

Clinical and Professional Ethics Guidelines for the Practice of Thyroidology

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INTRODUCTION

A VARIETY OF MEDICAL PROFESSIONAL SOCIETIES have developed ethics practice guidelines or position statements regarding specific ethics issues (1–6). The Endocrine Society published its Code of Ethics for practice in 2001 (1); however, none of the practice guidelines are specific to thyroidology. In the field of thyroidology, specific clinical ethics issues arise in different clinical contexts. For example, autoimmune thyroid disease raises different clinical ethics issues compared with thyroid oncology. Within thyroid oncology, each type of thyroid cancer raises unique and distinct clinical ethics issues and dilemmas. For example, the clinical ethics dilemmas that present in hereditary medullary thyroid cancer surrounding genetic screening are not the same as in thyroid cancers that are not familial or do not yet have defined germline genetic markers. The dilemmas associated with poorly differentiated and aggressive thyroid cancers (such as anaplastic thyroid cancer) and raising end-of-life issues such as code status, existential suffering, and palliative care are not the same that present in well-differentiated thyroid cancers that respond well to treatment. In many cases, there is clinical disagreement over what constitutes beneficent care for patients.

Additionally, new clinical ethics dilemmas are resulting from drug shortages (e.g., recombinant human thyrotropin), medical isotope shortages (e.g., ¹³¹I), as well as nuclear disasters where priority-setting guidelines for distributing potassium iodide are not in place or not identified.

Despite the prevalence of clinical ethics dilemmas in thyroid disease, clinical ethics guidelines specific to the thyroid disease context have been notably absent. Clinical ethics expertise can provide morally sound frameworks for (i) the nuances and complexities of diagnosis and treatment, and (ii) allocation of resources in situations where the demand is greater than the supply. The field of thyroidology comprises both clinical ethics and research ethics issues; in both arenas, complex professional

ethics and research integrity dilemmas may arise as funding for basic research shrinks, investigators move from clinical to corporate cultures, and competition for funding increases. Conflicts of interest are often poorly understood, which can range from financial to interprofessional conflicts of interest.

The clinical and professional ethics guidelines presented here are intended to provide clear guidance about specific, yet common, ethics dilemmas and questions that arise in this unique subspecialty. These guidelines mainly address two groups of ethics dilemmas that are typically encountered by thyroidologists: clinical ethics dilemmas—those that arise in the patient care setting; and professional ethics dilemmas—those that revolve around disclosure of conflicts of interest and professional integrity. These guidelines also provide clear guidance on research ethics issues, such as when innovative therapy becomes “research,” the role of an institutional review board, as well as publication and data-sharing integrity issues.

Finally, as enormous changes begin to take effect consequent to *The Affordable Care Act* (www.healthcare.gov/law/index.html), thyroid practitioners find themselves in a new clinical landscape involving numerous resource allocation decisions. As aggressive, non-iodine-avid thyroid cancer continues to rise in incidence, more questions about end-of-life care, palliative care, or clinical trial candidacy have arisen. We offer these guidelines in recognition of this unique subspecialty that confronts wide clinical and research diversity.

METHODS

In 2011, The American Thyroid Association (ATA) Ethics Committee agreed that an ethics guideline was necessary and useful for practice, and undertook the process of reviewing the 2001 Endocrine Society’s Code of Ethics to see if it could be adopted in its entirety as a “Code of Ethics” for the ATA. After rigorous review and the undertaking of a separate literature review, there was consensus that this document was outdated

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from a bioethics perspective, and contained few relevant guidelines specific to thyroidology. The document was then considered as a model framework from which to craft an original ethics guidelines for ATA members and the thyroidology community. This article did not arise as an effort from the ATA Board of Directors in which a task force was appointed to create guidelines. Instead, this article is a product of independent authorship, in which a group of authors, through common scholarly interests and goals, independently collaborated to fulfill a need for their peers in response to a noticeable absence of meaningful ethics guidelines for this subspecialty. Authorship roles followed the guidelines established by the International Committee of Medical Journal Editors (ICMJE) for authorship and contributorship. Several drafts of the document circulated among ATA Ethics Committee members throughout 2011–2012. A final draft was circulated to the ATA Board of Directors for review and commentary in 2012 to seek the ATA's opinion, endorsement, and adoption. These guidelines were ultimately approved in 2013 by the ATA Board of Directors and are presented here as the first formal set of ethics guidelines for thyroidology.

