words have different connotations and are not interchangeable, though they are often used as if they are. Perhaps the best example of such presumed interchangeability is in the 1990 National Census. Instructions on the outside of the packet mailed to every household in the United States prior to April 1, 1990 were to *complete your form and return it by April 1, 1990*; but the first item on the form asked the recipient to *list on the numbered lines below the names of each person living here on Sunday, April 1*. Clearly, no one at the Census Bureau had any concern regarding the logical inconsistency involved in expecting recipients to complete and return the form *by* April 1 while at the same time asking them to report the number of people living in the household *on* April 1. Clearly, as a literalist, I had to either guess as to my whereabouts on April 1 and comply with the instruction on the outside of the packet or ignore the instruction and wait until or after April 1 to fill out the form. For all we know, some of the undercounting was due to literalists being driven to inaction by contradictory instruction.

On in relation to time should refer to a point in time and *for* to an interval of time. *On* is sometimes confused with *for* and used instead of *for*. For example, baseball announcers, for reasons that remain a mystery to me, invariably speak of batting average *on* the year, eg, *Cal Ripkin is batting 287 on the year*. Why not *for the year*?

To means reaching or extending as far as, reaching or extending to some point or limit. *Through* means from the beginning to the end, in or during an entire period or

interval, to and including. *For* is a function word for indicating amount, extent, or duration. *To*, in relation to a time point or continuous measure, may include the point indicated or may be inclusive of all points or measures up to but not including that point. Hence, its use leaves room for confusion. For example, does the statement *applications accepted up to January 15* mean the 14th is the last day they will be taken or will they be accepted through the 15th? The situation is not helped much by using *by* in place of *to*. A reasonable operational rule is to assume, unless one is told or otherwise indicated, that the use of *to* excludes the point of reference, and, hence, in the example above, plan on being done with the application by the 14th. The IRS avoids use of *by* or *on* with an instruction telling us that our tax returns must be filed *not later than April 15*. Does it mean we must file before April 15 or do we have until the midnight separating April 15th and 16th? Even a casual observer of activities on April 15 learns the answer. We should avoid such confusions by being explicit about whether the designated time point is included or excluded from permissible time points, eg, by indicating that *applications will be accepted through January 15th* or that *applications will be accepted up to and including January 15th* and that we have *through April 15* to file our tax return.

From is used as a function word to indicate a starting point, eg, ***from** this day forward* or ***from** January 16th on*. The term is subject to ambiguities when used as a reference point, eg, *people having weights from 150 lbs and greater*. The reader is in doubt about whether the statement is intended to include or exclude the value of 150. The problem is avoided by writing *people with a weight of 150 or greater*.

The language of praise, implied value judgment, and presumption

We have a variety of words and terms for expressing or intimating praise or value judgment. They are useful in everyday discourse but have a limited role in the discourse of science, where emphasis is on fact rather than on praise or value. The responsibility of the writer is to convey the necessary information to enable readers to reach their own conclusions. It is pointless, if not bad form, to coach readers as to the values they should adopt, except on editorial pages of journals or perhaps on the discussion pages of a manuscript.

A dispassionate writer avoids use of qualitative labels or characterizations such as *good*, *careful*, *accurate*, or *precise* in relation to his or her methods or procedures. They are what they are and laudatory characterizations do not make them better.

The use of self-laudatory language in relation to one's own work is foolhardy. It is presumptuous, pompous, and short-sighted to label one's own work original, unique, or innovative; likewise, it is a sign of consummate naivete to characterize work still in planning or execution as *definitive*, eg, *we are carrying out a trial to provide a definitive answer to the question*. Typically, *definitive* is a characterization applied in

retrospect by others, years hence. By the same token, one should avoid characterizations such as *modern*, as in *we used modern methods to determine concentrations of the compound*. Modern is in the eye of the beholder, and the mere application of a label does not serve to make a method modern nor does absence of the term imply antiquation. Ditto for *easy* or *simple*.

Implied praise by use of laudatory language in relation to the work of others should be genuine. Avoid it as fluff or as a prelude to a wilting attack or criticism.

The clinical trialist should take pains to avoid implied conclusions or presumptions in the nomenclature used for key measures, variables, or phenomena. One reason for doing so has to do with the need to avoid confusion when doing the trial, for example, as discussed in a usage note for *endpoint* (page 160) as a synonym for *outcome*. Reaching an *endpoint* implies cessation or completion. Its use as a synonym for *outcome* may be justified when the event being referenced is death or some other event that, when it occurs, means the end of treatment or followup, but not in other uses.

Another reason has to do with the need for avoiding implied conclusions, for example, in most usages of *treatment failure* when applied to individual patients, eg, *the patient was considered to be a treatment failure because of the side effects associated with the treatment* or *patients having an MI were considered to be treatment failures* (see usage note for the term, page 507). Both uses imply cause and effect relationships. For the first use to be justified, one should be convinced that the side effects being referenced are unique to the indicated treatment. Even placebos have side effects. The second use implies that the treatment is known to prevent MI — an implication, which in all probability, presupposes more knowledge of the drug and its mode of action than actually exists.

