such as a linguist is highly recommended for this meeting to help in the discussions of whether equivalence between the original version and new-language version has been reached. All decisions should carefully be documented with their reasons.

The third step is the back-translation of the synthesis version T12. This back-translation should be performed by 2 bilingual persons with the language of the original questionnaire as their mother tongue. They should have no medical background and no knowledge of the original questionnaire and its concept. Both back-translations should be performed completely independently; they produce versions BT1 and BT2. The back-translations can reveal ambiguous wording in the translation or that the translation was incorrect.

The fourth step is the expert committee meeting that finally discusses the synthesis version, as well as the back-translations, and its equivalence to the original questionnaire. All forward- and back-translations and the original and synthesis versions should be available at this meeting. The expert committee should preferably consist of all 4 translators, 1 language professional, 1 medical advisor, and 1 methodologist. They discuss whether the synthesis version can be used for the next steps or whether some phrases need to be changed because of obvious findings from the back-translations. A pre–final version will be created.

In step 5, this pre–final version is tested in 30 subjects/patients for comprehensiveness. This test should not only include the translated questionnaire but also a section where the subject can describe difficulties in understanding or give an idea of his or her interpretation. The results of this test, all documentary material of the process, and all versions should be sent to the inventor of the score for approval of the new-language version.

After approval, the psychometric properties of the new-language version must be assessed, i.e., it must be tested for reliability, validity, and responsiveness.

1. The test-retest reliability is important to determine whether the score is stable, i.e., the score does not change if the patient's health condition has not changed. It is, for example, tested in a symptom-stable interval where the patient has to complete the new questionnaire twice within a few days (usually not more than 1 week).
2. The validity must be tested to determine whether the new score measures what it is supposed to measure. For example, a new score of the hip can be tested together with an HRQL instrument such as the SF-36 or with a region-specific instrument such as the WOMAC. If 2 instruments correlate well with each other, this indicates convergent validity, and if not, there is divergent validity between the scoring systems. For a new score of the hip, we would expect high (convergent) correlations with the WOMAC and the physical function subscales of the SF-36 but low (divergent) correlations with the mental subscales of the SF-36.
3. Testing responsiveness is necessary to determine whether the score detects changes of a symptom or health condition over time or after a treatment.

Only if the new-language score performs well on all these tests is it deemed a sufficient and reliable instrument.

A different cultural background can be an important confounding factor. If a patient self-assessed questionnaire shall be used in another language, it cannot be simply translated. It must undergo a careful process of cross-cultural adaptation and testing.

Influence of Comorbidity

Because different and severe comorbidities exist in older patient populations, clinical results may not be representative of all patient types presenting with knee problems. If patient-oriented measures are used only for healthy and lucid patients, PROs will be ineffective in the 31% to 45% of patients in geriatric orthopaedic rehabilitation units who are reported to have cognitive impairment.[257] Patients who fall into this category are often challenging to deal with because of a lack of compliance or mortality rates that lead to a loss in follow-up. RCTs should diagnose comorbidities and screen patients for either inclusion or exclusion according to the research question and monitor higher degrees of disability through functional outcome assessment. Impaired physical function has been linked to many indicators of increased health services utilization and has become fundamental for researchers, clinicians, and funding agencies.

We can gain greater understanding of the patient's perspective by using the appropriate instruments that measure all aspects of functional recovery. Health in elderly patients is often compromised by various comorbidities of differing levels of severity. These areas need to be further investigated with the aim of finding a common metric to assess specific populations implicating a change in the future conduct of EBM. The implications of obtaining results that are not representative of

all patients are major, and future research needs to investigate the potential use of proxy responders.

The Use of Proxy Responders: Ethical Considerations

Cognitive impairment does not necessarily lead to an assessment of incompetence. Cognitively impaired elderly persons may still be able to make morally responsible decisions, based on different degrees of decision making and on their personal history.[258] The solution is more complex, and assessment instruments need to be used with caution when dealing with multiple interactions between medical personnel and patients and their family members. With regard to the ethical considerations and care of patients with dementia, the approach needs to encompass the patient's feeling of being cared for and approached as a competent or free individual. Because the elderly are regarded as a vulnerable group, it is important to use a method that can protect those who cannot decide, as well as to provide the opportunity to participate in research for those who are able to decide for themselves. Especially because the law prohibits scientific research on incompetent patients, unless special conditions are fulfilled, a close investigation on the issue of informed consent is needed and should be recommended for future research. Patients with mild to moderate dementia still have moral capacity.

Proxy and patient responses are not interchangeable; however, proxy responses can provide an option for assessing function and health status in patients who are unable to respond on their own behalf. In a prospective longitudinal study examining agreement between patient and proxy respondents using the Health Utilities Mark 2 and Mark 3 (Health Utilities Inc., Dundas, Ontario, Canada) over time during a 6-month recovery after hip fracture, the authors reported ICC values from 0.50 to 0.85 ($P < .001$) for physically based observable dimensions of health status and from 0.32 to 0.66 ($P < .01$) for less observable dimensions.[259] Future investigation of the proxy interrater agreement with the use of health status instruments is needed.

GENERAL CONSIDERATIONS FOR MULTICENTER STUDIES

The homogeneity of observations throughout the whole study group plays an important role, as does the absolute number that can be achieved within a given time frame. Whereas clear inclusion and exclusion criteria combined with well-defined outcome measures help to limit variability, these factors also limit patient recruitment and generalizability.[260] Therefore extreme unification of variables and criteria may lead to problems in statistical power. Nevertheless, a number of boundary conditions should be defined to limit variability. They include the following:

- preoperative patient preparation, e.g., positioning
- standardization of surgical intervention including approach, concomitant interventions, e.g., soft-tissue release or any tenodesis, and wound closure
- perioperative antibiotic protocol and subsequent infection prophylaxis
- anesthesia and postoperative pain management
- thrombosis prophylaxis
- postoperative rehabilitation protocol including timing and extent of passive and active range of motion, casts, and weight bearing.

Illustrations, flowcharts, pocket charts, and checklists are helpful to achieve a similar information level at all sites. It is of paramount interest to integrate the surgical staff as well as colleagues from anesthesiology in the information flow. Only if all persons involved in the treatment process are informed and act according to the study protocol can the quality of outcome measures be ensured. For example, an incorrect anesthesiology protocol may lead to patient exclusion if it possibly interferes with an outcome measure such as postoperative pain. All changes to the protocol have to be communicated as protocol amendments to all persons and the appropriate institutional review boards.

