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Review

European Psychiatric Association guidance on the conflicts of interest

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ABSTRACT

Conflict of interest (COI) is a set of circumstances that creates a risk that professional judgments or actions regarding a primary interest will be unduly influenced and compromised by a secondary interest. It might arise in clinical practice, research, and education, and might include individuals and institutions. Primary interests include the pursuit of well-being of patients, ensuring the independence of medical education, and protecting the objectivity and integrity of medical research. Secondary interests might involve financial interests, pursuit of recognition and professional career advancement. COI might result from the multiple roles of physicians in patient care, research, administration, provision of expert opinion and policy advice, and consultancy to commercial organizations. The purpose of the COI policy is to protect the interests of the patients, strengthen the integrity of the profession, and preserve public trust in medicine and psychiatry. The aim of the guidance is to eventually prevent these conflicts from arising rather than remediate them *ex post*. It is desirable to identify factors that might lead to their occurrence, offer a framework for their recognition and assessment, introduce the principles and standards of their disclosure, and provide recommendations for their transparent resolution.

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1. Introduction

Conflict of interest is a configuration of circumstances that creates a risk that professional judgments or actions regarding a primary interest will be unduly influenced and compromised by a secondary interest [15,18,21].

Conflict of interests might arise in clinical practice, research, and education, and might include individuals and institutions. Primary interests include the pursuit of well-being of patients, ensuring the independence and excellence of medical education, and promoting and protecting the integrity of medical research. Secondary interests might involve the pursuit of recognition and professional advancement and financial interest.

Conflicts of interest might also result from the multiple roles of physicians in patient care, research, administration, provision of expert opinion and policy advice, consultancy to commercial organisations, and service to the government.

The purpose of the conflict of interest policy is to protect the interests of the patients, strengthen the integrity of the profession, and preserve public trust in medicine and psychiatry.

The aim of the guidance is to eventually prevent these conflicts from arising rather than remediate them *ex post*. Therefore it is crucial to identify factors that might lead to their occurrence, offer

a framework for their recognition and assessment, introduce the principles and standards of disclosure, and provide recommendations for their transparent resolution.

In order to address issues of conflict of interest and general principles relevant for the European Psychiatric Association (EPA), this guidance draws on documents, statements and policies developed by the World Medical Association [20–23], the World Psychiatric Association [1,24], the Council of International Medical Sciences [9], the International Committee of Medical Journal Editors (ICMJE) [12], the Council of Europe [7,8], the United Nations [19], report of the Institute of Medicine of the National Academies [15] as well as additional literature in the field of psychiatric ethics [3,4,11] and biomedical ethics [2,10,13,14,16–18].

2. Patient care

The primary obligation of physician is towards their individual patients. It is therefore the primary duty of physicians to warrant their trustworthiness and confidentiality, and uphold the standards of good psychiatric practice.

Physicians should seek to avoiding harm to patients, act in their best interest and promoting their well-being within the limits of their professional relationships.

Physician's expertise must be based on objective and professionally accepted knowledge, and they need to balance the recommendations of evidence-based medicine with their

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experienced clinical autonomy to ensure optimal treatment and care of their individual patients.

Physicians are required to secure from the patient fully informed consent with any diagnostic and therapeutic procedures they recommend. Provided information must be adequate and veracious communication of the nature, purpose, risk, benefits, and alternatives of their participation in treatment regime and care. Physicians need to ensure that the patient is competent to grant his consent, that they fully understand this information, and that their consent is voluntary. In specific situations, the involuntary and/or compulsory medical intervention and coercion is needed in the interest of the patient. These measures aimed primarily to protect a patient and/or other persons in his/her environment are regulated by law in the respective European countries.

The information and recommendation provided to the patient must not be distorted by any competing interests, such as inconvenience of time and resources, intention to include patient into research project, or personal benefit from preferred form of treatment (such as referrals to private institutions, rewards or remuneration of prescription practices).

Therapeutic recommendations and prescription practices must not be unduly influenced by competing interests of third parties, such as private (for-profit) institutions, pharmaceutical industry, and insurance companies that would not be congruent with the best interest of the patients. It might also concern compliance with government policies, if the public interest (e.g. introducing a new drug into clinical practice) is in clash with the individual interest (not to serve as an experimental subject). Therefore, physicians are recommended not to accept any gifts or enter into gratuitous relationships with these third parties, since that might bind them to reciprocity and favourable response in situations that should be independent of external influences. If they indeed do accept gifts, sponsorship, or enter into contractual relationship with these parties (such as consultancy or membership at advisory boards), they are required to disclose this to their employers, professional bodies and affiliated academic institutions, as well as to their patients, to ensure the transparency of potential conflict of interests.