Most uses of *treatment failure* are as implied indictments of a treatment arising because of the "failure" of the treatment to have prevented or delayed some adverse health event or outcome. Study personnel should be taught to use operationally neutral language (eg, event or outcome) in place of the characterization. In addition, they should be taught to avoid use as a collective label for an aggregate of events or outcomes having various explanations (as in a table entitled *Treatment failures by treatment group* with counts of a heterogeneous collection of events or outcomes observed in the different treatment groups). The term is meaningless in settings where used without regard to treatment assignment.

It is meaningless as well in settings where one of the study treatments is a placebo or null treatment. Use in such settings is indicative of a certain sloppiness of language and will likely cause discerning readers mild befuddlement as to ways in which placebo or null treatments could "fail".

The term *drug reaction* carries a cause and effect connotation as well. Similarly, many uses of *side effect* in relation to drugs imply such a relationship. Both terms should be avoided when the relationship is in question, or when they are used in settings where only some of the uses are justified (eg, a placebo-controlled trial where some of the "drug reactions" are due to placebo or in which some of the "reactions" occur in the absence of any drug).

Qualitative labels such as *mild*, *moderate*, or *severe* carry implied judgments that should be made explicit. Except when obvious, the implied rationale behind the labeling should be explained (eg, by indicating the sense in which something is considered to be *mild*, *moderate*, or *severe*).

For the most part, a label such as *toxic drug reaction*, should be avoided because of what it implies. For the use to be justified, one should be convinced that the reaction is in fact due to the drug and that the reaction is serious and life-threatening. Whenever possible the label should be replaced by neutral, more descriptive, and less presumptive language.

Many of the everyday examples of presumptive uses arise from erroneous assumptions (as in assuming that a woman answering the phone at a place of work is a secretary, that the captain of a plane is a man, and that a nurse is a woman). Uses based on presumption should be avoided.

Euphemisms

Our everyday language is filled with euphemisms that shield us from the harsh reality of life. Hence, a person "passes away" rather than dies. A veterinarian "puts a dog to sleep" instead of killing the animal, and the laboratory scientist "sacrifices" his rabbits. We know what these terms mean, so to that extent they are acceptable. Such expressions are troublesome only when used to purposefully obscure, eg, when telling a child that her "mommy has gone away" rather than that she has died.

The medical profession has its own form of euphemism to the extent that some of the most obnoxious procedures or treatments can have innocent sounding names or labels. Hence, as a patient I may not realize what is being proposed when I am told that they want to give me a retro-vulvar injection or that they want to enucleate my eye. The technical jargon of the medical profession has its place in classrooms, textbooks, and manuscripts but not in dialogues with patients and most assuredly not in dialogues carried out as part of a consent process. Investigators have a responsibility to ensure that the consents they obtain are ***informed***. They are not, by definition, if the person being asked to consent does not understand what is being proposed.

Trialists have their own euphemisms to obscure and confuse. As a group, they are more likely to label trials in which the physician or patient chooses the treatment to be administered as **open trials** (defn 1) than as **nonrandomized trials** and to speak of **open label trials** instead of **unmasked trials** when the study treatments are administered in unmasked fashion. The careful writer avoids euphemisms in favor of more informative terminology. Failing that, uses should be in conjunction with sufficient supporting detail to make their meanings clear.

Currency words

A currency word or phrase is one that implies use of an underlying process or procedure, eg, ***validation*** *was carried out by monitors, the study involved* ***documented*** *data collection procedures, patients gave their* ***informed*** *consent*. Words, such as *documented, validated,* or *informed* should not be used without supporting detail to indicate sense of use. Words such as *demonstrate, shown,* or *proven* become currency words when used in declarative statements, eg, *the results demonstrate the cost efficiency of the approach*. The writer should indicate the basis for the conclusion, or delete the claim from the finished manuscript.

Randomize, as in *patients were randomized,* is a currency word and should not be used in simple declarative statements without supporting detail about the process or procedure used to randomize. Failure to provide such supporting details has the potential of leaving readers uncertain about whether the use is in the formal or the lay sense of that term (see usage note for **random**, page 399).

Informed, as in ***informed*** *consent,* is an important currency word in trials. Use of the modifier *informed,* in relation to *consent* as in *patients gave their informed consent to be randomized,* should be limited to cases involving explicit steps or procedures to ensure that the consents were truly informed or where data are presented to indicate the degree to which consents were informed. Without such detail or supporting data, the writer should use *consent* without the modifier (see usage note for **informed consent**, page 235).

The careful writer will avoid unsupported use of currency words. Manuscripts should be read prior to submission to identify them. Those that are not supported by accompanying detail or data should be deleted.

The language of criticism

The language of criticism is negative by definition and for that reason it is usually flavored with suitable praise and accolade. Critics who are sensitive to the feelings of those being criticized will try to deliver their message as gently as possible and with as little personal harm as possible. Hence, we come to be apprehensive of meetings with our bosses that start with perfunctory praise for fear of what is to follow.