Authorship

The group of authors, all ATA members except one (S.G.F.), included three bioethicists with doctoral degrees in bioethics who direct clinical ethics and academic bioethics programs at their institutions (M.S.R., S.G.F., and P.A.). M.S.R. and S.G.F. are full-time humanities-based bioethicists and direct their institutions' bioethics programs. P.A. is both a bioethicist and practicing endocrine surgeon and codirects the surgical ethics program for his institution. The senior author (G.D.B.) and all other coauthors in the group are practicing endocrinologists with subspecialties in thyroidology and are based in either large university hospitals or other medical settings. The senior author and Committee Chair (G.D.B.) selected a first author (M.S.R.) to generate the article and incorporate the various levels and layers of comments at various stages. The coauthors each provided substantive changes, detailed comments, and/or careful peer review of the article, making unique and/or significant contributions.

BACKGROUND

Thyroid disease specialists play an important role in all aspects of medical treatment across different patient populations: preventive care through screening for thyroid diseases; acute care in managing and treating thyroid diseases; as well as end-of-life care, in some contexts. Patients comprise adult, prenatal, and pediatric populations. Providing the best care for patients entails more than simply providing interventions that make physiological sense; interventions should also be consistent with well-established core ethical principles (7) and concepts relevant to medical practice. The first is the Principle of Respect for Persons, which obligates healthcare providers to respect autonomous patients' wishes and to guide care in accordance with patients' values, beliefs, and preferences. In situations where patients are not fully autonomous because they lack decision-making capacity, this principle obligates healthcare providers to seek a surrogate decision-maker to make a substituted judgment consistent with the patients' stated preferences or values if known, or, if not known, to make decisions that are in the patients' best interests. In situations where an Advance Directive is applicable [see Section II], it may guide patient care. To fulfill this

obligation, the Principle of Respect for Persons further requires that valid informed consent to treatment is sought from patients or their surrogate decision-makers [see Section II].

The Principle of Beneficence, a second core ethical principle, obligates practitioners to improve patient well-being by maximizing clinical benefits and minimizing clinical harms. When balancing benefits and harms, healthcare providers must recognize that there may be limits to patient autonomy and what physicians should offer as therapeutic—especially when patients request (or demand) interventions otherwise judged to be medically ineffective and/or inappropriate.

The third core ethical principle, the Principle of Non-Maleficence, obligates practitioners not to cause or introduce intentional harms for which there is no expectation of resulting greater benefits, not to neglect patients, and to warn identifiable third parties if the patient is known or perceived to pose certain threats or risks to third parties. Under this principle, medical error (unintentional harms) should be fully disclosed to relevant parties.

The Principle of Justice is the fourth core ethical principle, which, in the clinical context, concerns access and barriers to healthcare. This principle is concerned with resource allocation, priority-setting, and ensuring that patients are treated equally without discriminatory practices based on such matters as income, psychosocial issues, health insurance coverage, age, cultural backgrounds, sex, or sexual orientation.

Thyroid disease specialists should provide care consistent with these core ethical principles, but also recognize that patient care occurs within a framework defined by an array of values: personal, professional, institutional, economic, religious, cultural, and societal. When considered along with factors such as education, literacy and numeracy, and communication skills, these may present additional barriers to good decision making and lead to conflicts. Some conflicts arise between healthcare providers who disagree about approach, while others occur between patients/family members and their healthcare providers. Whenever such conflicts occur, a clinical ethics consultation should be sought, if institutionally available. If a clinical ethics consultation service is not available, advice may be sought by contacting The American Society of Bioethics and Humanities (www.asbh.org).

I. PROFESSIONAL ETHICAL DUTIES TO PATIENTS

(a) Equality

Patients should be treated respectfully and equally, regardless of health status, socioeconomic, cultural, and religious backgrounds, age, insurance status, lifestyle, or gender. For example, while cultural competence is now typically part of hospital culture, patients with obesity, or those with a history of addictions, frequently report overt discrimination by healthcare providers.

(b) Competence

Physicians have an ethical and legal duty to remain competent in their field, and not to cross practice boundaries without sufficient training or knowledge. When appropriate, referral to other subspecialists who may be better able to meet a patient's needs respects physician integrity and veracity. For example, physicians with no training in endocrinology should not promote themselves as thyroid specialists.