Newsletters to all sites and all collaborators are good instruments to ensure a similar information level among all sites and collaborators at one site. They may also motivate partners for active patient recruitment and subsequent adherence to the study protocol (Tables 37-38).

TABLE 37. *Multicenter Checklist*

- Reach an agreement within the study group about the exact protocol of intervention and related treatment (preoperative patient preparation, anesthesia, pain management, thrombosis prophylaxis, postoperative rehabilitation)
- Ensure compliance with the protocol at all sites
- Define measurement devices and units
- Define time points for follow-up including tolerance
- Consider cross-calibration of devices, e.g., with phantoms
- Define each (!) variable including measurement procedure

TABLE 38. *Tips and Tricks*

- Teach the study nurses of all sites at the beginning of the study
- Train the investigators in the correct performance of objective tests
- Provide pocket flowcharts for patient monitoring
- Use newsletters to keep all sites updated
- Publish the study protocol, e.g., at www.clinicaltrials.gov

Data Acquisition

For participation in a multicenter study, it is not enough to treat patients who potentially might be included in the specific study. A few more conditions are mandatory to act as a study site and to successfully contribute observations. If surgeons agree to participate in a study, they should be aware of the necessary infrastructure. This includes a person who will collect the data. In the best case, this is a well-trained study nurse who is responsible for all study performance–related issues at one or more clinics. Experiences with high-quality study nurses show that they ensure not only completeness of data but also a high follow-up rate. A local scientific contact person with a key interest in the study subject also helps to get a study locally established. This person can be instrumental in the necessary application to the institutional review board or local ethics committee. In addition, he or she has to inform all necessary partners at the study site, such as anesthesiologists, members of the operating room staff, and physiotherapists.

A central infrastructure for data collection is required because of differences in local infrastructure. Whereas in most single-center studies the clinical information system can be used, in multicenter studies additional data collection is mandatory. The system used has to be tailored to the specific needs of the study (e.g., acquisition of image data in contrast to patient self-assessment) but also to legal boundary conditions such as data safety, query management, or guidelines of good clinical practice.[261] In many studies paper-based data acquisition with subsequent telefax transmission is still a valid option. Web-based databases are an interesting alternative. They have the advantage that data validation and query management can be implemented electronically, thus improving data quality, but more time is usually required to insert data and to comply with data safety issues. So far, no general applicable gold standard for data acquisition exists, but this issue has to be addressed during the planning phase to avoid missing data or data loss. It requires a separate budget for programming and maintaining the database and for data processing, if applicable.

TABLE 39. *Feasibility Questionnaire*

- How many cases of the study disease/injury (according to inclusion criteria) do you have per year?
- How many cases (%) of the study disease/injury (according to inclusion criteria) come to your clinic for follow-up examinations on a regular basis?
- When do your patients usually come to follow-up examinations with the study disease/injury?
- How many cases (%) of the study disease/injury (according to inclusion criteria) do you expect to come for the follow-up examinations planned for the study?
- In case patients could not come to a follow-up, could you perform telephone interviews?
- Do you treat your patients according to the study protocol?
- Do you perform the same postoperative treatment/rehabilitation?
- Which devices/techniques do you use (specific question, e.g., for densitometry, strength measurement, gait analysis)?
- Do you have a study nurse or dedicated person who could run the study and manage the operational affairs?
- How long do your institutional review board submissions usually take until approval?
- Do you prefer electronic data capture or paper-based CRFs?
- Can you perform and send radiographs in DICOM (Digital Imaging and Communications in Medicine) format?

CONCLUSIONS

Multicenter clinical studies offer a unique chance to obtain high numbers of patients even for rare diseases or fractures. They are of higher value than single-center studies because they show a more real-world approach and not only the high quality of a well-skilled orthopaedic surgeon in an ideal clinical environment. The great opportunities of a multicenter clinical study sometimes induce the planning clinicians to assess as much as possible, i.e., numerous PROs and objective measures. However, the best clinical study is only as good as it is feasible. Therefore a feasibility questionnaire in the planning phase of a multicenter study is often helpful (Table 39).

Finally, it is of utmost importance to carefully plan finances for managing multicenter studies!

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SECTION 17

Reporting of Complications in Clinical Trials

Complications in orthopaedic trials are an essential source of information. They may result in discontinuing unsuccessful treatment strategies, help to identify potential for development, and form the basis for shared decision making with patients. However, the term "complications" implies different things to different people. For surgeons, they seem to cause trouble in the first instance. In addition, they impair any success rate, they may need re-intervention, they often require extensive communication with patients, they sometimes lead to legal problems, and they are, all in all, associated with more problems and high costs. Given their perception as failures, it is not surprising that some surgeons tend to neglect them—at least in terms of reporting them. Other surgeons are more critical, and they document and report more complications. So, what is regarded as a complication is dependent on the surgeon's understanding and awareness. The great variability of reported complications for specific indications illustrates this fact. A recent survey among orthopaedic surgeons supports this observation by showing different awareness levels of complications.[262] Herein, we suggest a standardized approach to documenting, assessing, and reporting complications in clinical trials.

COMPLICATIONS FROM DIFFERENT PERSPECTIVES

For legal authorities, complications are so-called adverse events that must be reported according to the guidelines of good clinical practice. They are interested in information—for instance, whether the complication leads to death or another stay in the hospital (serious adverse event) or whether it is device related.[263] Reported complications may lead to a study being stopped or implant withdrawal from the market or may have legal consequences.

