Conflicts of Interest in Clinical Practice: Cleveland Clinic Policy and Experience

Kathleen A. Derwin[1], *Cory Anand*[2], *Susannah L. Rose*[3], *and Raed Dweik*[1]

1. THE CLEVELAND CLINIC, CLEVELAND, OHIO, USA. 2. CITY OF HOPE, DUARTE, CALIFORNIA, USA. 3. VANDERBILT UNIVERSITY, NASHVILLE, TENNESSEE, USA.

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Abstract: The Cleveland Clinic Innovation Management and Conflict of Interest ("IM&COI") Program implemented a policy on Conflicts of Interest in Clinical Practice in 2013. The policy requires review of financial interests greater than $20,000 in a year, or more than 5% equity in a company, when the clinician is prescribing or using products of the company with which they have a relationship. The IM&COI Committee developed definitions for low, medium and high levels of annual compensation and risk and uses a "Matrix" to guide disclosure based on these factors.

Financial relationships between clinicians and pharmaceutical, device and biotechnology companies are common.[1] These relationships can be essential to usher early discoveries from the laboratory to clinical trials to ultimately benefit patients as part of standard care. However, they create conflicts of interest which may increase the risk of bias in clinical decision-making related to the company with which the clinician has a relationship, which may in turn increase risk to patients. Many studies have identified associations between payments from industry and a practitioners' prescribing patterns to favor the company or product with which they have a relationship.[2] Physicians are more likely to prescribe the product for which they have a financial relationship over competitors' products, and physicians are more likely to prescribe the name brand product over a generic alternative[3] across a wide range of clinical practice areas, including oncology, urology, heart disease, diabetes, orthopedics and many more.[4] These prescribing practices related to conflicts of interest may therefore also be linked to increased costs,[5] which raises additional ethical concerns.

There is a paucity of published literature on conflicts of interest in clinical practice and institutional policies. Currently, there is no federal regulation on conflicts of interest in clinical practice (excluding illegal activities such as Stark Law or Anti-Kickback violations, which are outside the scope of this manuscript). In 2010, the Association of American Medical Colleges ("AAMC") released a report, "In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making."[6] The authors note, "The presence of individual or institutional financial interests in the patient care setting may create real or perceived bias in clinical decision making and may distort the values of medical professionalism. The interests of the patient are

Kathleen A. Derwin, Ph.D., *is Associate Staff and Vice Chairman of the Department of Biomedical Engineering and a Vice Chairman of the Innovation Management and Conflict of Interest Committee at the Cleveland Clinic.* **Cory Anand, J.D.,** *is System Director, Conflict of Interest, City of Hope.* **Susannah L. Rose, Ph.D.,** *is Core Faculty, Center for Biomedical Ethics and Society and Associate Professor in the Department of Biomedical Informatics, Vanderbilt University Medical Center.* **Raed A. Dweik, M.D., M.B.A.,** *is the E. Tom and Erica Meyer endowed Professor and and Chief of the Integrated Hospital Care Institute (IHI) and Professor of Medicine in the Cleveland Clinic Lerner College of Medicine.*

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at stake, as is the trust of the public."[7] In light of this, the AAMC appointed a task force to review and make recommendations on academic medical centers' policies and practices regarding conflict of interest (COI) in the practice of medicine.

Following review of the current state in 2010, the task force called for academic medical centers to promulgate procedures for the evaluation and management of conflicts of interest in clinical care. The recommendations included a description of which types of financial interests should be considered for review and stated that a threshold for reporting as well as the circumstances under which the relationship should be disclosed to a patient should be delineated. While most institutions have rigorous policies addressing conflicts of interest in research, which are generally grounded in National Institutes of Health and other funding agency rules and regulations, at the time of the AAMC's report, few academic medical centers had adopted policies on COI in clinical practice.[8] The AAMC report urged transparency regarding these relationships, including public disclosure by academic medical centers as well as by the Centers for Medicare and Medicaid Services pursuant to the Patient Protection and Affordable Care Act of 2010.[9]