Additionally, physicians have an ethical duty to provide competent care transition, which may require that more time is made available to properly communicate patient care needs to transitioning healthcare providers or trainees. For example, endocrine residents who are working within a maximum hour limit still have an ethical duty to safely “hand off” their patients to the incoming provider team.

(c) Cultural Values

Religion and culture are valid reasons for refusal of treatments by autonomous adult patients. When parents invoke religious or cultural reasons for limiting treatment for their children, however, efforts must be undertaken to ensure the legitimacy of those decisions; ethics and legal consultations should be sought (8). For example, parental refusal to provide thyroid hormone therapy to a child who has had a thyroidectomy would require such a consult and the involvement of child protective services.

(d) Physician–Patient Communication

Physicians must be available to communicate with patients. Social networking venues, however, should be carefully considered and cleared with institutions and legal counsel, as they provide several opportunities for breaches in confidentiality. For example, physicians should not “friend” their patients on Facebook or post details of patient encounters on Facebook, even if overt personal health information is removed.

(e) Conflicts of Interest

Conflicts of interest and duality of commitment exist when there is a financial or other reward (*e.g.*, personal inurement) attached to a project or research, which poses a threat to patient welfare, or the Public Trust, or to the Professional Community with which the physician enjoys membership. Perceived conflicts of interest and duality of commitment must be considered to be potentially as problematic as actual conflicts of interest or duality of commitment, as the consequences of each may be identical. All relevant conflicts must be disclosed to patients, a faculty member’s institution, and societies and venues in which the individual is invited to speak or serve in a decision-making or authoritative role. [See Section IV for more details on relationships with industry.] For example, enrolling your patient in your own clinical trial testing Drug A when the patient may be a more suitable candidate for a colleague’s clinical trial testing Drug B would only be ethically permissible if you fully disclosed your conflict to the patient and the availability of a clinical trial with Drug B.

(f) Sexual Relationships

Engaging in flirtation, “sexting,” or sexual relations with patients or those individuals supervised by physicians or scientists is considered to be frank ethical misconduct until the therapeutic, employment, or mentorship relationship has formally ended.

(g) Privacy and Confidentiality

Compliance with the Health Insurance Portability and Accountability Act, and its Privacy Rules (Public Law 104–191) is ethically and legally required unless circumstances warrant

mandated reporting or a specific Duty to Warn (*e.g.*, child or elder abuse, threats to a third party). In thyroidology, genetic screening issues are particular concerns. [See Section II(g).]

(h) Treatment of Family Members

There is broad professional consensus that physicians should not treat family members because of serious conflicts of commitment that may interfere with objectivity and sound medical care (9). There are, however, situations where it is permissible to treat immediate family members, such as in an emergency or in isolated settings where no other physician is available, or when the medical intervention is of significantly low risk in relation to potential benefits (9). In the context of thyroid disease, there may be no thyroid expert available in some geographic areas; in such instances, it would be permissible to establish peer oversight with a similarly trained clinical colleague to review treatment plans and goals and correct problems caused by subjectivity or bias.

(i) Maintaining Ethical Integrity in Unethical Environments or Cultures

Thyroid practitioners work in a variety of settings, where institutional culture may not foster ethical integrity, leading to moral distress, a situation in which the practitioner knows what is morally required, and the ethical course of action, but is constrained from acting on it. These constraints may come from within the corporate/hospital culture; risk management; or from wider government in which program cuts or insurance affect patient care. Thyroid practitioners in these circumstances are encouraged to discuss concerns with their supervisors and other members of institutional management, recognizing that they may have additional legal protections under The Whistleblower Protection Program (www.whistleblowers.gov). If necessary, members of the ATA Ethics Committee may be consulted for further guidance.

II. CLINICAL ETHICAL DUTIES AND CONSIDERATIONS

(a) Informed Consent

The components of valid informed consent comprise full disclosure of diagnosis, and planned therapies for autonomous patients. Consent is invalid if the patient does not have decision-making capacity, which means that the patient must demonstrate Understanding, Appreciation, Rationality, and Expression of a choice or preference (U-ARE) (10). Some patients may require a capacity assessment, which may need to involve a psychiatric consultation. Practitioners must recognize that there are many barriers to capacity, which, in thyroidology, may include severe hypothyroidism (11) or thyrotoxicity, other metabolic or physiologic barriers, psychosocial barriers, which include literacy and numeracy, and untreated mental illnesses. Informed consent is ethically and legally required for all planned therapies. A signature on a consent form does not necessarily mean that valid informed consent has occurred and can be challenged in the courts if the practitioner has not documented verbal discussion with the patient about therapies and procedures as well as warnings about precautions while undergoing therapies (12). For example, Graves’ disease patients frequently do not understand or appreciate that a consequence of ¹³¹I therapy is hypothyroidism, even if they seem to understand that the goal of

therapy is to “ablate” the gland. In this case, while they may understand what ablation means, they may not appreciate that hypothyroidism follows ablation as a natural consequence.