We follow the same practice when writing a critique. We start with the positive and proceed to the negative. Hence, we might start with laudatory preambles followed by wilting critiques.

Trials producing "bad news" are more likely to be viewed with suspicion and doubt than those producing "good news". The "bad news" may be in the form of results challenging an accepted treatment or in the form of results running counter to prevailing beliefs. When the medical community at large is presented with such challenges, there is a tendency for its members to question the results and integrity or competence of investigators rather than their treatments or prevailing beliefs.

There is a tendency to regard any study failing to produce the "right" result as being *flawed*. Hence, we have grown accustomed to critics, especially when in front of audiences or on camera, who characterize a controversial result as being the product of a *flawed study*. Such claims, unless supported by detail that justifies use of the characterization, are vacuous and should be viewed as forms of empty rhetoric. A responsible critic does not use the claim without supporting facts and ignores flaws having little or no bearing on the issue at hand.

In our everyday life, we are exposed to a bewildering array of half truths and lies and to an unending chain of denials and claims of innocence or ignorance. Hardly a day passes without hearing or seeing such words or phrases as *categorically deny, absolutely innocent*, or *no knowledge of* in relation to some event or activity. We become increasingly skeptical of all such claims as we age and may eventually, with sufficient age, quietly translate the categorical denial of a politician into tacit admission of guilt.

It is no wonder, therefore, that claims of researchers are greeted with skepticism, not so much because we expect them to have lied, but because we are uncertain of their motivation and their competence. Hence, we may be inclined to accept a criticism of a trial as valid without much thought if it jibes with our biases, and reject it as irrelevant or invalid if it does not.

The form and language of criticism depend on the underlying motivation of the critic. All criticism is in some sense constructive, even if devastating and "destructive".

Hence, an archenemy can provide constructive criticism even if the intent was to discredit or destroy. Similarly, a review undertaken by a person to better understand the limitations of a study and its finding may end up destroying the study by highlighting weaknesses.

We are familiar with language aimed at discrediting and increasing doubt for the purpose of blunting the effect of a result. One need merely watch a few interviews with opponents of a finding to learn the language of this form of criticism. One can anticipate what critics employed by tobacco companies will say of the next study on passive smoking if the results are suggestive of harm. The study design and method of conduct will be characterized as *flawed* and the results will be labeled as *equivocal*, *inconclusive*, or *not definitive*.

Every study is imperfect and, hence, *flawed*. The issue therefore is not whether the study is flawed, but rather whether the flaws detected are so serious as to warrant rejection of the results.

Results are usually *equivocal*, *inconclusive*, or *not definitive* in that they leave room for doubt. Hence, the label can be applied to findings of any study, including those considered to have produced convincing results. These terms should be used sparingly and more as conclusions than as labels. Use should be supported by a detailed recitation of the facts and features of the study leading to the characterization.

The clever critic has a collection of universal criticisms that apply to all settings. One of those, in the case of trials, has to do with the fact that only persons consenting to enrollment can be studied. All randomized trials involve populations that are, by definition, select and not necessarily representative of the general population of interest. Hence, the statement that *the trial involved a highly select study population* is more a statement of fact than a criticism, though it is often used to leave the impression that the selectivity is the result of a bad study design or of improper study practices. It is used to suggest that the results are useless because they cannot be applied to the general population of interest. The critic is either unaware of the difference between **generalizability** and **validity** or is content to confuse the two issues (see pages 200 and 532).

A characteristic shared by both types of critics is in regard to the nature of their conclusion. Both are likely to underscore the need for more research on the issue at hand though their motivations for the statement are different. The statement from the constructive critic arises from a genuine desire for more information on the question at issue, whereas the destructive critic uses it more as a ploy than as an expression of desire for more information. The call is used to suggest that the current results are *equivocal* or *inconclusive* and as a tactic to dissuade groups or bodies from taking

action in relation to the results. Critics with a vested interest in maintaining the status quo can be expected to achieve that end by whatever means possible, including use of the clarion call for more research to provide a "*definitive* answer" to the question or to resolve the issue.

Serious critics avoid grandstanding. They forego the use of cute tricks and clever phrases aimed at creating impressions without supporting substance. They stick to the facts and avoid use of generic claims as if they were unique to the study at hand. They concentrate on the issues that matter and ignore inconsequential "flaws". They avoid the use of value-laden words in favor of describing the features considered to be sources of concern.

The language of exception

Words such as *only*, *unless*, and *otherwise* are difficult to understand when they are used to indicate exception, as in the following from the Code of Federal Regulation for IRBs:

> *Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy* (45 CFR 46, § 46.101; 18 June 1991 revision) (33 words)

Part of the problem is with the exception, *unless otherwise*. The statement is improved slightly by rewriting so the exception follows the rule:

> *Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy, unless otherwise required by Department or Agency heads* (33 words)

Only is a difficult word when used as an indicator of exception. One way to reduce use of the word is by elimination from constructions where it is unnecessary, as in *only once* or *only when*, and by deletion of only in the example above so as to read:

> *Research activities in which the involvement of human subjects will be in one or more of the following categories are exempt from this policy, unless otherwise required by Department or Agency heads* (32 words)

Only, when it precedes the main point, may be indicative of constructions that require more than the simple fix suggested above. For example, the better fix for the example above is to eliminate the clause *involvement of human subjects will be in one or more of the following categories* — a clause made necessary by use *only* in the example. Elimination of the clause would have allowed the drafters to have written:

> *The following categories of research are exempt from this policy, except where otherwise indicated by Department or Agency heads* (19 words)

The elimination would have reduced the word count from 33 to 19 and increased clarity of exposition.