Patients must be treated fairly and without discrimination based on their attitudes and convictions. Treatment and care should be sensitive to social, psychological, cultural and spiritual needs of the patients, and physicians need to collaborate with other professionals to address these needs. Communication regarding their patients must respect confidentiality and discretion. Physician should not pursue any additional interests in specific forms of treatment, such as personal preference of psychotherapeutic, religious, or moral orientation.

With respect to their fiduciary role, physicians are obliged to truthfully disclose and apologize for any error and negligence they are responsible for in the course of the treatment. This should take place in a sensitive manner in appropriate time and setting, and need to be followed by adequate restitution.

Physicians should aim for close collaboration with the family and community of the patient, as far as these might contribute to their patient's well-being. However, if these families or communities pursue interests that might be detrimental to the well-being of patients, physicians are obliged to protect patient's best interests and rights. Physicians also need to be concerned with the well-being and safety of patient's families and communities if these are adversely influenced by the condition and actions of their patients, and must address these concerns in collaboration with other health care professionals, social workers, and relevant civil authorities, where necessary. However, these concerns should not compromise the primary obligations of physicians to their patients.

Physicians are responsible for advocating the interests of patients to the state and other relevant authorities. When appointed to administrative, consultancy, or political posts, they must aim for fair and just treatment of their patients as citizens.

When the physician is appointed to witness in civil or forensic legal matters regarding a patient or other person (i.e. addressing their competence, capacity, or accountability), they must offer honest and truthful account. There must also be a clear demarcation of the physician's dual role in advocating the interests of patients or clients, and protecting the interests of the society. The patient or an investigated person must always be fully informed on the nature and possible consequences of the assessment. Physicians should not accept the role of expert witness in the case of their own patients.

Additional guidance on the ethical and legal framework of clinical practice is to be sought in the Convention on Human Rights and Biomedicine of the Council of Europe [7,8], Madrid Declaration on Ethical Standards for Psychiatric Practice of the World Psychiatric Association [24], the Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care of the United Nations [19] and the CIMP code of conduct [6]. For a comprehensive review of ethical issues arising in psychiatric care and research we refer to recently published book *Ethics in Psychiatry: European Contribution* [11].

3. Medical research

Medical research aims to contribute to the advancement of medical sciences and their application for patients benefit in preventive, diagnostic, and therapeutic interventions.

The society delegates this task to physicians and researchers, which implies their responsibility for ensuring the integrity and overall asset of research as well as responsible custody over public funds in both clinical and preclinical (basic) research. To ensure this, the research initiated or conducted by the physician should address a question of sufficient value, the study must employ a scientifically valid design to answer the research question, must be conducted honestly, and research findings must be reported accurately and promptly, without exaggeration of benefits or minimization of harmful effects. Physicians are advised to conduct research only if it is related to their field of expertise, should pursue adequate training in the conduct of research and principles of research ethics, and undertake research only after the research project approval has been granted by the competent institution (usually ethics review committee) that independently examined its ethical acceptability. Authorship should be determined prior to the research commencement and should be based on substantive scientific contribution.

In any forms of research with human participants ('subjects'), physicians must protect the life, health, dignity and identity of human beings, respect their rights to integrity and freedom. The well-being of individual research participants must take precedence over all other interests of society or science, and their participation in research should not put them at a disadvantage with respect to medical care. Research on human participants is regulated by international documents and national legislations, and researchers are obliged to acquaintance and abide with principles stated in these documents, namely the Declaration of Helsinki of the World Medical Association [20], Convention on Human Rights and Biomedicine with its Additional Protocol concerning Biomedical Research of the Council of Europe [7,8], and International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organisations of Medical Sciences [9].

Consent to participation in research must be voluntary and informed. The physician is responsible to inform patients/research

participants about the purpose, nature, risks, benefits, and alternatives associated with their participation, and ensure they understand this information. All data must remain confidential and may be used only for purposes specified in the informed consent documentation.

Clinical trials that evaluate medical interventions and provide an analysis of quality, safety and efficacy of particular compound or evaluate multiple compounds for their comparative value can be randomized and non-randomized. Randomization should follow the principle of equipoise, i.e. randomization should be employed only in situations where there is genuine uncertainty as to which one of the available treatment is the most effective and safest for given condition. Randomized studies should aim at using standard treatment rather than placebo to ensure that participants are provided standard care in accordance to currently available evidence. The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

Research in the area of public health (epidemiology, health policy, service research, prevention of disease research) should in addition to the concern for individual patients give a due consideration to the risks and benefits to society, and should be guided by the principle of justice. Researchers should be aware of the potential conflict of interest arising from the involvement of the government that might potentially compromise the interests of individual patients in the name of greater societal good.