For patients, complications mean a decrease in quality of life in the first instance. A treatment may take longer than usual, may cause more pain than expected, may result in a poorer result than promised, and may lead to long-term sequelae. It could also result in a re-intervention to correct these conditions or to prevent long-term consequences. Primarily, patients are not interested in the surgeon's perspective or in the legal perspective. They simply want to have function and quality of life re-established, and they regard everything that deviates from the normal course of healing and rehabilitation as a complication. In addition, they should obtain unbiased information about expected complication risks as a basis for shared decision making.[264]

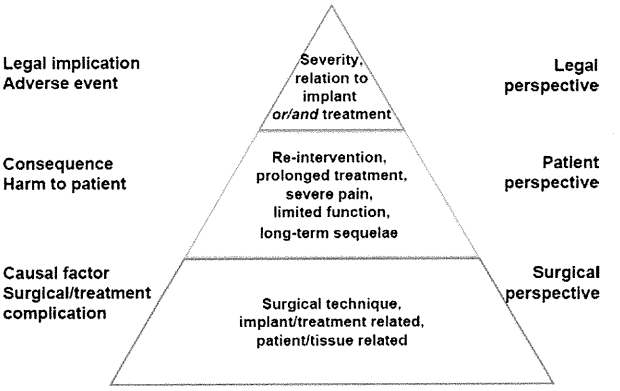

FIGURE 13. Hierarchy of complications. The pyramid illustrates the hierarchy from causal factor to patient harm until legal adverse event classification. This corresponds to the different perspectives on the right side of the diagram.

The outlined consequences show that it seems almost impossible to satisfy all perspectives at the same time. Therefore a pragmatic approach is required that should acknowledge relevance. A severe complication may lead to a decrease in surgical reputation and/or withdrawal of an implant with some financial consequences for the manufacturer. However, a patient may suffer from consequences of complications for the rest of his or her life or even die. So, complications have the highest relevance for the person experiencing them. Therefore definitions of complications have to be patient centered.

This leads to a hierarchy of complications (Fig 13). Whereas the surgical perspective is based on experience and always includes reasoning and causality, the patient perspective serves as a filter. Any event without any harm or consequences to the patient might not be considered as a complication.

On top of the hierarchy, the legal perspective determines the relation to any tested implant or treatment and classifies the severity according to

established guidelines. It is mostly a subset of the complications that may matter to the patients as described above.

In accordance with the good clinical practice guidelines [E2A and E6(R1)] of the International Conference on Harmonization, a serious adverse event is clearly defined as any untoward medical occurrence that

- results in death
- is life-threatening (it should be noted that the term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- necessitates medical or surgical intervention to prevent permanent impairment to a body structure or a body function
- leads to fetal distress, fetal death, or congenital abnormality or birth defect.

CASE EXAMPLE

The importance of the patient perspective as a filter should be demonstrated with the following example.

In the treatment of an unstable trochanteric fracture using a dynamic hip screw, the screw was misplaced very close to the articular surface. The patient claims to have severe pain during weight bearing.

- Surgical perspective: the complication is a screw cutout. Possible causes can be initial misplacement (surgical technique) and/or poor bone quality (patient/tissue related).
- Patient perspective: the patient has severe pain and reduced function and may have long-term consequences if untreated or will face a re-intervention to prevent them.
- Legal perspective: the severity classification depends on the possible re-intervention. The possible relation to the implant depends on the judgment of the surgeon in terms of whether the malpositioning was related to poor surgical technique and/or device.

The case example demonstrates different issues: (1) The patient suffers under all circumstances regardless of the causative factor or the legal classification. (2) The surgeon can influence the classification of adverse events, e.g., by accepting poor functional outcome or neglecting re-intervention.

NORMAL EXPECTED COURSE OF HEALING

If the patient perception of a complication is any deviation from the normal course of healing and rehabilitation, then a definition of "normal" is required. Healing of any tissue such as bone, cartilage, or tendon has a broad range depending on patient characteristics as well as on the specific intervention. For instance, time to fracture union is not clearly defined and depends on many confounding variables and on the assessment method.[265-267] Therefore thresholds are required that distinguish the normal course from a pathological course of healing. The same is valid for pain and return to function.

Whereas a certain amount of pain caused by wound and tissue healing after a surgical intervention is related to the normal course of healing, prolonged pain has another cause in most cases. The same is valid for return to function and activities of daily living. A certain improvement of function with a wide range is expected at given time points after intervention. However, complete loss of function or significantly lower function than expected and subsequently impaired activities of daily living have to be considered complications.

Thus, for both pain and return to function, thresholds have to be determined for the normal expected course of healing. Everything outside of these has to be considered as a complication or the consequence of a complication. Pain and low function are often only symptoms of an underlying, often anatomic problem (e.g., articular step or valgus deformity). If patients report severe pain and/or limitation of function, it is necessary to search for the causative problem.

COMPLICATION REPORTING

For each study, the normal course of healing and rehabilitation including an evidence-based range should be defined. This includes pain and functional status at each follow-up, as well as healing of any investigated tissue such as cartilage or bone.

Anticipated complications/adverse events should be listed in all study protocols with clear and objective definitions along with appropriate scientific references.

TABLE 40. *For Each Complication, a Minimum Set of Information Should Be Documented Because of Regulations and to Allow Clinically Meaningful Evaluation and Reporting*

Domain	Variables
Identification	*1.* Investigator's name and phone number
	2. Study name
	3. Patient identification (trial number, initials, age, gender)
Treatment	*4.* The treatment number (if applicable, such as in a randomized clinical trial)
	5. The name of the suspect medical product and date of treatment
	6. Product serial number (in case of SADE)
Complication	*7.* Complication type
	8. Date of occurrence or onset
	9. Short description (open text field)
Action(s)	*10.* Subsequent action taken (e.g., operative)
Outcome(s)	*11.* Outcome of the complication at the time of reporting (or end of the study)
Assessment	*12.* Seriousness of the event
	13. Most likely causative factor, e.g., relation to the surgical intervention or the implant used; we recommend using the 4 categories presented in this chapter.

NOTE. This is the minimum information to be collected by means of an adverse event form/complication CRF to be adapted for each study. Investigators are asked to fill in 1 form for each complication; however, more than 1 event may be recorded on the same form if they occurred simultaneously and were unambiguously causally related.

Abbreviation: SADE, severe adverse device effect.

It is important to quantify the standard complication rate known from the clinical literature, the common salvage procedures, and the final outcome that can be expected.

- *For each complication, a minimum set of information should be documented because of regulations and to allow clinically meaningful evaluation and reporting.*
- *In clinical research these variables should be presented as a standard adverse event/complication case report form (CRF) that is adapted for each study.*

In Table 40 minimal requirements for record keeping of complications in clinical studies are listed. Investigators are asked to fill in one form for each complication; however, more than one event may be recorded on the same form if they occurred simultaneously and were unambiguously causally related (e.g., an implant failure simultaneously with a loss of reduction).

Because complications occur as part of a more or less complex chain of events, a clear distinction should be made between the complications/adverse events themselves and the following, as illustrated in Fig 14: their causal trigger factors, their treatment (which could actually be no action), and their consequences or outcomes.