Patients who do not have decision-making capacity require a surrogate decision maker. Some states have family hierarchy laws, while others do not. Guardianship may need to be pursued for patients who lack decision-making capacity, have no Advance Directives, and have no family. Practitioners should seek a legal or ethics consultation if there are questions about who may serve as a surrogate or how to proceed when a patient lacks decision-making capacity. In such situations, treatment decisions should be guided by patient preferences and values if known (substituted judgment), or, if not known, by a best interest standard. For example, patients who are severely hypothyroid may not have sufficient decision-making capacity until they are euthyroid, which would necessitate involving a surrogate decision-maker until their thyroid levels were restored.

(b) Informed Refusal and Noncompliance in Thyroidology

The Principle of Respect for Persons obligates physicians to respect the preferences of autonomous patients. This means that patients may accept *or* refuse recommended treatments. Practitioners may disagree with patients’ refusals, but disagreement does not entitle physicians to override such refusal. In cases where a thyroid patient’s noncompliance (a.k.a. nonadherence*) places third parties at risk or in harm’s way (as in cases where severely hypothyroid patients are driving; or patients refuse to follow post-radioactive iodine treatment guidelines), physicians do have an ethical and legal Duty to Warn (11,14). In the pediatric context, parents usually do not have the legal or ethical right to refuse life-saving treatments for their child (such as refusing treatment for hypothyroidism, hyperthyroidism, or thyroid cancer). In such cases, both ethical and legal consultation should be sought. In some circumstances, the Harm Principle may be invoked as the theoretical threshold for seeking state intervention and removal of parental authority (15,16).

(c) End-of-Life Decision Making in Thyroidology[†]

End-of-life decision making generally arises in the context of patients suffering from aggressive thyroid cancer that no longer responds to treatment. For such patients, advance care planning should occur, with all of the following options discussed.

i. **Prognosis.** The patient’s prognosis, both with and without disease-targeted treatment, is a key factor in end-of-life decision making.

*Some bioethicists favor the term “nonadherence” instead of “noncompliance” as a way of emphasizing how psychosocial factors (e.g., personal resources, social supports, or nontraditional coping strategies) influence patients’ abilities to follow medical recommendations (13).

[†]The reader is also referred to the American Thyroid Association guidelines for management of patients with anaplastic thyroid cancer (17).

ii. **Treatment options.** The patient has the right to accept, refuse, or withdraw from any offered treatment, including life-sustaining treatment. The patient also has the right to receive disease-targeted treatment or to participate in a clinical trial, if an appropriate trial is available.

iii. **Code status and preferences regarding nutrition, hydration, and intubation.** Patients may elect to have cardiopulmonary resuscitation initiated in the event of acute cardiopulmonary arrest (full code status). However, cardiopulmonary resuscitation is not legally or ethically required when it is medically inappropriate. Patients may also elect to have cardiopulmonary resuscitation withheld, in which case a DNR/DNAR (do not resuscitate/do not attempt resuscitation), or AND (Allow Natural Death, a newer term that some institutions use) order is appropriate.

iv. **Palliative care.** The patient has the right to receive palliative care (including palliative surgery and radiation), as well as comprehensive pain and symptom management. Discussing the option of palliative care is now legally required in some states (such as New York State’s *Palliative Care Information Act*).

v. **Hospice care.** Distinct from palliative care, the option of hospice care should be discussed.

vi. **Physician/Medical Orders for Life-Sustaining Treatment.** Physicians may develop Physician/Medical Orders for Life-Sustaining Treatment (POLST/MOLST), which can incorporate patient preferences while recognizing the nuances of medical care that Advance Directives typically cannot. POLST orders follow the patient to various institutions, and forms may be obtained through www.polst.org.

vii. **Advance Directives.** Patients may have Advance Directives, but such documents do not always accurately or fully reflect patients’ preferences. It is for this reason that even if a patient presents an Advance Directive, it is vital that physicians engage in direct and explicit conversation with the patient about his or her end-of-life preferences; an Advance Directive does not replace an Advance Care Planning discussion.