The language of intimidation, implication, and position

We have various tricks to establish positions of superiority and for telegraphing our mental prowess. Hence, statisticians are likely to sprinkle their discourse with telltale signs of their skill or mental prowess by use of words such as *obviously*, *elementary*, *trivial*, *easily*, and *clearly* in relation to their mathematics and proofs. They are used as if the characterizations are useful to the receiver when, more often than not, they serve only to remind receivers of their own limitations, especially when confronted with things labeled as *trivial* or *easily shown* that are obscure and imponderable. Nor is it useful for the sender to "explain" by simply repeating that already stated or written, except to underscore one's own state of dementation.

Some of the signaling of standing and position occurs naturally and is useful in its proper context. For example, it may be appropriate and even useful for the statistician to describe something as *easily shown* when speaking to other statisticians, but not when speaking to members of another profession.

The setting of clinical trials involves people from different disciplines, each with their own peculiar language conventions and terminology. Much of the language of medicine will be foreign to others from different disciplines. The same is true for the language of the statistician as heard by others in the group.

People coming to this setting must be sensitive to the general state of knowledge of others in the group. They must be willing to adapt their language and methods of communication to the setting and must be willing to explain and educate as needed over the course of the trial. The vernacular of "household" terms within a discipline will be confusing and uninformative to others in the group not of that discipline. Members of the majority discipline need to recognize that use of esoteric lingo and jargon has the potential of being perceived by members of minority disciplines in the group as subtle forms of intimidation. The risk of intimidation exists whenever something complicated or esoteric is passed off as elementary or obvious.

Most forms of posturing, positioning, or intimidation via language are subtle and often the product of unconscious behavior. It arises as a natural consequence of the use of discipline-specific language in multidisciplinary settings such as those represented in clinical trials. The physicians, in a collaborating group, may use language and terminology foreign to other collaborators simply as a means of excluding them from the discussion or as a subtle reminder to keep their mouths shut. The statisticians may appear to speak in tongues and may converse without explanation as to how what they are saying relates to issues at hand.

Those in the majority in any setting have special needs to guard against the tyranny of numbers and assumption that it is they who represent the core of the activity. In the setting of trials, the majority of those involved in a multicenter trial will be MDs. Researchers from other specialties, including biostatisticians, will be in a distinct minority.

The language of division

We have various ways of communicating division or separation. When they are personal, we speak of we and they. When they are dispassionate, we have other means.

Taxonomies are based on divisions defined by mutually exclusive classes. Hence, the trialist may speak of randomized and nonrandomized trials and be content that the two classes cover the waterfront and that they are mutually exclusive.

Binary classification involving a seemingly well-defined characteristic, eg, in regard to one's gender, is straightforward. Problems arise when the line of demarcation is ill-defined, eg, with the characterization black or white as a surrogate for "race".

Problems also arise when a division is created with overlapping boundaries. For example, an epidemiologist may find it useful to classify studies as *observational* or *experimental*. The problem with the division is twofold. One has to do with the fact that the complement of *observational* is *nonobservational* and it is difficult to envision studies not involving observation of some sort. A second problem has to do with the fact that all members of the class *experimental study* are also members of the other class, *observational study*, to the extent that the class involves observation.

Problems are compounded when the applied labels also carry implied value judgments. A case in point is in the use of *basic* and *applied* in relation to the categorization of research. *Basic*, as an adjective and as defined in Webster's Ninth New Collegiate Dictionary means *of, relating to, or forming the basis or essence; fundamental; constituting or serving as the basis or starting point*. *Applied* as an adjective and as defined therein means to *put to practical use; especially applying general principles to solve definite problems*. The two terms are not complementary, and it is a mistake to use them as if they are.

That said, the fact is that many of the uses are as if the two terms are complementary. Such uses are unfortunate because, whether so intended or not, they have the potential for being divisive, if for no reason other than that they have the possibility of being viewed by those not in the valued class as degrading or as forms of "putdowns".

Vacuous language **Vacuous language**

In the broad definitional sense, trials are as "basic" to medicine as bench research is to the laboratory sciences. Yet it is invariably those sciences that are designated or regarded as "basic" and those related to clinical medicine as "applied" and thereby labeled as being something less.

The trouble with the categorization is with the notion of basic. The complement of basic, if meant to mean *essential* or *important*, is *nonessential*, *unnecessary*, or *irrelevant*. Hence, the term has unfortunate connotations, especially in settings where it is used to set the work of one profession apart from that of another profession. Use in this way can be demeaning to the work of the profession not qualifying for the label. The characterization may have the effect of suggesting that its work is of less import than that of the profession characterized as basic.