FOLLOW-UP OF COMPLICATIONS

- *If an original complication record states that the complication was resolved or that the recovery process is completed (with or without damages), no further data are required.*

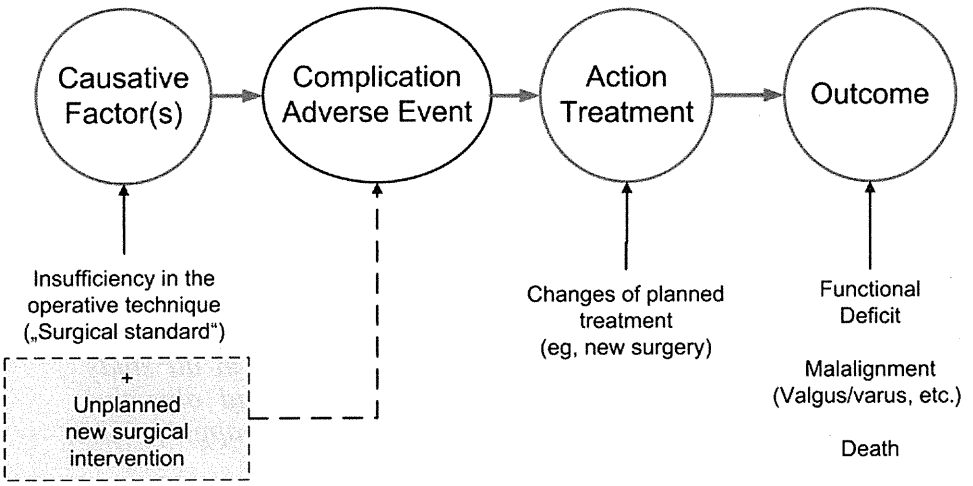

FIGURE 14. Clear distinctions should be made between complications/adverse events themselves, their most likely causal factors, their treatment (which could actually be no action) and their consequences or outcomes.

TABLE 41. *Classification of Complications*

Category	Class	No.	Example
Treatment related	Related to surgical technique	1a	Malpositioning of screws, wrong procedure
	Related to device/treatment	1b	Loosening of polyethylene glenoids due to wear
Patient related	Related to local tissue condition	2a	Cutout of correctly placed screw due to poor bone quality
	Related to overall patient condition (e.g., systemic)	2b	Myocardial infarction

- *Alternatively, it is necessary to follow up the complication until it is resolved, in particular in terms of its treatment, outcome, and assessment, and all new information must be documented.*

In clinical studies a follow-up adverse event/complication CRF should be distributed to investigators to capture this information until complications are resolved or finally evaluated at the end of the study.

CLASSIFICATION OF COMPLICATIONS

We propose 2 main categories, treatment related and patient related, and 2 subsequent classes for the classification of complications based on their most likely causative factor (Table 41).

Of course, many cases remain where the causal relation is a topic of debate. For instance, it is still not clear whether an avascular head necrosis is the result of the surgical treatment of a humeral head fracture or would correspond to the normal course of disease.

However, careful planning combined with prospective definition of complications and their causal relation increases the study quality. This planning phase may lead to an extensive list of anticipated complications, as shown in a recent trial,[238] but helps to categorize complications before the study and will result in an unbiased complication analysis at the end of the study.

DATA QUALITY CONTROL AND FINAL REVIEW OF COMPLICATIONS

Active monitoring and quality control are essential to avoid or limit under-reporting and misleading complication results. To favor completeness and correctness of documentation of complications, 1 or more of the following measures can be implemented in any study:

1. Source data verification during monitoring visits
2. Active reporting: implement systematic assessment of any complication at each examination visit (e.g., using standard CRF or asking whether another physician was visited other than for routine assessment)
3. Incentive to report: facilitate simple recording process and ensure anonymous reporting of complication statistics outside the involved clinics so that results cannot be traced back to the individual treating surgeon
4. Obtainment of additional information on putative events from the patient's family doctor, if necessary
5. Evaluation of reported complications by the study's principal investigator, an independent experienced clinician, or any specifically established complication review board (CRB)

The final complication review should be conducted based on complication/adverse event forms, as well as available related diagnostic images, which might be made anonymous to limit bias. Complication data are reviewed for their clinical pertinence, classification, and severity, as well as relation to the investigated treatment or medical device. All changes and data corrections should be thoroughly justified and documented.

ANALYSIS OF COMPLICATIONS

A minimum set of complication analyses should be conducted in any study. However, it should be noted that if regulatory requirements oblige investigators to document all complications occurring during a study, only a specific clinically relevant subset may be analyzed to answer a study objective. It is critical to clearly define which complications are included in such a subset and to specify the period of observation (e.g., intraoperative, postoperative, and follow-up periods) to allow appropriate interpretation of the results. In the context of prospective clinical investigations, the timing of observation for each patient starts with the initiation of treatment or primary surgery and

TABLE 42. *Example of Presentation of Complication Risks*

Type of Complication	n*	Risk (%)†	95% Binomial Exact Confidence Interval
Postoperative local implant/ bone complications	18	10.2	6.1-15.6
Implant			
Blade migration	1	0.6	0.01-3.1
Implant breakage	3	1.7	0.35-4.9
Cutout	2	1.1	0.14-4.0
Other implant complications	2	1.1	0.14-4.0
Bone/fracture			
Loss of reduction	1	0.6	0.01-3.1
Neck shortening	8	4.5	2.0-8.7
Other bone complications	6	3.4	1.3-7.2

NOTE. The number of patients (N) equals 177.
*Number of patients with at least 1 complication (meaning that the patient can have >1 complication, but for the risk calculation, the number of patients having complication[s] is used).
†Number of patients having a specific complication divided by the number of patients being enrolled in the study.

ends at the end of the study. For the report of complications, complication risks can be calculated and presented as shown in Table 42.

Complication risks should be presented based on the number of patients experiencing complications and not the total number of documented complications.

POINTS TO CONSIDER

According to our experience, for many surgeons, an event that is unrelated to the treatment may not be considered as a complication and must therefore not be documented. In addition, clinicians may sometimes believe that they do not need to document events that have no or limited consequences for the patients to avoid documentation overload. Nevertheless, harmonized standards for the conduct of clinical trials define a complication as "any untoward medical occurrence" not necessarily related to potential causal factors or severity[268]; even mild anticipated complications in the framework of clinical research require official reporting to authorities if their rate of occurrence is higher than what can reasonably be expected in any study. Whereas all complications must be documented from a regulatory viewpoint, the primary analysis can be focused on the patient-relevant complications.