(d) Withholding and Withdrawal of Treatment

At any time, autonomous patients who have decision-making capacity or the surrogates for patients who lack decision-making capacity (who are not autonomous) may request the withholding/withdrawal of treatment, including life-sustaining treatments. Additionally, practitioners have the ethical and legal right to withhold or withdraw any treatment, which, according to the best medical judgment and practice standards, is considered to be medically ineffective and/or medically inappropriate (18).

(e) The Principle of Double-Effect

It is well recognized and accepted that, in the context of a patient’s end of life, it is permissible to provide medications for the sake of the relief of pain and/or suffering even if the consequence may result in hastening an anticipated and inevitable death. However, if the intent of providing such

medical intervention is simply to hasten the patient's death, except in states with explicit Physician Aid in Dying laws, it is not legally permitted (19–22).

(f) Management of Fertile Female Patients

i. Prenatal patients and fetal patienthood. In pregnant patients, it is generally accepted that a previsible fetus is considered to be a patient when the pregnant patient "presents" her fetus as a patient (23,24). She does this by declaring her interest in her fetus' well-being, thus establishing "fetal patienthood" in which the previsible fetus is morally considered. In this scenario, the practitioner thus has a dual obligation to offer care that maximizes clinical benefits and minimizes clinical harms for both the mother and fetus. In this context, the practitioner must weigh the consequences of screening or not screening for thyroid disease, and treatment of thyroid disease on the developing fetus (25). Viable fetuses, on the other hand, are typically assumed to be patients unless there are extraordinary circumstances. With the viable fetus, avoiding those harms not clearly outweighed by potential benefits is essential.

ii. Fertility patients. Patients undergoing fertility treatment may also present their not-yet-implanted embryos as "patients" (26); in this context, there is an obligation to evaluate the consequences of various tests or thyroid disease treatments on the success of implantation.

(g) Genomic Issues in Thyroidology

Genetic screening in the context of thyroid disease is typically done in cases of hereditary medullary thyroid cancer, which refers to familial medullary thyroid cancer and medullary thyroid cancer arising from MEN 2 syndromes (MEN 2A and MEN 2B). There are many psychosocial barriers to genetic screening, which must be recognized. Patients who are suspected of being carriers of mutations responsible for hereditary medullary thyroid cancer should be recommended for genetic screening and genetic counseling with a certified genetic counselor, as surveys demonstrate that many practitioners are not trained in proper genetic counseling. The following should be considered in patients undergoing genetic screening:

i. Positive results and psychosocial consequences. When considering genetic testing, the patient/proband and affected family members should be fully informed about the potential for psychosocial harms consequent to positive results, which could include emotional distress and genetic discrimination. Practitioners involved in such cases should become familiar with the *Genetic Information Nondiscrimination Act* (Public Law 110–233), which is intended to protect individuals against the misuse of genetic information for health insurance and employment (27).

ii. Potential for false-positive or false-negative results. The informed consent discussion should also include information about the meaning of negative or inconclusive results; the risk of false-negative or false-positive results or other laboratory errors; as well as the technical limitations of genetic testing (28).

iii. Duty to warn. Patients may refuse genetic screening and counseling, but if there is compelling evidence that such patients may represent a large kindred, ethics consultation should be requested for the sake of assessing whether there is an ethical duty to warn at-risk third parties. Legal counsel may also need to be engaged. In cases where patients who test positive for mutations but choose not to disclose their results to at-risk relatives, ethics consultation should be requested for the sake of assessing confidentiality obligations when there is an ethical Duty to Warn (14).

iv. Screening in pediatric populations. Practitioners dealing with genetic testing in pediatric populations should be familiar with the guidelines published by the American Society of Human Genetics and the American Academy of Pediatrics (29). Such guidelines recommend deferral of genetic testing in children that offers no potential benefit until adulthood. In cases where there are pediatric patients at high risk of developing medullary thyroid carcinoma in childhood, practitioners should refer to the specific pediatric ethics guidelines regarding medullary thyroid carcinoma (16), which, in some cases, may warrant removal of parental authority and involvement of Childhood Protective Services.

v. Obtaining genetic material for research. Gene sequencing, establishing cell lines, or other tissue collection cannot be done without valid informed consent and, potentially, institutional review board approval if such material is to be used for data collection, data sharing, and research (30).