4. Research sponsored by commercial entities

Clinical research (pharmaceutical trials) is predominantly sponsored by commercial entities. Patients and public benefit from constructive collaboration between academic medicine and industry that introduces new diagnostic and therapeutic possibilities. However, this collaboration poses additional risks to the neutrality and objectivity of research by introducing new incentives and compensations that might unduly influence professional judgments. Moreover, the determination of priorities of clinical research and direction of basic medical research might be distorted by the interests of third parties. It is therefore necessary to acknowledge these potential conflicts of interest that might arise in any stage of research, and introduce precautionary measures to ensure the integrity and objectivity of scientific investigation.

In order to protect the interests of patients and society, the following principles should be observed in addition to conditions specified by national legislations:

Patient interests and scientific integrity must be paramount. Researchers should not agree on participation of the study that does not represent significant contribution to substantial research question and that might only serve marketing purposes.

Physicians may conduct research funded by a commercial entity only if they do not allow themselves to be subject to external pressure regarding the design, results, and publication of their research. The terms and condition of their contract must be disclosed to their employing institution and ethics review committee. Researcher's compensation should be based on their time and effort and must not be connected to the result of the research. Psychiatrists engaged in research should affirmatively disclose the existence and nature of their relationships with industry to potential research subjects.

The researcher should ensure that participants included in the study have given written agreement in accordance with principles of informed consent. Information about research participants must not be passed to the sponsoring company without the consent of the individuals concerned. The researcher retains the right to release relevant information to research participants in any point of the study.

It is reasonable that participants in research may be reimbursed for their time, expenses, and inconvenience. However, researchers should also ensure that these reimbursements do not constitute an inducement to participate.

Researchers should retain control of and have full access to all trial data, and should decline non-disclosure clauses. Any business confidentiality must be time-limited. If data for jointly authored publication are analyzed by commercial organisation, full access to the raw data and analyses must be available to the participating researcher, who should have full access to the entire process of data analysis. Ownership of research data should rest with the investigator, who has the right to publish negative results and thereby prevent exposure of future participants to potential harm if the research is to be repeated. The responsibility of individual researchers in the team has to be declared and contracted in advance.

The presentation or publication of the results must not be unduly delayed or otherwise obstructed or subject to censorship or distortion of findings. Authorship should be determined prior to the research commencement and should be based on substantive scientific contribution. Researchers should not agree to 'author' articles that have been ghostwritten for them by commercial entities or their contractual partners. The results are made public with the name of the sponsoring entity disclosed, along with the statement disclosing the information on who initiated and requested the research.

The researcher may not enter into affiliation with a commercial entity such as consulting or membership on an advisory board, unless the affiliation does not compromise their integrity and obligations to their patients. These affiliations must be fully disclosed in all relevant situations such as articles, reports and lectures.

All relevant and material researcher relationships and interests must be disclosed to potential research participants, research ethics committees, institutions where research is conducted as well as to the regulatory oversight bodies. This information must be also disclosed to medical journals publishing the results of the study, as well as to the audience to which the results are presented at medical conferences and educational events. Researchers should not have financial interest in a company sponsoring research or compound being studied. Some authors [5] propose a radical reform of researcher-industry relationships: Manufacturers should produce, not evaluate new drugs. The independence of regulatory bodies should be strengthened and patent protection should be reduced.

5. Medical education

Education of medical students and physicians is essential for ensuring excellence of clinical care and medical research. In the course of clinical training, the educational needs of students and residents and the quality of their training experience must be balanced with the best interests of patients, which must take precedence if these are in conflict. Students need to be taught to be sensitive to their patients' needs and to advocate their best interests. Physicians must ensure that trainees receive supervision commensurate with their level of training. Patients should be made aware that their medical care might be performed partially

by students and physicians in training and consent to this. Refusal by a patient to involve trainees in their care should not affect the amount or quality of care they subsequently receive.

The responsibility for ensuring the quality of medical education rests on the educators and institutions involved. These institutions also need to regulate the rules of the sponsorship of educational events by commercial organisations, to prevent unjustified and biased influence on the medical profession. If the commercial organisations support medical educational activities, the professional institutions must retain control of the title, scientific and educational content of any event, and the acceptance of advertising must never imply an endorsement of the commercial organisation's products.