In 2008 the Cleveland Clinic began to publicly disclose its physicians' and scientists' relationships with industry as a section of their biographies at myclevelandclinic.org, and many other institutions have since adopted public disclosure practices as well. Further, recommendations in the 2009 Institute of Medicine report[10] led many organizations to restrict speakers bureaus, ghost authorship and industry representative provided meals and gifts.[11] Yet even now, more than a decade later, widespread adoption of disclosure to patients is lacking, as is consistency in clinical practice policies amongst institutions. Furthermore, there are no reports on the experience or findings of these policies by the institutions that have implemented them.

Torgerson and colleagues discuss in their article entitled, "Ten Years Later: A Review of the US 2009 Institute of Medicine Report on Conflicts of Interest and Solutions for Further Reform" that little has been done to assess methods for managing such conflicts of interest in clinical practice and more research is needed in this area.[12] One study conducted at our institution indicated that disclosure of COI can have counterintuitive impacts on disclosure recipients, including increased trust and increased reliance on the advice of conflicted advisors.[13] We conducted a randomized experiment with patients and their physicians to assess the impact on physicians' disclosures of COI and messaging on patients' knowledge and trust. We found that a mailed disclosure significantly improved patients' knowledge of their physicians' COIs, and patients wanted to know this information. However, these disclosures, even when the risk and benefits were highlighted to patients, did not affect their trust in the physician or in the hospital. Importantly, when patients were *unsure* of their physicians' COI, they experienced reduced trust in their physician.

To assess the impact of the Physician Payments Sunshine Provision of the Affordable Care Act, Dr. Pham-Kanter and colleagues reported that preexisting states' disclosure laws had only a small impact on patient awareness of physicians' conflict of interest.[14] More recent investigations of the national Open Payments website have demonstrated that while patients had an overall increased awareness that such information was available, the disclosures had little to no impact

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on patient knowledge of their physicians' conflicts of interest.[15] These findings are leading experts in the field to be skeptical of the impact of the passive disclosure approach offered by the Open Payments Database.[16]

In 2013, Cleveland Clinic developed a formal policy addressing financial interests related to a clinician's practice of medicine, titled "Conflicts of Interest in Clinical Practice." Our policy is rooted in our research demonstrating that more transparency appears to be better in terms of patient perspectives.[17] The purpose of this paper is to describe the Cleveland Clinic's policy and recent five years of experience making Clinical Practice COI determinations to aid other organizations in their efforts to develop or enhance their policies and procedures regarding management of COI related to clinical practice.

Methods

Cleveland Clinic is a non-profit academic medical center and hospital system with 19 hospitals and over 70,000 employees worldwide, including more than 4,500 physicians and scientists and approximately 3,000 advanced practice providers. Under Cleveland Clinic's policies on conflicts of interest, employees who need to disclose are identified based on their role at Cleveland Clinic and their ability to make decisions regarding clinical care, research, business or education on behalf of Cleveland Clinic. Included in the disclosing population are physicians, researchers, managers, fellows, advanced practice providers (nurse practitioners, physician assistants and certified registered nurse anesthetists), pharmacists, and certain other administrative groups such as law, audit, and technology transfer. There is a zero dollar de minimis for disclosure, and the disclosures are made via a customized online disclosure system hosted and developed by Huron Consulting Group. Currently, more than 12,000 employees are required to submit financial interest disclosures at least annually and also whenever there is a material change to their financial interests.

Cleveland Clinic's COI in Clinical Practice Policy

Cleveland Clinic's COI in Clinical Practice policy requires that the organization's IM&COI Program review and approve provider's financial interests greater than or equal to $20,000 in the previous 12 months (excluding meals and other travel reimbursement), or greater than 5% equity in the company, if the financial interest is in a company making drugs, devices or other products being used by or at the direction of the provider. The threshold was selected based on informal benchmarking with other academic medical centers at the time the policy was drafted. While it is recognized that even gifts of nominal value may affect behavior,[18] organizations also must contemplate the associated administrative burden and risk. Absent a regulatory requirement, many organizations struggle in defining the point at which review or management of a potential conflict of interest is appropriate.