At the end of a clinical study, complications/adverse events should be assessed and discussed by a complication review board in a complication assessment meeting. The completed complication case report forms, additional documentary material, and all images of the patients should be available for such a meeting.

We want to stress the importance of conducting an independent review of complications for the credibility of safety data. Complication rates in the literature are most often elusive.[262] In addition, they are likely underestimated, in particular when documented by the inventor(s) of any surgical technique. Despite all efforts at standardization, the assessment and reporting of complications will always require clinical judgment and therefore remain partly subjective. A CRB can address such limitations and, in our opinion, can also be established for single-center studies at a low cost. A CRB can, for instance, consist of 2 to 4 orthopaedic surgeons (at least 1 of whom should not be involved in the study), a radiologist, and a methodologist. It is to be distinguished from any data monitoring committee[269] established as part of large multicenter studies; whereas the CRB is set to control the relevance and integrity of the complication records, the data monitoring committee is set to review the occurrence of complications (i.e., assess the validated data and decide on the continuation of a study). The primary role of the CRB as we propose is to perform quality control and consolidate complication data before their analyses.

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SECTION 18

How to Write a Scientific Article: A Painless Guide to Putting it All Together

Before we get started, we have to say it: it takes a great deal of discipline to complete a scientific article. So many authors start; so few finish. But, most important of all is to start. If you don't start to write, you will never finish. If you just start and get going, it is often easier than you thought in the beginning.

DISCIPLINE

Have you ever heard of the 80:20 rule? Some argue it takes 20% effort to get 80% of the results. This is not true when it comes to writing a scientific article. We introduce a different rule; we call it the 90:10 rule. With average effort, an author can complete 90% of the paper. However, it takes just as much time to do the last 10%. Be prepared, because the last 10% often is the part that makes a difference. So we tell you in advance that finishing a scientific article takes time and discipline.

PASSION

Young ambitious authors sometimes do research for no other point than just doing research. Some do research to boost their career or because their work requires it. Perhaps the research is a requirement of an educational program, or perhaps the author is ego driven and wants to make a contribution, add to his or her curriculum vitae, or just get involved in something new. The problem is that such authors are at risk of choosing a research topic about which they lack passion. Then only pure discipline becomes the motivation for driving to completion of a dispassionate paper. Such authors are unlikely to continue a long research career.

Experienced and successful authors write about topics for which they have passion. You might say that brains are good, but passion is better. They get into a flow and putting it all together is a pleasure. The trick is to select a research topic for which the author has passion and interest. This shouldn't be difficult, because the purpose of a research study is to answer a question. Therefore, if authors really have a question, then they really want to know the answer. In other words, they like to make a difference.

If an author really wants to know the answer to a question, then he or she is by definition interested in the topic. Passionate interests in finding answers to clinically relevant questions prevent authors from becoming bored with their research before they get anywhere close to completing their projects.

SELECTING THE CLINICALLY RELEVANT QUESTION

Start by selecting the journal in which you are interested in publishing. Read that journal. Collect that journal. Then, when you're ready to start a research project, sit down and go through the last year or 2 of all the relevant articles. But don't overdo it; you don't have to read everything. Take your time and select the relevant papers; not more. Already at this stage and over and over again throughout the entire project, stay updated. Don't rely on old references only. The classical ones are still good, but things happen fast.

Read the articles in which you are interested in. Read the discussions of those articles, and at the end of the discussion, before the conclusion, search for the limitations of the study. The authors should have spelled them out. In fact, an honest report of limitations is often what brings the science forward. It creates new interest and poses new questions. So when you start to write yourself, don't forget to state the limitations of your own study.

In the limitations portion of the discussion, good authors suggest future research that will be necessary to address current limitations in the medical literature. Good readers should be able to think of other limitations of the study and future research to address those limitations. Taken in sum, this is how to choose a topic.

To review: read the literature, find the limitations, list future research to address the limitations, *and perform this future research as your new project.*

PURPOSE

The purpose of your study is to answer a question. To review the section on passion above, make sure it's a question in which you're really interested in finding the answer. Otherwise, you may risk never finding the answer.

HYPOTHESIS

Don't wait. The best research is prospective. Before you start your study, choose your hypothesis; it doesn't matter whether the hypothesis is right or wrong, because your research is to test this and you will find out the answer later. The hypothesis is what you think the answer to your question will be before you start the study. In other words, what do you expect to find or prove with your study?

LEVELS OF EVIDENCE

First, familiarize yourself with the tables summarizing levels of evidence.

Remember, editors prefer original scientific articles of the highest possible evidence level. Sometimes, they get what they want, but too often they don't.

Level V evidence (expert opinion) is the lowest level.

Level IV is a case series and is also low level of evidence. Unfortunately, while a case series can be of value, case series are the most common in the surgical literature. The problem is that case series do not include a control group.

Level III evidence is retrospective comparative research. Comparison of a control group is excellent, but prospective study is better than retrospective study. Strict inclusion and exclusion criteria mitigate against selection bias. There are several types of biases, but selection bias is probably most common and can easily skew results.

Level II evidence is prospective comparative research. However, this method is not randomized, which can result in selection bias. Strict inclusion and exclusion criteria mitigate against selection bias.

Level I evidence is a prospective randomized controlled trial. Randomization mitigates against selection bias. Level I evidence is the highest level of evidence.

Studies of higher levels of evidence are required to compare the effectiveness of one technique versus another technique. Chances of acceptance of an original scientific article are increased for studies of higher levels of evidence.

INTRODUCTION

The body of the introduction frames the question you will be asking. The purpose and hypothesis of your study should be stated at the end of the introduction.

Warning: no one is going to read your paper if the introduction is boring. Therefore, the introduction should not be overly long. Further warning: you're not going to want to finish writing the paper if your topic is boring. Therefore, stop right here, and go back to the purpose section above, and choose a more controversial and interesting question. Controversy in science is good; don't be afraid of it.

The good news is that you have selected a topic that is not boring. Good job, and congratulations because your introduction will draw the reader into reading your paper. One good thing leads to another and at the end of the day, your paper will be cited by other researchers, because it was passionate and not boring. People will bother to read it.