Presentations and lectures at such conferences and continual medical education events must be scientifically accurate and give balanced review of current evidence. Students, residents and attendees of continual medical education events should be granted objective and state-of-the-art information, based on the evidence and undistorted by additional interests of educators, institutions involved in provision of training, or interests of third parties, such as commercial entities. Students and physicians must be provided with means to assess the independence and objectivity of information provided at educational events. Any affiliation of medical educators with commercial organisation including consulting and membership on an advisory board must be made publicly available in order to maintain the transparency and objectivity of the educational process. In a more radical approach, the industry should be excluded from medical education at all [5]. Honoraria for speakers or delegates at conferences and educational events must be declared to the participants, and their presentation must include declaration of any competing interests, such as affiliation with commercial entity and sponsorship of presented research. This information must also be disclosed in all publications resulting from the meeting. Participating physicians must not receive payment directly from a commercial entity to cover their travel expenses, room and board, or compensation for their time, must not accept unjustified hospitality, and receive payments to cover expenses for accompanying persons.

6. Issues related to professional organisations and institutions

The Academic organisations and institutions responsible for clinical care, medical research and education must retain their independence from the adverse third party influence to ensure the quality and objectivity of medical practice, science and education. It is recommended that institutions providing medical care, conducting medical research and are involved in medical education adopt conflict of interest policies, including standards of disclosure of potential conflict of interests. Principles of disclosure should be established independently by scientific journals, institutions of medical research and education, and these need to be required and monitored by independent body and made available to the interested public. Advertisement of commercial entities should be regulated by organisers of medical conferences and publishers of scientific journals.

7. Clinical practice recommendations

Commercial sponsorship and advertising may not be used to support the publication or distribution of guidance on good practice, or consensus statements such as clinical guidance. Where physicians are appointed to advice on the diagnostic classification manuals, they need to be aware of the potential pressures from commercial organisations to advocate for their interests. Physicians are advised to ensure their recommendation is based on the

evidence provided by independent research, and their recommendation is not influenced by the interests of third parties. Increased attention to declaration of potential conflict of interest should be required by the organisation requesting the advice.

8. Research/ethics review committees

With regard to medical research, institutions should establish independent committees to assess research protocols, both in terms of scientific merit, soundness of research design and methodology (this is a questionable requirement which is still a matter of discussions - ethical aspects, however, involve often also factual and methodological justification and acceptability of a trial) and the ethical acceptability of such research. The purpose of this independent and multidisciplinary examination is to protect the dignity, rights, safety and well-being of research participants, and examine the objectivity and scientific asset of the research project. Measures must be taken to assure the independence of the ethics committee, which must not be subject to undue external influences. Members of the ethics committee must declare all circumstances that might lead to a conflict of interest. Should such conflict arise, those involved must not participate in that review.

The ethics review committee must be given detailed description of the research project in written form, information on participant and their consent, and other information including description of ethical issues and potential conflict of interest. Specific guidance on information to be given to the ethics committee is to be sought in the Appendix of the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research of the Council of Europe [7]. The committee must produce an opinion containing reasons for its conclusions, and must be satisfied that no undue influence, including that of financial nature, will be exerted on persons to participate in research, with particular attention to vulnerable or dependent persons.

9. Journals (following the recommendation of International Committee of Medical Journals Editors)

All contributors to professional journals must clearly disclose their potential conflict of interest, including the funding of research, sponsorship and initiation of research. Editorial boards should do their best to ensure these disclosures are honest and complete.

All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such relationships is also important in connection with editorials and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

Authorship credit should be based on substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content, and final approval of the version to be published. Authors should meet all of these conditions and each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

For further guidance, see conflict of interest guidance of ICMJE [12].

10. Psychiatric Associations (following the recommendation of World Psychiatric Association)

Psychiatric associations should seek to minimize reliance on industry support of their activities. Public disclosure should be made of all industry support, and association leaders should disclose their relationships with industry on at least an annual basis. Psychiatric associations should not participate in marketing activities on behalf of pharmaceutical companies, including endorsement of commercial products. Finally, psychiatric associations have a responsibility to develop guidelines for their members regarding members' relationships with industry.

When organizing national or international conferences or congresses, psychiatric associations can accept support from industry, but should make efforts to seek sponsorship from multiple sources. All commercial support should be openly disclosed to attendees. Psychiatric associations should identify the topics, content, and presenters at their meetings independent of influence from pharmaceutical and other companies, and insure that they meet appropriate guidelines for continuing medical education. Satellite symposia should be held to identical standards as presentations that are part of the official program. Psychiatric associations should place limits on exhibits and exhibitor conduct to insure that the tone of the exhibit area is professional in nature.

Health care organisations working in the psychiatric field and psychiatric associations should establish a process to develop and implement guidelines regulating organisational relationships with industry, consistent with the recommendations above.

For further guidance consult the World Psychiatric Association's recommendations [1].

Disclosure of interest

C. H. Study coordinator: Servier; grants: Eli Lilly; advisory board: BMS, Janssen Cilag; Lectures: Lupin, Eli Lilly, Janssen Cilag, Medicom; Faculty Member, LINF.

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