Cleveland Clinic's IM&COI Program consists of the conflict of interest office, the COI Triage Group, which consists of the office and select members of the Committee, and the full IM&COI Committee. The office does not make any determinations regarding clinical practice, but screens which disclosures need to be reviewed. All decisions are made at either the level of the COI triage group or the full IM&COI Committee (**Figure 1**).

During review, each conflict is assigned a Compensation Level and Risk Level (low, medium, high), defined according to **Table 1**. The rationale for the various levels of compensation was largely arbitrary, but based on the tolerances of the IM&COI Committee members. Risk Levels were prospectively defined based on the clinical judgment of the IM&COI members. They were intentionally broad and representative, since the full scope of clinical activities could not be anticipated or described. For example, use of commonly used drugs or supplies/built-in equipment was considered a low risk clinical activity, whereas prescribing drugs with "toxic" side effects or performing minimally invasive procedures was considered medium and performing invasive surgery or procedure was considered high risk.

Each conflict is then assigned a Disclosure Level based on its Compensation and Risk Levels (**Table 1**). The Disclosure Determination Matrix_1 is used as a guide for disclosure, but an alternate Disclosure Level can be assigned if deemed more appropriate. Disclosure Level 2 requires either verbal or written disclosure and documentation of having done so, however the choice is left to the individual to choose the means that is most conducive to their practice. In instances where Disclosure Level 3 is recommended by the Matrix but the clinical practice does not involve a procedural Informed Consent (e.g., drug prescription), Disclosure Level 2 is assigned. Disclosure is required only when the practitioner uses or prescribes products of that company. If a generic or a similar product of another company is used, disclosure of the financial interest to patients is not required. The assigned Disclosure Level remains in effect until the level of compensation in the previous 12 months changes sufficiently to trigger re-review or the conflict is eliminated.