Usurpative language

Societies have a propensity for usurpative usage. For example, *African-American* in the United States has come to be used in place of negro or black in reference to the cultural or racial heritage of peoples with negro ancestry, even though not all peoples of Africa are black. On a broader scale, we use *American* to mean peoples of the United States to the exclusion of all others living in the Americas. From the perspective of geography, a Canadian is as American as "Americans", but neither we nor they (in large measure) refer to peoples of Canada as Americans. They prefer, instead, to be called Canadians and thereby tacitly surrendering the term to us. Colin L. Powell (Chairman of the US Joint Chiefs of Staff in the Bush Administration), in remarks on 19 September 1994 following his return from Haiti, observed that we had only narrowly averted the prospect of *American youngsters killing Haitian youngsters and Haitian youngsters killing American youngsters*. He could just as well have spoken of Americans killing Americans, since Haiti is part of the Americas.

The language of usurpation arises from the use of a general term or label in a specialized circumstance that has the effect of usurping all other interpretations or implying that there are no other interpretations, for example, use of the labels *pro-life* and *pro-choice* as used in the abortion rights struggle. The alternative to *pro-life* is *anti-life* and *anti-choice* for *pro-choice*. The terms are used to paint people into corners by suggesting that a person labeled as *pro-choice* favors abortion on demand and that a person in the other corner opposes all abortions when, in fact, most people are likely to be both pro-life and pro-choice in the broad sense of those terms.

Most everyday forms of usurpation arise from failures to adopt usage patterns learned in one setting to a new and unfamiliar setting. The biggest "culprit" in the setting of clinical trials is likely to be the MD investigators: because they are at the top of the "pecking" order in the medical setting and because of their number. As a rule, the majority of people represented in any trial are MDs.

Clinical trials involve forms of clinical research, and most such research is, by definition, performed by MDs. Hence, the clinical investigator is prone to assuming that all investigators engaged in such activities are members of the medical profession and that the label *doctor* is synonymous with MD. Other members of the group with doctorates in other fields may feel slighted by uses implying that the only people in the setting with such a degree are MDs, eg, *the doctors doing the study recruited and enrolled a total of 400 patients.*

There is also need for care in the use of the label *investigator*. Often in the case of clinical trials, the label is used to imply that investigatorship status is limited to those in the group with an MD degree, eg, *investigators doing the trial saw patients every 3 weeks over the duration of the trial*. Other members of the group, as key to the investigation as those treating patients, may be peeved by the slight.

The designation *principal investigator* has varying interpretations, as discussed in a usage note for that term (page 379). Usages of this term in the multicenter trial are especially troublesome because there are, in effect, multiple principal investigators. If the term is used to denote heads of centers, then it should be used to apply to all heads of centers (not simply to heads of clinics). Usages where the term is reserved for heads of clinics (eg, to the exclusion of heads of resource centers) implies a higher standing for clinician investigators than for other kinds of investigators in the trial.

A form of usurpation arises in the multicenter trial when *center* is used as a synonym for clinic (see usage note for **center**, page 61), eg, *the 11 centers in the trial recruited a total of 842 patients*. People at other centers in the trial not responsible for recruiting patients may resent being written out of the study.

The language of implied subjugation, as in the use of *subject* (see usage note, page 478), though technically not usurpative, also should be avoided. That language is inconsistent with the notion of partnership as required for success in trials. The language of ownership is to be avoided for the same reason, as in *my statistician* or *my programmer*. The statistician or programmer is not likely to be warmed by usages that suggest that he or she is the property of a person or group. The same is true for persons enrolled in trials being referred to as *subjects*.

The language of positivity and negativity

Much of what we say or write is intended to express acceptance or rejection, generality or exception, inclusion or exclusion, presence or absence, permission or prohibition, approval or disapproval, or affirmation or rejection. Terms such as *yes* or *no, present* or *absent, certain* or *uncertain*, or *known* or *unknown* are used for characterizing or stating binary choices or states. The language of exception is

expressed with qualifiers such as *only*, *few*, or *many*. Terms such as *not* or *no* are used for negation or for expressing some negative condition or state.

Binary states or conditions such as those covered with use of terms such as *all* or *none*, *yes* or *no*, or *present* or *absent* can be thought of as positive or negative and to that extent can be viewed as having arithmetic signs. Similarly, one can think of terms of exception or exclusion such as *only* or *closed* as negative, and terms of acceptance or inclusion such as *most* or *open* as positive.

The notion of signing in the mathematical sense is useful when analyzing or interpreting sentences containing several signed terms, and especially when the sentences involve terms of opposite sign or when they involve two or more negative terms. The rules of sign management for arithmetic operations apply to signed language. Crossing a positive with a positive produces a positive product. Crossing a negative with a positive produces a negative product, and crossing a negative with a negative produces a positive by negation of the negatives.

We are inclined to accentuate the positive and for that reason tend to use positive words in tandem, eg, *most certainly*, *absolutely sure*, or *Yes, we are open*. We have no trouble understanding the message conveyed, but it would have been conveyed as well (and with fewer words) by *certainly*, *sure*, or *open*.