(h) Clinical Equipoise

A state of "clinical equipoise" (31) exists when a community of experts responsible for setting the standards of care is uncertain whether treatment A is better than treatment B. Thus, clinical equipoise provides the ethical basis for conducting a randomized controlled trial of the two interventions in order to resolve the question about which is superior. In current thyroidology, clinical equipoise exists when there is disagreement among the community of thyroid experts in approaches to treatment of various thyroid diseases. There is a duty to resolve clinical equipoise to improve patient well-being without doing harm, but this can only be done through properly designed randomized controlled trials with enough statistical power to disturb clinical equipoise. So long as a state of clinical equipoise exists, however, practitioners may have an ethical obligation to inform patients regarding other medically appropriate or reasonable approaches available as part of the informed consent process. For example, in a thyroid cancer patient with recurrent iodine nonavid tumors in the neck, who has already undergone surgical resection, some practitioners may offer external beam radiation therapy, whereas others may not, preferring to monitor. Each practitioner may be convinced s/he has the correct approach. However, in these cases, patients have a right to know that there are two different approaches, and have the right to choose. In a different example, for patients with severely thyrotoxic Graves' disease and advance orbitopathy, some practitioners may offer radioactive iodine therapy with systemic steroids, whereas some might elect to do a thyroidectomy to alleviate thyrotoxicosis so as not to aggravate thyroid eye disease. Both practitioners may be convinced that they are

correct in their approach, but patients have the right to know both approaches.

III. ETHICAL CONSIDERATIONS ASSOCIATED WITH RESEARCH IN THYROIDOLOGY

(a) *Research Ethics*

ATA members are expected to follow national guidelines with respect to the Responsible Conduct of Research, as well as nationally established ethics and regulatory guidelines in human subject research (32–34). Research ethics issues also may arise in authorship, peer review, and in editorship of publications.

i. **Authorship.** The ATA supports authorship and contributorship criteria established by the ICMJE (www.icmje.org). ATA members are encouraged to become familiar with the ICMJE authorship guidelines. Authorship misconduct occurs when data are fabricated; another author's published or unpublished work is significantly paraphrased, or quoted without citation (plagiarism); and credit is not attributed to the work of students or other mentees. Authorship integrity is also compromised by practices such as ghostwriting or by adding authors who did not contribute for political gain. When a citation oversight is brought to the corresponding author's attention, it is the corresponding author's responsibility to contact the journal editor and arrange an erratum or correction.

ii. **Peer review.** Unbiased, independent peer review is critical for scientific integrity. In a small expert community, conflicts of interest must not interfere with peer review. Blocking publication of competitive research by rejecting it for disingenuous reasons violates scientific integrity.

iii. **Editorship.** The ATA supports the ICMJE's criteria for ethical editorship, which includes the responsibility to publish negative results that may financially compromise a sponsor or close colleague; or question articles that raise suspicions about the Responsible Conduct of Research, authorship integrity, and conflicts of interest; and to question reviews that appear dishonest or biased.

(b) *Innovative Therapy versus Research*

Practitioners have a responsibility to use evidence-based therapies that at least meet the threshold of the standard of care. Nonstandard interventions using off-label medications or other unproven modes of treatment are considered "innovative" if they are planned for a single patient, data are not to be collected, and there is no intent to produce generalizable knowledge. With respect to surgical innovations (*e.g.*, robotic thyroidectomy), the Society for University Surgeons defines surgical innovation as "a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient" (6). When innovative interventions are recommended, patients must be fully informed that the recommended treatment is "innovative" and not standard of care; innovative interventions may be believed to be superior, but until sufficient evidence from well-designed clinical trials demonstrates such interventions are actually an improvement

over the standard of care, they remain innovative. Nonstandard treatments intended for data collection and data sharing for generalizable knowledge are considered experimental and must be provided under protocols for which institutional review board approval has been granted. In these cases, the practitioner becomes an investigator, and must follow research ethics guidelines for human subject experimentation (32,33).

IV. INDUSTRY RELATIONSHIPS AND CONFLICTS OF INTEREST

Since the ATA is accountable to the public trust, its members have a professional ethical duty to disclose all potential or perceived conflicts of interest surrounding relationships with private industries, including, but not limited to, drug and device manufacturers, biotechnology companies, diagnostic testing companies, and for-profit healthcare companies. Manageable conflicts of interest are defined here as manageable to the ATA, in which transparency and disclosure deal with most perceived and/or actual conflicts of interest without interrupting member activities or service on the ATA. Unmanageable conflicts of interest are defined here as conflicts that can be manageable only through recusing members from serving on some or all ATA committees, which may also extend, in some cases, to presenting.