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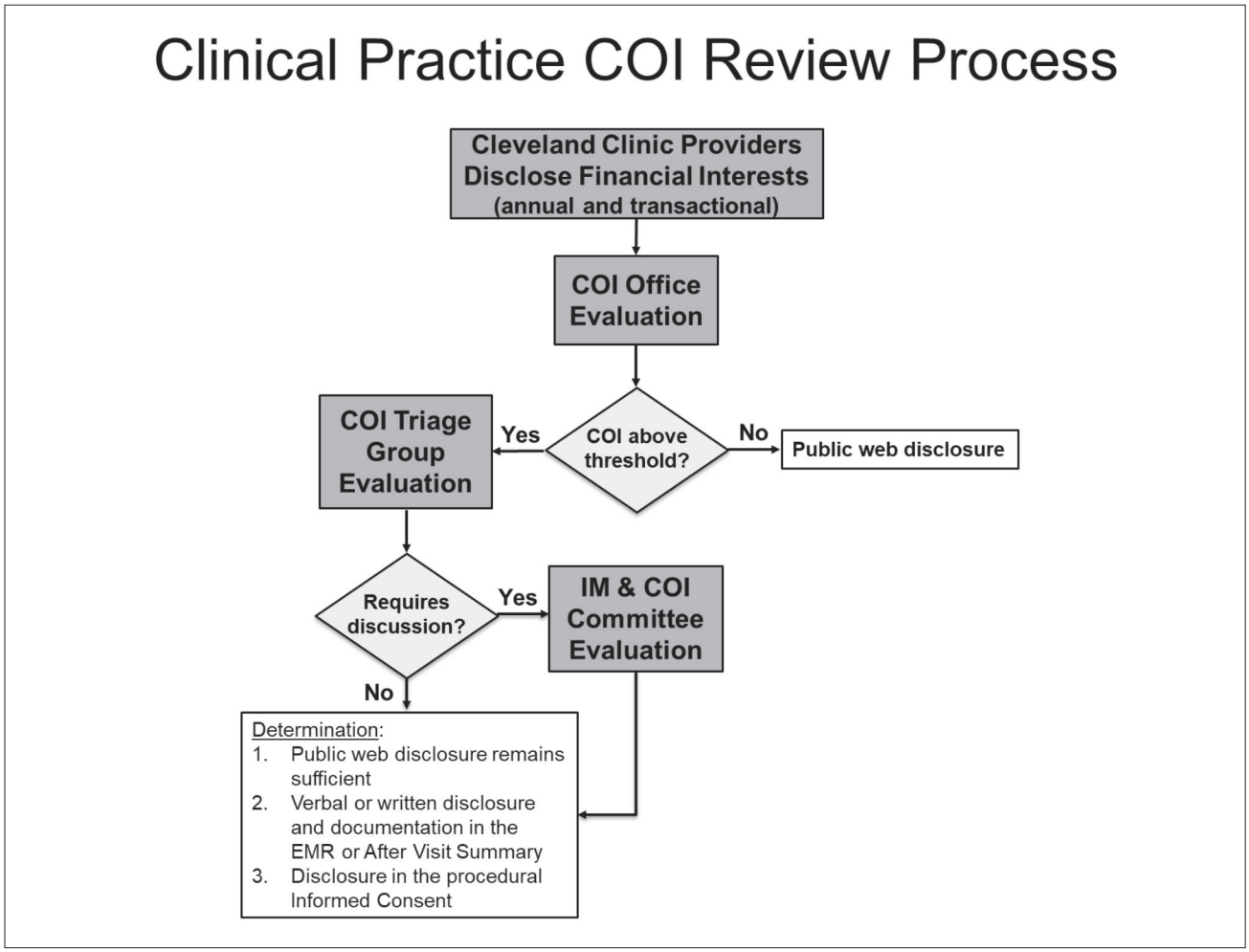
Figure 1

Cleveland Clinic process for review and determination of conflicts of interest in clinical practice. Select employees[1] are required to submit financial interest disclosures at least annually and also whenever there is a material change to their financial interests. The Conflict of Interest Office[2] screens the disclosures to determine whether financial interests exceeds $20,000 in a company making drugs, devices or other products being used by or at the direction of the provider. If yes, then the disclosure is reviewed by the COI Triage Group[3] to make the disclosure determination, or if substantive discussion is necessary, sent to the full IM&COI[4] Committee for determination. If not, financial interests greater than $5,000, excluding personal stock, are disclosed our public website regardless of the existence of a clinical practice COI.



[1] Physicians, researchers, managers, fellows, advanced practice providers (nurse practitioners, physician assistants and certified registered nurse anesthetists), pharmacists, and certain other administrative groups such as law, audit and technology transfer.
[2] Consists of the Director of COI, administrative program coordinators and a systems analyst.
[3] Consists of IM&COI Chair and Vice Chairs, the COI Office, and a representative from the Law Department and the Chief of Staff's office.
[4] Consists of IM&COI Chair and Vice Chairs in addition to approximately 10-12 other physicians and scientists and representatives from Human Resources, Law Department, Board of Directors, Institutional Review Board, Chief of Staff's office, Corporate Communications and Technology Transfer group.

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Table 1

Disclosure Determination Matrix_1. Definitions for Compensation, Risk and Disclosure Levels are provided below.

		Annual Compensation		
		Low	Medium	High
Risk	High	2	3	3
	Medium	1	2	3
	Low	1	1	2

Compensation, Risk and Disclosure Level Definitions:

Compensation:
Low, ≥ $20,000 - $50,000;
Medium, > $50,000 - $100,000;
High, ≥ $100,000 or ownership/equity/options of any amount in a small privately held company.

Risk:
Low, commonly used drugs or supplies/built-in equipment;
Medium, drugs with toxic side effects and minimally invasive procedures;
High, invasive surgery or procedure.