Don't waste the reader's time. Make your introduction short and highlight the controversy.

METHODS

The methods should be reproducible. Other researchers must be able to copy what you did. We teach this the same way every time: the methods should be like a cookbook. Give a step-by-step description so that your study can be repeated by other authors. It should include clear inclusion and exclusion criteria. Everything that you plan *before the study starts* should be a part of the methods.

At the end of the methods, include a description of the statistics that you will use to analyze your results. If it is a comparative study, be sure to include a power analysis to determine the cohort size. This is far too often missing or incorrectly done. A power problem is probably the most common problem in the majority of clinical studies. One might say that an overwhelming number of clinical studies are underpowered and therefore not conclusive. A study should include enough patients, not fewer than needed and also not too many. It is unethical to perform a clinical study on a new (possibly experimental) surgical technique, and either underpower or overpower the study.

Therefore, before you start your study, hire a statistician. *Hire a statistician before you start your study.* This is so vital that we said it twice!

People sometimes ask us, where do you find a statistician? They tend to work at universities, especially in those with research departments. If you don't work at a university, we would suggest that you contact the nearest department of public health to solve the problem. In addition, sometimes industry partners may employ statisticians whose non-commercial interests include research and education.

Since we're not statisticians, we really tried to keep this simple. Let's just focus on the most common statistical mistake.

The number one statistical mistake is doing a study that has too few patients. This is a study with inadequate power.

Underpowered studies mean authors might show no difference between two groups. And the results could be wrong. If there is not an adequate number of patients in each group, the authors could be making an error (we call it beta error) and this is probably the most common error in clinical studies.

The good news is that you performed a power analysis and it determined the minimum number of patients you need to avoid beta error. What do you do next to determine how many patients are required in each group? Once you know the minimum number of patients, add 25% more. Why? To mitigate against transfer bias, which is loss of patients to follow-up.

Maximum acceptable transfer bias is 20% of patients lost to follow-up. This is an arbitrary journal standard of the highest threshold of transfer bias accepted at 2 years follow-up. Some journals consider that a "worst case scenario," i.e., any patient lost to follow-up is disappointing.

Before you start your research, make sure you have a mechanism in place to ensure staff and research support funding so you can build a team with the ability to achieve a high number of patients completing follow-up after 2 years. Multiple ways to find the patients (friends and relatives) placed in the database will help. A researcher does have to work very, very hard to follow patients over the long-term. You must be patient because a disease has a tendency to disappear when a randomized study is started.

If you do find a difference between 2 groups, then you can determine if that difference is or is not statistically significant.

We test statistical significance with P value reporting. By convention, $P < .05$ means that there is only a 5% chance of a statistical finding of significant differences between groups occurring by chance. Confused? If $P < .05$, then a finding of a difference between two groups is probably a correct study conclusion. However, statistical significance does not equal clinical significance and this is something you must always bear in mind.

CLINICAL SIGNIFICANCE

Statistically significant differences between groups must be distinguished from clinically relevant differences. The P value does not measure clinical significance. Researchers are usually happy if their P value is significant, but their patients may not be equally happy. This possible discrepancy must always be taken into account.

What really matters is overlapping confidence intervals. Overlapping confidence intervals suggest no clinically significant difference between groups, and this represents clinical relevance.

We're not statisticians, and researchers must find a statistician to help them calculate confidence intervals. Or, maybe there is, or will be, some new computer app that will allow new research for us to calculate confidence intervals. Either way, authors must learn to take a careful look to see if there is numerical overlap between the confidence intervals to determine if there are clinically significant differences between 2 groups being compared.

If the confidence intervals overlap, results may not be clinically significant (even if they are statistically significant).

RESULTS

Results include everything you have found after you started the study. The most efficient way to display the data is usually to put your results in tables.

In the text, focus on highlighting the most important results. Present the details in the tables and do not repeat each and every detail in the text. Repetitions are never helpful and never make a manuscript better, only longer.

Everything mentioned in the methods should be noted in the results. Everything noted in the results should be mentioned in the methods.

DISCUSSION

A great first sentence for your discussion is "Our results demonstrate . . ." or "The most important findings of our study are . . . ." Obviously then, briefly

summarize your most important results. Then compare your results with the published literature. Then, contrast your results to the published literature. If your results do contrast, try to explain why. This is most probably the highlight of your paper. After you compare and contrast your results to previously published literature, remember to state study limitations before the study conclusion.

LIMITATIONS

Limitations are the last paragraphs in the discussion. Be honest about your limitations.

How do you determine your study limitations? You're off to a good start. You've already contrasted your study with other studies in the discussion, and you have already looked for possible explanations for the contrasts. Don't forget that one possible explanation is that your study methods may have limitations. Differences between your results and other published results are the first clue to help you find the limitations of your study.

Warning: editors prefer authors who disclose all study limitations. If editors find limitations that the author didn't mention, the editors are more inclined to develop a negative feeling about the quality of the manuscript. Authors should try to state all study limitations.

BIAS

The next way to detect study limitations is to review various categories of bias. There are long lists of various types of bias, but they can also be combined in a short list: transfer bias, recording bias, reporting bias, performance bias, and selection bias.

Transfer bias is patients lost to follow-up. Journals prefer 2-year follow-up, with transfer bias of less than 20%. Transfer bias of greater than 20% should be mentioned as a limitation.

Recording bias depends on who measures the data. Patient-reported outcome forms minimize recording bias, but for objective data collection, someone other than the surgeon who performed the procedure should measure and record physical examination and other clinical outcome measures. Ideally that recorder should be blinded as to which treatment the patient received.

Reporting bias considers how outcome is reported. Outcome measures must be validated for the condition being tested or measured. To minimize recording bias, authors should select outcome measures that are commonly used in the literature. This allows study results to be compared and contrasted to other published studies, so *select the correct outcome measures before you start your study*. If you fail, your study will be limited by reporting bias, and you won't be able to compare and contrast your results with other studies, so it will be very difficult to write an interesting discussion. In other words, your conclusions may have clinical meaning, but that meaning may go unnoticed or be unappreciated.

Performance bias depends on who performs the research and who performs the surgery. Single-surgeon studies introduce bias. Multi-centered studies introduce bias. No methods can eliminate performance bias entirely, because someone always has to perform the study. In the limitations section, consider and disclose performance bias.

