In this issue…

Protected health information

– Bryan Tutt

Anyone working with patient data or writing about clinical studies should be aware of what is and is not considered protected health information (PHI). Under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), PHI is health information (a patient's diagnosis, treatment, imaging or laboratory results, etc.) combined with identifying information (a patient's name, date of birth, geographic information, facial photograph, etc.).[1] Notably, the definition of identifying information is broad and includes "any other unique identifying number, characteristic, or code."[2] For patients with extremely rare cancers, for example, the diagnosis itself might be considered a unique characteristic.

In general, PHI should only be used or shared for the purposes of treatment, payment, or health care operations. Otherwise, the data must be de-identified, or written authorization to share the information must be obtained from the patient or their legally authorized representative.

A HIPAA authorization form differs from the informed consent form signed when a patient agrees to participate in a research protocol, although the two forms might be signed at the same time. The HIPAA authorization form describes the PHI that will be used, the purpose for which it will be used, the person or group requesting the use, and the expiration date of the authorization (e.g., "none" or "end of research study"). Such authorization is needed if PHI, such as a patient's name or image, is used in marketing or in a publication in which the patient might be identified, such as a case report.[3]

HIPAA authorization is not needed to access PHI for certain research purposes. These include preparatory activities, such as recruiting study subjects and preparing a protocol. Once the protocol is submitted to the institutional review board, access to PHI is governed by the informed consent agreement or waiver. But the most notable exception to HIPAA authorization is for de-identified data.

Data that have been de-identified no longer meet the definition of PHI because the individually identifiable information[2] has been removed. For example, in a report of a clinical study, a table of patient characteristics might list patients' ages at diagnosis (not considered identifiable for ages younger than 89 years) rather than their dates of birth.

In addition to HIPAA, other state and federal laws, and MD Anderson policies, protect patient privacy.[4] Questions or concerns about compliance with these laws and policies should be directed to the Institutional Compliance Office at Institutional_Compliance@mdanderson.org or 713-745-6636.

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Literature reviews: Which type should I write?

– Kate Krause

There are over 1.8 million new articles added to PubMed each year. Literature reviews are a great resource for keeping up to date with the exponentially growing body of medical literature. They quickly provide an overview of a topic and can help practitioners make evidence-based decisions about their clinical practices. Here are the types of literature reviews that are the most common in medicine.

Traditional (or narrative) literature reviews gather and summarize the literature, usually journal articles, on a topic to give a comprehensive overview. They can also make conclusions and highlight areas that need more research. They allow a reader to quickly get an overview of a topic and stay up to date in an area. Because there are no official rules on how to conduct a traditional literature review, there is wide variety in their quality and transparency. In the past, authors didn't often disclose how or why they chose the articles they did. Today, it is much more common for authors to describe their search and selection process. For an excellent overview of how to write a literature review, watch the Research Medical Library's 30-minute webinar on [Writing an Effective Narrative Review](#).

Case reports with literature reviews present a patient's rare or unusual experience and place it in the context of the literature. Case reports often describe the presentation of a new disease, rare manifestations of a known disease, and unusual side effects of drugs. Case reports are often accompanied by a literature review describing
- what is already known about the topic,
- how the patient's particular case differs from what is already known, and
- the relevance and value of this case and how that adds to future practice.

For guidance on writing case reports, see the [CARE Case Report Guidelines](#).

State-of-the-art literature reviews describe the most current knowledge in a field. They often present a summary of how a particular field has developed over time and the seminal research that has impacted the field. They identify new and emerging trends, cutting-edge projects, priorities for future research, and the potential for new developments. For an example, see [Potential Biomarkers for Treatment Response to the BCL-2 Inhibitor Venetoclax: State of the Art and Future Directions](#).

Systematic literature reviews summarize clinical trials and other studies in order to answer a specific clinical question. They search for all the studies that have data answering the question and then use prescribed methods to evaluate the quality of the studies and summarize the data. If they find enough good-quality evidence, they make recommendations for practice and policy. In the past, most systematic reviews have concentrated on the effectiveness of interventions. Today, they are also used to answer several other types of questions regarding
- etiology and harmful effects of an intervention or exposure,
- prognosis (the likely progression of disease),

- diagnostic accuracy of tests and screenings,
- prevention effectiveness, and
- cost-benefit and economic evaluations.

For more information on how to conduct systematic reviews, see the [library's systematic review help guide](#).

Cochrane systematic reviews are internationally recognized as the highest-quality systematic reviews. Their reviews are vetted by the Cochrane Collaboration, an international organization created to facilitate high-quality reviews. Cochrane reviews follow extensive guidelines with stringent requirements and are written in a pre-determined structured format. For extensive guidance on writing a Cochrane systematic review, read the [Cochrane Handbook](#).