Disclosure:
1, Approve relationship as is; disclosure on web is sufficient;
2, Require one of the following: (a) verbal disclosure to patient of the specific clinical conflict and documentation of having made said disclosure in the electronic medical record (EMR) or After Visit Summary [provided to patient] or (b) written disclosure to patient of the specific clinical conflict by a handout and documentation of having made said disclosure in the EMR or After Visit Summary [provided to patient];
3, Require verbal disclosure to patient of the specific clinical conflict and documentation in the procedural Informed Consent.

Table 2

Type of Relationship (n=157 clinical practice COIs; some had multiple types)

Type of Relationship	Count (%)
Speaker, Trainer, Educator	91 (58%)
Consultant	69 (44%)
SAB or Other Research Advisory Committee	34 (22%)
Holder or Owner of Personal Stock	21 (13%)
Receive or Rights to Receive Royalties	12 (8%)
Equity (e.g. stock or options)	5 (3%)
Paid Editor or Author	0 (0%)
Future distribution of Cleveland Clinic Interest	0 (0%)
Fiduciary Role or CMO	0 (0%)

Cleveland Clinic's COI in Clinical Practice Experience

Beginning in January 2016, determinations on Cleveland Clinic COIs in Clinical Practice were prospectively recorded in a password-protected Research Electronic Data Capture (REDCap) database that included physician name, date of disclosure, entity, type of relationship, type of compensation and the amount of compensation. Also recorded were the names of the two or three assigned reviewers, whether the determination was made in a triage meeting or full Committee, and the date of the meeting when the decision was made. All determinations made between January 2016 and January 2021 are summarized below.

Results

About 2% of our approximately 7,500 practitioners carry a financial conflict with their clinical practice that requires review according to our policy (i.e., greater than $20,000 per year or more than 5% equity in a company with related clinical practice).

157 determinations on COIs in Clinical Practice were made at Cleveland Clinic between January 2016 and January 2021. During the first 2.5 years of the reporting period, 32 of 78 (41%) of determinations were made in full Committee Meeting, whereas only 7 of 79 (9%) were made in full Committee in the most recent 2.5 years. The most common types of relationships reviewed were Speaker, Trainer, Educator (58%) and Consultant (44%) (**Table 2**). The most common type of compensation was cash (85%) (**Table 3**). Most COIs in clinical practice (70%) involved Low compensation whereas less than half (39%) involved Low risk activities. The majority involved Low/Low (29%) or Low/Medium (27%) combined Compensation and Risk Levels (**Table 4**).

Disclosure Levels were assigned according to the guidance provided by the Disclosure Determination Matrix_1 (**Table 1**) in 116 (74%) determinations (**Table 5**). 23 of 41 (56%) of the deviations from Disclosure Determination Matrix_1 come from the Low compensation with Medium risk scenario, where Disclosure Levels 1 and 2 were assigned to approximately half of these conflicts respectively. In the time period investigated, 79 of 157 (48%) of Cleveland Clinic's conflicts in clinical practice were determined to be of insufficient compensation and/or risk to warrant more than our standard public web Disclosure Level 1.

Discussion

Cleveland Clinic's COI in clinical practice policy considers the level of compensation and clinical risk associated with each COI to assign one of three levels of disclosure. This paper describes the first five years'

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experience managing clinical practice COIs according the initial definitions of Compensation, Risk and Disclosure Level, and we will now discuss our current refinements to these definitions that derive from lessons learned.

Whereas the definition and determination of Compensation Level remained constant over time, the definition and determination of Risk Levels evolved through full committee discussions. For example, we initially considered the risk of a procedure by whether there was any added risk to the patient beyond the risk of having the procedure itself (relative risk). Over time, however, the committee began to consider the absolute risk of the procedure as driving the risk determination. So, for example, consider a surgeon in financial conflict with the company who makes the machine for assessing blood flow during breast reconstruction surgery. Initially, the Committee assigned this "low" risk because use of the machine was part of routine standard of care and added no additional risk to the patient beyond having the surgery itself. Eventually, the committee's majority voted to designate this scenario as high risk because it involved invasive surgery which is inherently high risk for the patient. We now categorize all clinical conflicts involving "minimally invasive procedures" as medium risk and "invasive surgery or procedures" as high risk. Furthermore, the committee has now refined the definition of drug's risk by the "frequency and/or severity of an adverse event leading to a subsequent intervention or treatment," in order to allow for designation of drugs as low, medium and high risk.