Selection bias occurs when 2 groups being compared have different prognoses. There is an old saying about apples and oranges, and we agree that you cannot compare apples and oranges as equals. They look different and taste different. In research, selection bias occurs when comparing 2 groups that are not equal. For example, comparing children and adults is like comparing apples and oranges.

The best way to mitigate against selection bias is prospective randomization. Another good way to minimize selection bias is to have strict study inclusion and exclusion criteria. And, such criteria must always be carefully reported. For example, a study could include children age 12 to 18 and exclude adults. These are strict inclusion and exclusion criteria that will limit the differences between patients and allow comparison of groups while minimizing selection bias.

PROSPECTIVE BY DEFINITION

Retrospective review of prospectively collected data is not prospective research.

Prospective, by definition, means the research methods, *including the research question*, are designed and written before the first patient is treated.

Warning: prospective, by definition, means that all the research methods must be written before the first patient is treated. This includes the statistical methods. Therefore, be sure to hire a statistician and write the statistical methods before you actually begin your research. Prospective research *always* lowers the chance of bias.

CONCLUSIONS

Are you feeling excited? People are always happy to reach the ending; *some even start reading the ending and don't read anything else from your paper.* So when you state the conclusion, you'll have the full attention of the reader. Don't ruin it.

The conclusion is simple. Yes or no? Do the results support your hypothesis?

Many young authors have trouble here. The conclusion must be based on the results, nothing else. But inexperienced authors always add something else. They go on and on when they shouldn't. Don't state anything that is not supported by your data. Regrettably, many people do.

The conclusion can be only one of two simple possibilities: either the hypothesis is supported by the data or it is not. Many authors forget to mention the hypothesis, either proven or disproven, in their conclusion.

Statements about future research are not appropriate for the conclusion. Such statements should be integrated within, or follow, the discussion of study limitations, just prior to the conclusion. The conclusion should not just be extended discussion. If you have to explain your conclusion, you must go back and do it in the discussion. Only then, when you have said everything that you feel like you have to say, then and only then are you finally ready to state your simple conclusion.

Warning: editors are not happy if the study conclusion is different from the conclusion in the abstract.

TITLE

Obviously the title comes before the conclusion. The problem is most authors select boring titles. Review the section on the introduction above. Controversy spices things up. After reaching the conclusion, go back and rewrite the title to make it more controversial. Remember you need to draw the reader in.

The title should be short and succinct. Put some work into it.

ABSTRACT

The abstract has 4 sections: purpose, methods, results, and conclusion.

In *Abstract:* Purpose, sum up the controversy in a single sentence, stating the purpose in terms of the hypothesis being tested (but do not actually state the hypothesis). Don't use abbreviations in the abstract.

In *Abstract:* Methods, sum up who, what, where, when, and especially why. Sum up the type of study, inclusion or exclusion criteria, primary outcome measure, consideration of statistical power, and documentation of institutional review board approval.

In *Abstract:* Results, state the *P* value, mean (range), and confidence interval.

In *Abstract:* Conclusion, remember, "Our results demonstrate . . . ," then mention limitations in terms of bias, and consider clinical relevance.

FIGURES

It is said that a picture is worth a thousand words. Include ample (but not too many) figures.

Legends

Figure Legends must "stand alone," i.e., contain a complete, take-home, educational message, as if a reader viewed only that figure without looking at any other figure or without reading the text. Be sure to point out what you want the reader to see. It may be obvious to you but the reader may miss it if you do not point it out. For anatomic or arthroscopic figures, be sure to mention patient position, side, and viewing portal. Labels are generally always helpful. The Figure Legend is equally important as the figure itself.

TABLES

Similarly, tables must "stand alone," i.e., contain a complete, take-home, educational message, as if a reader viewed only that table without looking at any other table or without reading the text. Tables should include explanatory table notes as needed.

As above, the best Results are tabulated clearly, with a brief text section pointing out the highlights of each table. To reiterate, limit textual repetitions to the Table highlights.

REFERENCES

High-impact references must be recent. Editors almost always prefer references from the last 5 years. When it comes to references, like most things in life, quality is more important than quantity. It's not a competition to have the most references.

Keep the references recent and relevant. Look for new publications and do it often during the course of your study.

ETHICS

Compliance with journal, academic, patient protection, and industry regulations is mandatory. It is incumbent upon authors to independently research these issues and insure self-regulation and compliance.

CONCLUSIONS

Choose a research question in which you are interested in knowing the answer, state your purpose and hypothesis, and prepare methods and statistical methods prospectively before treating the first patient. Be sure your conclusion is based on the results. You just put it all together and write a winning scientific paper.

James H. Lubowitz, M.D.
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SECTION 19

Common Mistakes in Manuscripts and How to Avoid Them

Poor quality research should not be published, award-winning research methods should be published (but sometimes require extensive revision), and average manuscripts have the best chance of being published when they are well written and all details are formatted in good order.

On the other hand, some good ideas—and even good research—never get through because of sloppy writing.

When looking at a manuscript—and now we are talking about clinical studies—there are four common mistakes. It is interesting that these mistakes are repeated over and over again in terms of writing a manuscript.

1. *The manuscript is too long.* In fact, it may be said that all manuscripts are too long. This means that manuscripts contain nonrelevant and/or very well-known facts. As an example: you start your paper on osteosynthesis of hip fractures by stating that "Hip fractures are very common . . ."

   OK, this is correct. Hip fractures are very common, but everyone in the world knows this and the paper will not be better by writing for the 5,000th time that hip fractures are common. The manuscript will just be longer and more difficult to read. Including tangentially related material is another bad way to add unnecessary length to the article. Manuscripts need to be focused. Look at your purpose and hypothesis and if something does not directly relate to these two things, then it should not be in the manuscript.
2. *Repetitions.* A good rule of thumb is that a manuscript should be as long as necessary but as short as possible. In too many manuscripts, too many issues are repeated. This is especially true for the results section versus figures and tables. We find that a well-designed table with an explanatory note is most commonly the best way to present data. Then the written results need only mention the highlights and refer the reader to the table(s).
3. *Flow.* Finally, we need to talk about the "flow" of the writing. This is very important. Your ideas must flow so your manuscript is easy to read and to follow from beginning to end. A manuscript without a logical flow will probably never be published, so you should devote a good deal of time to this. Most often, the best way to improve the flow is to make the paper shorter.