Some double positives are crude and grammatically incorrect. For example, we know what is meant when someone tells us that *A is more better than B*, though it would have been less jarring to the ear had we simply been told that *A is better than B*.

Some uses of double positives are downright confusing. For example, what does it mean when Tariq Aziz, Deputy Prime Minister of Iraq, tells the world (Baghdad, Saturday 16 January 1993; prepared statement) that Iraq has complied with "*more than most*" of the UN stipulations? The statement is vacuous in the absence of definitions for *most* and *more*.

Most positive x positive crossings are unnecessary and, hence, are to be avoided. If a state or condition is positive, adding a positive descriptor does not make it "more" positive.

The two other kinds of crossings are more problematic. Of the two, positive x negative (or negative x positive) crossings are less objectionable than negative x negative crossings.

Many of our road signs involve the graphic equivalent of positive x negative crossings. Examples involve the use of recognized positive indicators, eg, P for parking

or a right or left turn arrow to indicate that such turns are allowed, and a negator graphic, usually a diagonal line overlying the positive sign for the opposite message. Typically, it takes the brain a millisecond or two longer to inform the driver that such signs are proscribing the indicated activity as opposed to allowing it.

The arithmetical equivalent of this kind of crossing occurs with signed differences where a negative difference corresponds to something beneficial and a positive value corresponds to something bad, eg, a graphic display where values to the left of the y-axis denote improvement and values to the right of the y-axis denote worsening.

Our written language abounds in examples. Brewster Higley's familiar refrain *where seldom is heard a discouraging word and the skies are not cloudy all day* (Home on the Range, 1904) involves crossing a positive with a negative. The line is confusing because of the use of *not* and *all*. As a result, we remain uncertain as to whether he was telling us that the skies are clear all day or just part of the day. Higley could have avoided the confusion with the refrain *where words are usually encouraging and the skies are clear all day* (assuming that is what is meant by the line). Fortunately for us, Higley's concern was more with the sound and rhythm of words than with precision or efficiency of language.

As in Higley's line, most positive x negative crossings are subject to conflicting interpretations, for example, *No smoking is permitted* (announcements on commercial flights prior to takeoff). Does it mean no smoking or does it mean it is all right not to smoke? (The instruction *Please observe the no smoking sign when illuminated*, is no less obtuse. In a strict literary sense, a puffer could be in compliance with the instruction by fixating on the sign while puffing away.)

The announcement on Metroliners entering Union Station in Washington DC that *All doors will not open* has the same defect. Does it mean that only some of the doors on the right or left will open or that none will open? Imagine the panic of foreigners, unfamiliar with such constructions, if their conclusion is that none will open. Strictly speaking, the announcement applies to all stops, since egress is always from the right or left, depending on the location of the platform.

Other crossings of this form include expressions such as *busy doing nothing*, *driver carries no cash*, *no data were collected*, and *found no difference*. The problem in all these cases arises from crossing an active positive verb with a negator. The crossings lead to logical inconsistencies. How is it possible to be *busy* doing nothing? How does one *carry* nothing? How does one *collect* nothing? And how does one *find* nothing? Many of these apparent inconsistencies can be avoided, or at least made less jarring, by different constructions. For example, instead of *no data were collected*, write *data were not collected*, and instead of *driver carries no cash*, write *driver has no cash*.

Variations on the same theme have to do with the crossing of value terms, eg, *higher weight loss, lower weight gain, higher rate of loss, lower rate of gain,* or *survival as an endpoint*. A careful writer works to avoid such usages by various tricks. An obvious one involves a change in the base of comparison to enable the writer to express the difference in positive terms. For example, instead of *patients assigned to test treatment had a higher rate of weight loss than patients assigned to control treatment*, write *patients assigned to control treatment had a higher rate of weight gain than patients assigned to test treatment.* As noted previously, changes stated in positive terms are easier to understand than are negative changes.

Superfluous crossings can be avoided by expeditious editing. For example, use *none* instead of *none at all* (*none* is sufficient, *at all* is clutter). Similarly, use *not* or *no* instead of *absolutely not* or *positively no* (*not* or *no* is sufficient; *absolutely* and *positively* are unnecessary, except when used, for example, in a parent to child interaction, to distinguish this usage from others where something other than *not* or *no* is implied). Use of positive augmentations of negative terms is bad form in scientific writing in that they are unnecessary and tend to have the same effect on readers as on children when used by a parent — ie, it causes them to wonder whether unaugmented uses mean something less categorical than implied by the augmented terms.

The potential for confusion is greatest with negative x negative crossings. Some of these crossings can be avoided simply by deleting one of the negatives. For example, consider *Nobody can see the Great Oz, not nobody, not no how*. The guard making the pronouncement to Dorothy and her three companions at the entry to the Wizard's castle in the film version of the Wizard of Oz could just as well have proclaimed that *Nobody can see the Great Oz, nobody, no how* or simply *Nobody can see the Great Oz.*

The pronouncement of the guard, even if wordy, is clear. However, that is not usually the case with most double-negatives. For example, does the statement *Nobody doesn't like Sara Lee* mean that everyone likes Sara Lee or that no one likes Sara Lee? We know what the advertiser wants us to believe so why not claim *Everybody likes Sara Lee*? A good point, except that the latter statement is not as catchy as the former and, hence, not as revenue enriching — so much for literary accuracy.