The Disclosure Determination Matrix_1 was used as guidance for disclosure based on Compensation

Table 3

Type of Compensation (n=157 clinical practice COIs; some had multiple types)

Type of Compensation	Count (%)
Cash	133 (85%)
Personal Stock	21 (13%)
Royalties	12 (8%)
Ownership/Equity/Options	7 (4%)

Table 4

Compensation versus Risk Determinations (count (%) of total); n=157 total

		Annual Compensation		
		Low	Medium	High
Risk	High	21 (13%)	10 (6%)	6 (4%)
	Medium	43 (27%)	9 (6%)	6 (4%)
	Low	46 (29%)	9 (6%)	7 (4%)

Table 5

Disclosure Determinations (count (%) of sub-group; n=157 total). Disclosure Levels 1, 2 and 3 are defined in Table 1.

		Disclosure Level	Annual Compensation		
			Low	Medium	High
Risk	High	1	0 (0%)	0 (0%)	0 (0%)
		2	17 (81%)	0 (0%)	2 (33%)
		3	4 (19%)	10 (100%)	4 (67%)
	Medium	1	20 (47%)	1 (11%)	0 (0%)
		2	22 (51%)	7 (78%)	4 (67%)
		3	1 (2%)	1 (11%)	2 (33%)
	Low	1	46 (100%)	8 (89%)	4 (57%)
		2	0 (0%)	1 (11%)	3 (43%)
		3	0 (0%)	0 (0%)	0 (0%)

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and Risk Level, but an alternate Disclosure Level was assigned if deemed more appropriate based on the nuances of the case. The most common instance where we deviated from its guidance was in the scenario of low compensation and medium clinical risk, where Disclosure Level 1 was the default but Disclosure Level 2 or 3 was assigned over half of the time. The majority, 27 of 43 (62%) of designations in this box, were for "drugs with toxic side-effects", and these were approximately evenly assigned to Disclosure Level 1 and 2. This reflects the committee's decision to assign Disclosure Level 1 for use of a medium risk drug prescribed as a generic though possibly filled with the brand name, and Disclosure Level 2 if the drug existed only — or was prescribed only — by brand name.

Further, 12 of 43 (28%) of designations in this Low/Medium box were for "minimally invasive procedures," which were distributed 2:1 in favor of Disclosure Level 2 or 3 over Level 1, and 3 of 43 were for "invasive surgery or procedures" and assigned a Disclosure Level 1 at the time. Most of these deviations are explained by the evolving definition of Risk Level for procedures as described above and would be designated differently today. Minimally invasive procedures (now considered medium risk) in the setting of low compensation are now consistently assigned a Disclosure Level 2. Invasive surgery or procedures (now considered high risk) with low compensation are currently assigned a 2 or 3, depending on whether the use of a non-FDA cleared device is involved. We note that providers assigned a Disclosure Level 2 are always given the option to use the informed consent (Disclosure Level 3) if more convenient.

There are also situations when the Matrix recommended a Disclosure Level 3 but the clinical practice scenario does not involve a procedural Informed Consent, for example, in the situation when a physician with medium or high levels of compensation prescribes a medium or high-risk brand name drug. In these instances, we require verbal or written disclosure and documentation of having done so in EMR or After Visit Summary (Disclosure Level 2) since there is no procedural Informed Consent.