Meta-analyses are systematic reviews that combine the data from the included studies (usually randomized controlled trials) to increase the overall sample size and statistical power. Meta-analyses help clarify the inconclusive or disparate findings from multiple small clinical trials. They often use forest plots to summarize the statistical analyses. Meta-analysis can only be done with studies that have sufficiently similar types of data; all studies must measure the same intervention, patients, and outcomes in approximately the same way. For guidance on performing meta-analyses, see the Cochrane Handbook ([Chapter 10: Analysing data and undertaking meta-analyses)](#).

Rapid (or expedited) reviews use systematic review methods but set limits on the process to complete the review as quickly as possible. They are often used for emergency decision-making in critical situations, such as the onset of the COVID-19 pandemic. To produce results quickly, rapid reviews may employ slightly less stringent methods than systematic reviews. For example, they may
- search fewer journal indexes;
- narrow their search by geographical region, years, and languages;
- use fewer reviewers to select studies and extract data; and
- limit or eliminate the review of study quality.

For more information on how to conduct a rapid review, see the [NCCMT Rapid Review Guidebook](#) or the [Cochrane Rapid Reviews Methods guidance](#).

Mixed methods (or mixed studies or integrative) reviews are systematic reviews that include both quantitative (clinical trials) and qualitative (interviews, observations, and focus groups) studies. Unlike most systematic reviews, which focus only on the effectiveness of an intervention, mixed methods reviews try to give a more complete picture of the intervention, such as how patients experience the intervention and how the intervention can be adapted to specific contexts. They're often used in nursing research because they help practitioners determine how to best translate the evidence into practice. Mixed methods reviews can be difficult to conduct because of the heterogeneous nature of the included studies. This complicates the literature searching, quality assessment, data extraction, and data synthesis. For guidance, consult the [JBI guidance for mixed methods.](#)

Umbrella reviews are systematic reviews of systematic reviews. They compile evidence from existing systematic reviews and meta-analyses and are useful when there are already multiple systematic reviews on a topic with slightly different conclusions. Umbrella reviews are also useful when comparing multiple competing interventions, such as medication, diet, and exercise. For guidance, read [Umbrella Reviews: What They Are and Why We Need Them](#).

Scoping/mapping reviews identify the size, scope, and types of existing research on a topic to
- identify gaps in the literature to see where future research is needed;
- examine the extent, variety, and characteristics of the evidence on a topic; and
- determine if it's feasible to do a systematic review.

Like systematic reviews, scoping reviews require a comprehensive search, but they don't evaluate the methodological quality (risk of bias) of the included studies. For guidance, read the [Updated methodological guidance for the conduct of scoping reviews](#).

Interested in writing a literature review? Contact the Research Medical Library at RML-Help@mdanderson.org. Our knowledgeable staff can support you throughout the research, writing, and publishing process.

Finding examples of funded NIH applications

– Joe Munch

When it comes to preparing your NIH grant application, examples of funded applications can serve as useful models. In addition to often showcasing clean, focused writing, such examples can demonstrate other aspects of good grantsmanship, including how to use headings, subheadings, and paragraphs to organize text efficiently; how to include just the right level of detail in different sections; and when to use text, tables, or figures to convey ideas or present data. Examples of funded applications can also illustrate important technical details that can further improve readability, such as highlighting important information, providing sufficient white space, and sizing and placing figures and tables effectively.

Now, if only you could get your hands on one.

In seeking out examples of funded NIH grant applications, a good first step is to identify colleagues (or colleagues of colleagues) whose projects have received NIH funding and who might be willing to lend you a copy of their application. In addition to using personal and professional connections, you can use [NIH RePORTER](#), a searchable directory of information about active and inactive NIH projects, to identify principal investigators with NIH funding whom you can contact to request their applications or advice. (To be clear: inclusion in NIH RePORTER is a condition of receiving NIH funding, but sharing one's application with others is not.)

If you are unable to approach other researchers who might let you peruse their applications, the next best place to start is the [NIH sample applications webpage](), where you'll find links to many examples of funded applications, including [R, U, K, and F series applications]() from the National Institute of Allergy and Infectious Diseases (NIAID); [R series applications in behavioral research](), [cancer epidemiology](), and [implementation science]() from the National Cancer Institute's Division of Cancer Control & Population Sciences (as well as [R series applications in healthcare delivery research]() from the division); [R series applications in ethical, legal, and social implications research]() from the National Human Genome Research Institute; and [K99/R00 applications]() from the National Institute on Aging. The page also has links to [mock examples of scientific rigor]() and [a mock example of an authentication plan](). *Not* included on the page is a link to [examples of funded R01 and R21 applications]() from the National Institute on Deafness and Other Communication Disorders (NIDCD).