We have been taught from grade school onward to avoid constructions involving double-negatives. Our parents and teachers corrected us when we said, *I don't want no food* or *I don't have no money*. With that kind of training and conditioning, one would expect our writing to be free of such constructions. They are, to be sure, free of vulgar constructions such as the two listed, but not of more subtle and sophisticated versions of the same thing. Many of the double-negatives in the discourse of trials arise from the practice of stating things in the negative as a means of indicating a measure of

uncertainty. Hence, we speak of a patient as *not worse* because we are uncertain about whether the patient is better.

Other forms of the construction arise as a result of a desire to emphasis an unexpected result. Hence, the trialist describing results of a trial involving the use of a chemoprophylactic agent expected to cause weight loss, when presented with data showing no weight change, is more likely to write, *patients did not lose weight* than *patients did not experience a weight change*.

Another reason for such constructions has to do with our innate desire as researchers to maintain a measure of caution and conservatism in the interpretation given to results. Hence, we are usually more comfortable understating than overstating.

One has to be on constant guard for double-negatives with an eye toward elimination whenever possible. One means of elimination is by using complementary language (eg, by speaking of gain rather than loss). Others can be eliminated simply by using a different tack in the way results are presented or discussed. Those that remain should be analyzed to make certain that they are supported by sufficient discussion or detail to make their meaning clear. One way to do so in relation to a statement such as *patients assigned to the test treatment had lower weight losses than patients assigned to the control treatment* is by referring readers to the table or tables providing the basis for the statement or by following the statement with one containing results, eg, *Patients assigned to the test treatment had a mean weight loss of 3.4 pounds compared with a 5.3 pound weight loss for patients assigned to the control treatment*.

Pronouns

The practice in scientific writing is to avoid using the personal pronoun *I* in favor of the collective *we* or using impersonal references to the collective whole, such as *research team*, *research group*, or *investigators*. The practice is reasonable to the extent that most products are the result of collective efforts. However, there are instances where *I* is indicated, eg, in cases where a personal opinion is being expressed or stated. *We* should not be used as a synonym for *I*.

Persons enrolled into trials are broadly referred to as *subjects* or as *research subjects*. That characterization, as indicated in a usage note for the term (see page 478), is not well suited to treatment trials or other trials where enrolled persons stand to benefit from the participation. *Patient* is the preferred term for such trials and for most secondary prevention trials. Some other term such as *participant*, which is free of the connotations of patient, is preferred for primary prevention trials and for other types of trials involving healthy people.

The language of equivocation and weaseling

Every profession has language for equivocation and for weaseling (see weasel term for derivation note, page 540). Some of the language of equivocation is intentionally disguised. Hence, when the geneticist speaks of incomplete penetrance we are likely to believe the term is intended to describe a basic biological process. We are not likely to recognize it as a fudge factor for forcing data to fit an assumed mode of inheritance. Similarly, as patients we will not appreciate the nuances of what we are being told when we are told we have had a silent MI, or understand when the epidemiologist explains findings from a case-control study (or failure to find the obvious) as a result of "overmatching".

Some of the language of equivocation and weaseling is more universal. Virtually every discussion will contain words such as *perhaps*, *maybe*, *possibly*, *likely*, and *potentially*. Our conclusions are likely to be tentative and punctuated with caveats and reminders about the limits of the study and to end with the universal *more research on the subject is needed*.

Equivocation is equivocation, and once a clause is equivocated, adding other words of equivocation does not add to the degree of equivocation. Hence, it is sufficient to write *perhaps the results are due to* instead of *perhaps there is a possibility that the results are due to*. *Perhaps* and *possibly* mean the same thing.

Vacuous language and claims

A vacuous term (page 531) is one devoid of meaning in the context of usage. Everyday examples include the following:

country (as in *country ham*)
fresh (as in *fresh eggs*)
home (as in *home cooking*)
light or lite (as in *light butter, lite beer*)
live (as in *live from New York*)
natural (as in *all natural* or *natural food*)
open (as in *Yes, we are open*; sign on door of gas station with pumps entombed by tumbleweeds)

Examples more germane to research include the following:

careful (as in *careful observation*)
comprehensive (as in *comprehensive system*)
modern (as in *modern technique*)
user friendly (as in *user friendly computer*)

A term or phrase is vacuous if it can be deleted without affecting the thought or notion being expressed. Manuscripts should be scoured for excess baggage of this sort. If a

sentence works just as well without a word or phrase, the word or phrase should be deleted.