The Committee also needed to adapt to changes in the types of conflicts it reviewed and the means of disclosure available over time. The level of patient risk associated with apps, software, diagnostic tests and non-FDA approved drugs and devices was not anticipated when the policy or review framework was initially developed, nor was the ability to disclose a conflict in the procedural Informed Consent available in EPIC in 2016. Retrospective review of all 157 risk determinations suggested approximately 10 of 157 determinations of Low risk would have been assigned to higher levels of risk had they been reviewed contemporaneously, and several determinations would

Table 6
Risk Level Definitions

Type of Clinical Practice Conflict	Risk Level		
	Low	Medium	High
1. Supplies or Equipment	Commonly used supplies or equipment that involve no or low risk to the patient	—	—
2. Drugs	Drug associated with low frequency and/or severity of side effects (e.g., over the counter medication, supplement, commonly used, etc.)	Drug associated with moderate frequency and/or severity of side effects (e.g., chemotherapy, biologic, immunosuppressant, etc.)	Drug associated with high frequency and/or severity of side effects; Experimental drug that is not FDA approved
3. Diagnostic Test	Test leads to low-risk clinical decision**	Test leads to moderate-risk clinical decision**	Test leads to high-risk clinical decision**
4. App, Software or Predictive Model	Involves no or low-risk clinical decision**	Involves moderate-risk clinical decision**	Involves high-risk clinical decision**
5. Patient Procedures	—	Minimally invasive procedure	Invasive procedure; device not FDA approved

** *consider whether validated or not, the sole source of decision-making and the frequency and/or severity of an adverse event leading to a subsequent intervention or treatment*

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have been assigned Disclosure 3, had the option of disclosing in the procedural Informed Consent been in place at the time the case was reviewed.

As patterns of decision-making became more established and consistent over time, the COI triage group was able to render unambiguous decisions on approximately 90% of the cases it reviewed. Only new or complicated scenarios are now brought to the full committee for discussion. Based on our data, evolving practice patterns and lessons learned, we have recently adopted a more nuanced assignments of risk that consider relative vs .absolute risk, generic vs. brand name drugs, diagnostic tests and apps or software and whether the clinical practice usage is validated or not, the sole source of decision-making and the frequency and/or severity of an adverse event leading to a subsequent intervention or treatment (**Table 6**). We anticipate these definitions will continue to be refined as clinical practice and technology evolves.

We also have updated our Disclosure Determination Matrix (**Table 7**) to reflect our current actual practice of assigning a Disclosure Level based on Risk and Compensation Level. As we begin to use the more nuanced Risk Level determinations (**Table 6**), we will continue to record the level and rationale for our disclosure determinations and report on these and any further modifications to the Disclosure Determination Matrix_2 that may arise in future communications. Other opportunities for improvement are to seek and incorporate patient or community perspectives in our Compensation, Risk and Disclosure Level definitions. Next steps will include systematic incorporation of patients' perceptions of risk due to emotional harm as well as healthcare costs related to drugs, tests, supplies and procedures. We will do this by inviting Health Care Partners, who are patient volunteers who provide guidance on hospital policies and other activities, to evaluate these risk categories and incorporate their perspectives.

Summary and Conclusions

Cleveland Clinic has publicly disclosed the relationships of its physicians and scientists since 2008[19] and since 2013 has had a formal policy requiring review of physicians' and other practitioners' relationships with industry with respect to their clinical practice. Disclosure is currently the primary approach to managing COI in clinical care. The organization has developed a "Matrix" to guide decision-making regarding the appropriate type of disclosure to patients given the nature of the financial interest and the risk of the medical intervention. The definitions of risk and the disclosure matrix have been refined through 5 years' experience and technological changes during that time period. As academic medical centers, health systems and hospitals continue to develop and harmonize policies in this area, tools like these could be adopted and refined at other organizations.

Table 7

Disclosure Determination Matrix_2; Disclosure Levels 1, 2, and 3 are defined in Table 3

		Annual Compensation		
		Low	Medium	High
Risk	High	2/3	3	3
	Medium	1/2	2	3
	Low	1	1	1/2

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