TITLE

Many times we see that the title is neutral and doesn't really say much. Instead, be direct and say something controversial. Be provocative and let people know what you mean loud and clear. They should read your work and spread the word. But, it is up to you to make them interested. Being provocative does not mean being offensive.

An example of a boring, uninteresting title versus a vivid, thought-provoking one might be: "Two-Year Results After ACL Reconstruction" versus "Major Risk of Osteoarthritis and Inferior Knee Function Two Years After ACL Reconstruction."

ABSTRACT

The important task is to make the abstract concise yet still include the purpose, the key methods, results, and conclusions. It should *not* have any back-

ground, hypothesis, or discussion. The conclusions of the abstract and the text should be the same. Generally the abstract should be no more than 300 words.

Do not include an introduction or discussion. All material should be focused on the purpose and the results. There is no need to describe the methods in great detail in the abstract. It will only make the abstract longer and destroy the flow. To destroy the flow is the worst mistake an author can make; the abstract will be more difficult to read and understand, and marginal readers will lose interest and stop reading right there.

Finally, don't let the abstract fade out into nothing. The abstract should have straightforward and clinically relevant conclusions. And importantly, if it is basic science, you must give a clear picture of the relevance to clinicians. What do the results show and what is the clinical relevance?

INTRODUCTION

This is often the most difficult part of the manuscript—how to get started? Some people never do. A good rule is, just do it—just get started. The purpose of the introduction is to frame the question that you propose to answer. This is where you the author need to draw in the reader. It should be thought-provoking and supported by the latest literature. Be careful not to slip into discussion. You do not want to explain the reasons or answer the questions in the introduction. It should be designed to just whet the appetite of the reader. Do not let it ramble or be too general, but keep it brief and focused. The last paragraph of the introduction should state clearly your purpose and then your hypothesis or what you thought you would find before you started the study. This is very important and in too many manuscripts these two essential elements are not clear at all.

A general rule is that the introduction should be no longer than one manuscript page. It must tell the readers why the study is needed and what the controversy is. Scientific controversy is good; it is not personal. Don't be afraid of it.

METHODS

Similar problems are common in the methods and results sections: too long, too vague, and do not tell the full story. Methods must be so well described that other researchers can repeat them without trouble. It should be like a cookbook. Who are you taking into your study and what are you doing to them? This is important and means that you need to have clear inclusion and exclusion criteria as well as a description of exactly how each subject was treated.

We often find that decimals are a problem. Too often authors are reporting values up to three or even four decimal places. Why is that a problem? Two reasons:

1. The flow: the reader is drowned in numbers and readability is affected.
2. More importantly, the accuracy of the measurement and methods is not mentioned in the methods section. Are your methods truly accurate to that degree? And why is the test-retest reliability measurement so infrequently reported in manuscripts? Any study is only as good as its methods and that is why the measurement's accuracy is absolutely vital.

The study cohort is often too small. This is a very common mistake. It really doesn't have anything to do with writing a manuscript, but a good explanation of why the cohort is limited is necessary and is a help to the reader. The authors may discuss such things as power, sample size calculation, and compliance, and they may mention drop-out analysis.

Statistical methods are a necessary subheading. Any study that shows equivalency requires a power analysis with an explanation of the assumptions. For basic science studies, you need to explain and provide context for the rationale of the study design.

RESULTS

The results section must be succinct. A good rule is: make it less than one manuscript page. If decimals are a problem in the methods section, they are also a problem in the results section. Often we see duplication in the results, figures, and tables. This is problematic on several levels. It destroys the flow of the manuscript and it adds to the length of the paper. The flow of the article will be enhanced when the results section is constructed to parallel the methods section.

DISCUSSION

The mistake we often see is that the discussion is too long, too general, and too vague. We suggest that you start the discussion with a sentence stating your most important findings. This should be followed by comparing and contrasting your findings with those reported in the literature. If you have done a basic science study, you need to remember that you are

writing for a clinically oriented journal. Even though you have the most wonderful study on mice and rats, you should mention the possible clinical impact.

Two important words are key factors in discussion: *context* and *limitations*. Don't hide your limitations—make them visible and transparent. Classically, they should be stated at the end in the paragraph just before the conclusions. All studies have limitations; some major, some minor. And you should discuss them. Be honest about your limitations because the limitations may be the most important issue in your whole study. Why is this? A profound understanding of limitations will create new studies and new science that will lead to new understanding.

CONCLUSIONS

Conclude what you found from your data and nothing else. Too often, the conclusions section is too long and general and filled with feelings. If you have compared single- versus double-bundle ACL reconstruction, your conclusion should not be that all ACL injuries in children should be operated on because you feel that their knees will be better off after surgery. We often see trends reported in the conclusions. Trends may be in the discussion but only statistically significant findings may be in the conclusions.

REFERENCES

Two common errors that we see with references are

1. Incorrect order and incorrect format: each journal has specific instructions for references. These need to be read and carefully followed.
2. Not up to date: a possible reason for this is that the authors started the study several years back. They looked for relevant references when they started but they never updated the references by adding recent relevant citations. Why use the old ones? Bankart (1923) has been cited several thousand times. Is the manuscript really better if his study is cited once more?

Too often we see incorrect citations; what is that all about? Authors should have read the *original* publication and used that as the reference. A good example is the currently used Lysholm score that was published by Tegner and Lysholm in 1985 in *Clinical Orthopaedics and Related Research* and not by Lysholm et al. in 1982 in the *American Journal of Sports Medicine*. This error is common.

Update your references just before you send your manuscript to the editorial office. There is nothing that makes the reviewers and Editor so happy as updated references.

FIGURES AND TABLES

Figures should only be used to transmit key ideas and concepts. And don't forget that the key ideas also need to be pointed out in the figure legend. The combination of figure and legend needs to have a take-home message for the reader. Even if the point is obvious to you, it needs to be stated so the reader does not miss the point. Also, each figure/legend needs to stand on its own; the reader should not have to refer to the text to understand what you want to convey. The text should not rehash the information in the legend and vice versa. The same can be said for tables, which are the preferred method of presenting large volumes of data.

IN THE END

The good news here is that with a little care you can present your scientific work in a pleasing and accurate way that will have a high likelihood of being published.

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Gary G. Poehling, M.D.

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