Jargon

Jargon in the 2nd edition of the American Heritage Dictionary is defined as:

> *nonsensical, incoherent, or meaningless talk; a hybrid language or dialect; pidgin; the specialized or technical language of a trade, profession, or similar group*

Bayan, in The Cynic's Dictionary (Bayan, 1994) defines jargon as:

> *The prideful slang of the insider; an elaborate verbal disguise for commonplace ideas, used liberally to befuddle outsiders, secure the wink of approval from one's colleagues, and artificially inflate the stature of every profession from management tom mortuary science.*

There is no doubt that our everyday vocabulary is littered with jargon. We speak freely of *prioritizing*, *conceptualizing*, *defunding*, and *policy relevance*. Publications from governments and administrations are filled with it, and much of it is unintelligible.

All specialized activities involve the use of language having the characteristic features of jargon. The pages of protocols, manuals, and handbooks of trials are filled with jargon understandable to those doing the trial but not to others. A writer has an obligation to avoid the specialized jargon of the trial in manuscripts submitted for publication. That obligation should be met by repeated readings and editing for jargon prior to submission.

The detection of our own jargon is not so easy. The repeated use of jargonistic expressions over the course of the trial causes those expressions to become part of everyday speech. That familiarity increases the likelihood of use without notice in manuscripts produced from the trial. Therefore, repeated readings by authors for detecting jargon may not be sufficient. Readings by others outside the trial may be needed to aid in the identification of the strange and esoteric.

A good writer will define terms with specialized meanings key to understanding the manuscript. The definitions will be in the body of the manuscript or in a glossary appended to the manuscript. Terms needing definition include those basic to the trial such as *baseline*, *followup*, *loss to followup*, and *dropout*. The same is true for shorthand labels or abbreviations and for letter designations for terms or phrases.

Some expressions, when taken literally, are amusing. A case in point, relevant to trials, has to do with references to *placebo patients*, as in *placebo patients were seen on the same schedule as all other patients in the trial*. There is no such patient (except for one coated with sugar) nor is there a *placebo group*. The proper designation for a

patient assigned to the placebo treatment is to refer to the assignment in relation to the patient or group, as in *placebo-assigned patient* or *placebo-assigned group*.

Truth by declaration and repetition

Much of what we do proceeds on the basis of trust. As a rule, we do not demand proof for the claims or statements made by a colleague. Generally, the closer the relationship the greater the trust. At the same time, however, we also recognize that the mere repetition of a claim, no matter how often or loudly proclaimed, does not constitute substantiation of the claim. Nor do protestations against a claim, no matter how vehement, render the claim false or vacuous. If so, we would not have overcrowded prisons and politicians being forced from office because of wrongdoing. Conversely, one cannot establish a truth by mere repetition of a claim. If so, we would still believe the earth to be flat and to be the center of the universe.

Data are needed to establish a claim as fact. Beliefs and perceptions, no matter how convincing or logically plausible, are different from data. For example, there are many who believe that women have been systematically excluded from trials. The perception is widely held and has helped to propel the US Congress to write legislation regarding how trials are designed, carried out, and analyzed (NIH REvitalization Act of 1993). The fact that the perception is widely held and perceived to be "plausible" because it jibes with our beliefs does not elevate the perception to fact. The perception cannot be established or dispelled by claim or counterclaim.

The researcher is trained to avoid jumping to conclusions and to respect data. Hence, one should expect that what they write is devoid of unsubstantiated claims, statements, or conclusions. However, the reality is that the researcher has the same difficulties as the politician in differentiating between what is believed to be true and what is known to be true. Hence, researchers are capable of proceeding on the basis of an unsubstantiated claim simply because it is plausible. Their prior beliefs and opinions will color the way they view a new set of results. They are more likely to embrace claims of others, even if not substantiated, if those claims support their own views or beliefs.

The amount of critical analysis we do before accepting or rejecting the work of others will depend, in part, on the way those results fit with our views or positions. We are more likely to accept a negative criticism of someone else's work if the results run counter to our view than when they support our view.

We form opinions about the work of others by criticisms read or heard without ever bothering to check original sources to determine whether the claims or conclusions of critics are justified. Hence, it is enough to read a critical review of a trial offered by someone else for us to form our opinion about that trial without ever reading the

original article. Worse yet, we may do so without even realizing that the information being supplied is from sources with interests in promoting a particular point of view.

Though trained as researchers, as people we want to believe the things that fit our views and beliefs and reject, or at least question, those things that run counter to our views or beliefs. As a rule, we demand less evidence to support a belief than to change a belief. Further, though so trained, we are capable of trying to maintain an attitude of objectivity while espousing a particular point of view or promoting a cause we believe in by trying to justify the behavior on scientific grounds. Often we are not capable of recognizing the obvious dangers in mixing advocacy with research. The two notions are in large measure incompatible. Hence, as a rule, one must choose between being an advocate for some cause or approach and researching the merits of that cause or approach. Trying to do both at the same time will lead to "schizophrenia" and confusion.

Similarly, we must recognize the difference between the need for social reform and research that may lead to social reform. Social reform is social reform, and research is research. Research may lead to social reform, but it should not be undertaken as an instrument of social reform. Hence, the clinical researcher has to differentiate between that known to be true from research and that believed to be true from a social perspective.

In research, data speak. A scientific paper should be short on claims and long on data and facts.