Many of the example applications provided by the NIH include only the Abstract, Project Narrative, and Research Plan (i.e., the Specific Aims and Research Strategy), but some also include Biographical Sketches and/or other attachments. Other example applications, such as those from the NIAID and NIDCD, are full applications.

Aside from the NIH itself, some research institutions can be good sources of examples of funded NIH grant applications. For example, you can find other examples of R series applications at the [Implementation Science Exchange](), a public service of the North Carolina Translational and Clinical Sciences Institute at the University of North Carolina at Chapel Hill. (This service also has some examples of grant applications funded by the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the Department of Veterans Affairs.) The University of Alabama at Birmingham has [examples of applications for R, K, and F series and other grants](), available for browsing, and the University of Toledo has a similar resource, offering [examples of R and F series applications](). In addition, MD Anderson's own Training Grants & Fellowships Office has a newly published [proposal library](), which provides many of the example applications mentioned above, plus more, organized by activity code.

If you cannot find an example application specific to the program to which you are applying, remember that applications for different grant programs have many overlapping elements, so you may still find it helpful and informative to look at a sample application from a different program. Keep in mind, too, that any examples of funded applications you find online were likely prepared in accordance with older NIH instructions, and you should always prepare your application in accordance with current NIH instructions. You should also consider that the way information is presented in a sample application may not be the best way to present information in your own application, so always allow time to solicit feedback from colleagues, mentors, editors, and others.

New NIH policy for data management and sharing now in effect

– Sunita Patterson

As reported in our [Summer 2022 issue](#), the NIH has launched a new Data Management and Sharing Policy to promote sharing of scientific data.[1] The new policy went into effect for grant applications with due dates on or after January 25, 2023. It applies to all applications covering research that will generate scientific data—for example, research projects and some career development (K) awards, but not training (T) or fellowship (F) awards.[2]

The policy encompasses data "of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."[1] A few examples of such data given in an August 2022 NIH webinar[3] were single-cell RNA sequencing of T lymphocytes or other immune cells in a study of HIV/AIDS, electrophysiological recordings and fMRI images in a study of a rodent post-traumatic stress disorder model, and step activity from a wearable device in a cardiovascular-health study. You don't have to share lab notebooks, preliminary analyses, case report forms, manuscript drafts, communication with colleagues, or physical specimens.[1]

The policy requires a detailed Data Management and Sharing Plan (DMSP) with a specified outline. Here are some helpful resources for writing the plan:
- [NIH information on writing a plan](#), including guidance on what to include in each section, a downloadable Word template, and a variety of sample plans;
- [Checklist](#) and [example](#) created by the Working Group on NIH DMSP Guidance;
- [DMPTool](#), an open-source online application for creating data-sharing plans for various funders, including NIH.

Some costs of data management and sharing can be built into your grant budget; examples are costs for data formatting, deidentifying data, documentation, preparing metadata, and deposit fees for data repositories.[4]

NIH has provided lots of information on its [website](#) and in a series of [webinars](#). You can also contact the [Research Medical Library](#) with questions.

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Unusual terms used in scientific writing and publishing: Person-first language

– Bryan Tutt

Person-first language (also called *people-first language*) is a set of principles writers can use to avoid dehumanizing patients—that is, to avoid describing them in such a way that deprives them of human qualities, personality, or dignity.[1]

Person-first language helps writers to avoid referring to people by a specific characteristic, particularly a disease or disability.[2,3] For example, "The study enrolled 20 epileptics" would be written as "The study enrolled 20 patients with epilepsy" in person-first language. Likewise, a population of people would not be described as "the disabled" but instead as "people with disabilities." The main idea behind person-first language is that a person's medical condition should not define who they are as a person.

Another aspect of person-first language is that it helps writers to avoid using terms that imply helplessness or pity. Thus, a person with cancer would not be described as a "cancer victim" or said to "suffer from cancer."[3]

In most cases, authors of biomedical papers should use person-first language. However, there are situations that call for *identity-first language*—that is, situations in which a characteristic is such an integral part of a person's identity that they prefer to be identified by it. Some disability advocates use identity-first language because they want to emphasize that their disability is a fundamental part of who they are. For example, people in the deaf community generally prefer to be referred to as "deaf" rather than "hearing impaired."[4]

When you're not sure whether to use person-first or identity-first language to describe a group of people, it's a good idea to look online to see how people in that community refer to themselves.[5] If you're still not sure, choose person-first language as your default.

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