(a) *Manageable Conflicts of Interest*

Manageable conflicts of interest are those in which the relationship between industry and the ATA member is indirect. In these cases, no direct monies are paid from industry to the practitioner involved; funds, for instance, are paid to the institutions for which the practitioners work. Most, but not all, spousal connections to industry are likely manageable.

i. **Management through disclosure.** Managing a conflict of interest involves transparent disclosure of the relationship on all intellectual products, including presentations and publications.

ii. **Speaker and consulting fees.** These are generally manageable conflicts with disclosure and transparency. In cases where speaking and consulting fees to industry are part of a continuous service contract, recusal from some activities may be necessary.

(b) *Unmanageable Conflicts of Interest*

Unmanageable conflicts of interest involve a direct relationship or direct benefit between the Member and Industry that results in direct payments or personal inurement. ATA members who are employees or shareholders in biotechnology, medical device, pharmaceutical, or any other companies or industries that influence the treatment of thyroid disease are not appropriate candidates to serve on ATA committees or projects that set standards of care or influence patient care. Since these industries may be financially and intellectually entangled, and may not disclose all entanglements, all members with direct ties to these industries must be deemed to have at least the potential for a perceived conflict of interest and, as such, have the potential to erode, rather than uphold, public trust in the ATA. Such members must place the ATA's

interests and its relationship with the public at a higher priority. Additionally, it is also an unmanageable conflict if the member owns a patent or business that is competitive and could in some way use confidential intellectual information that s/he would be privy to as a member of an ATA committee to personally profit.

Note: for nonfinancial conflicts of interest, see Section I.

V. ETHICAL CONSIDERATIONS REGARDING RESOURCE ALLOCATION, RESPONSIBLE STEWARDSHIP, AND WHISTLE BLOWING IN THYROIDOLOGY

(a) Stewardship

As in any clinical specialty, ATA members should be responsible stewards of healthcare resources and be mindful of unnecessary or excessive testing, and should not offer medically inappropriate treatments. At the same time, patients should not be neglected or abandoned because they have no ability to pay.

(b) Scarce Resources

Common therapies and drugs used in thyroid treatment may, at times, become scarce resources. Shortages in medical radioisotopes, and recombinant human thyrotropin are examples of common treatments that may require rationing or priority-setting protocols (35). In most cases, rationing protocols that produce the greatest good for the greatest percentage of patients are ethically justified. Alternative priority-setting protocols that emphasize who can best pay for the resources, "first come, first served," or patients' insistence on the scarce resources demand ethical justification before considering their adoption.

(c) Potassium Iodide Distribution

Potassium iodide distribution in areas in proximity to nuclear power plants, or in the aftermath of a nuclear disaster, should be guided by a similar framework for producing the greatest good for the greatest percentage of people with the aim of reducing panic buying in a nuclear incident. In this context, ATA members may need to work with government agencies and the press to help guide responsible distribution.

(d) Reporting Ethical Misconduct

Practitioners have a professional ethical obligation to report frank ethical misconduct or professional incompetence to their professional associations in cases where misconduct or incompetence is compromising or endangering patient care (36). Examples may include sexual relations with patients; incompetence, where practitioners are not proficient, crossing practice boundaries, or practicing thyroidology with no knowledge or training; enrolling patients in unregulated clinical trials in violation of research ethics guidelines; or using innovative therapies that may introduce iatrogenic or other harms without any scientific basis. An example of inappropriate whistleblowing includes situations where there is honest, professional disagreement. Although each member of society should feel an obligation to report illegal or fraudulent activities to the appropriate authorities as a citizen, if such

activities are unrelated to patient care, there is no professional obligation to report these activities.

SUMMARY STATEMENT

We present these guidelines to help thyroid practitioners navigate through various ethical issues and dilemmas that present in clinical practice, research practice, and interprofessional relationships with both colleagues and industry. These guidelines are a product of independent authorship by members of the ATA Ethics Committee, which have been endorsed by the ATA Board of Directors. It is our hope that these guidelines can help to introduce ethics into the everyday discourse of our thyroid practitioner colleagues, but as all guidelines, they are consensus suggestions for practice, which may not apply to all clinical, research, or professional situations.

AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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