

Initial drafting of telemedicine's code of ethics through a stakeholders' participatory process

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Abstract

Telemedicine can improve access to healthcare services; however, it has raised ethical concerns demanding special considerations. This study aimed at developing the codes of ethics for telemedicine, and hence several approved national and international ethical guidelines related to telemedicine practice were reviewed, and 48 semi-structured interviews were conducted with medical ethics and medical informatics experts as well as with physicians and patients who had telemedicine experiences. Content analysis was then performed on the interviews' transcripts and a draft on code of ethics was prepared, which was further reviewed by the experts in the focus group meetings to reach a consensus on the final document. The final document consisted of a preface, five considerations, and 25 ethical statements. Considering the growing trend of adopting telemedicine worldwide, this document provides an ethical framework for those who use telemedicine in their medical practice.

Keywords: Code of ethics; Telemedicine; Health services; Iran.

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Introduction

Facility of sharing personal and professional information has influenced health care provision and made telemedicine prevalent (1). Telemedicine involves remote delivery of healthcare services, sharing related information through a variety of telecommunication technologies, facilitating synchronous or asynchronous communication, as well as data gathering and monitoring (2, 3). Communication in telemedicine occurs between the patient and service provider for remote care delivery, or among service providers for consultation purposes (3, 4). Telemedicine provides an opportunity to expand access to health services (1), especially in rural or deprived areas with a shortage of resources and specialists (2) or during COVID -19 pandemic crisis limiting interpersonal face-to-face interactions (3). Preferring telehealth services is not limited to homebound patients or rural residents, and patients with convenient access to face-to-face services may also prefer remote healthcare services (5), increasing as the public progressively adopts telecommunication technologies (1). Moreover, widespread acceptance of telemedicine during COVID-19 pandemic has resulted in its permanent integration into post-pandemic healthcare systems (3).

Observance of ethical standards in telemedicine has been considered by several national and international documents and biomedical ethicists. Regardless of the service delivery media, healthcare providers and recipients should adhere to loyal communication and respect professional

values (6). Ethical concerns in telemedicine included the following subjects: patient autonomy (7, 8), obtaining informed consent (8, 9), physician-patient relationship (1, 7, 8), patient privacy and confidentiality (1, 7, 9, 10), identity issues (1), prudence of telecare (7-10), beneficence, monitoring and coordinating the treatment, one-size-fits-all service provision (1, 10), as well as documentation and data storage (7). Several guidelines or codes of ethics have been developed to address these concerns (4, 10, 11). One such guideline is the World Medical Association (WMA) "Statement on Telemedicine Ethics", developed as an international reference point. However, WMA still recommends the development of national ethical codes or guidelines considering the telemedicine practice's international agreements (4).

Reviewing the existing international ethical charters and codes shows that despite common concepts, cultural differences should be considered in developing telemedicine's code of ethics. Hence, such documents for another context cannot be unchangeably adopted, and contextual aspects and local stakeholders' viewpoints must be included (2, 12). Some national guidelines in Iran provided general standards of medical ethics. The first version of the "Patients' Rights Charter" was ratified in 2001, and a more comprehensive version was notified and adopted by the Ministry of Health and Medical Education in 2009 (12). Furthermore, the first "Code of Ethics for Medical Professionals" was approved by Medical Council of Islamic Republic of Iran

in 2018 (13). General ethical and professional standards in these documents can be applied to telemedicine after customization; however, explicit national guidelines or specific ethical codes are not available, and hence this study aimed at developing the codes of ethics for telemedicine in Iran.

Methods

This study consisted of three main stages: (i) a non-systematic literature review, (ii) a qualitative study using semi-structured interviews, and (iii) a focus group discussion. PubMed, Scopus and Web of Science databases were searched for relevant guidelines and ethical codes using search operators—Boolean operators (AND, OR and NOT) —parenthesis, and truncation. The keywords as single terms or in combination with others were as follows: “telemedicine”, “tele-medicine”, “remote care”, “e-health”, “ethical codes”, “codes of ethics”, and “ethical guideline”. Then, relevant guidelines or codes of ethics (4, 10, 11) were reviewed to develop interview questions. Subsequently, interviews with telemedicine stakeholders were conducted, and content analysis on the interviews’ transcripts were performed to develop ethical considerations of telemedicine in Iran. Then, the preliminary draft of codes of ethics were prepared, which was further reviewed by the experts in the focus group meetings to reach a consensus on the final document.

Participants

Interviewees were purposively selected from four groups: (i) physicians with more than one-year telecare experience, (ii) medical ethics specialists, (iii) medical informatics specialists, and (iv) patients with at least one experience of receiving a formal telecare. Interviews were continued until reaching data saturation in each of the above-mentioned groups. Finally, 10 medical ethics experts, 15 medical informatics experts, 15 physicians and 8 patients were interviewed. Participants of the focus group sessions were 10 specialists in medical ethics or e-health as well as experienced physicians.

Semi-structured interviews

After obtaining participants’ consent, semi-structured face-to-face interviews were conducted, each lasting an average of 35 minutes. The predefined open-ended questions included the following items: “What is your understanding of telemedicine?”, “Could you name benefits of telemedicine for the patient and society while focusing on the ethical aspects?”, “How can justice be respected in telemedicine?”, “Could you name harmful aspects or disadvantages of telemedicine for the patient and society?”, “What do you think about the physician-patient communication in telecare regarding issues such as authentication, mutual trust and appropriateness of the tele-service?”, “What are the ethical challenges in telemedicine?”, and “How is the information confidentiality maintained in telemedicine?” If necessary, the interviewees were asked more detailed

questions to clarify, and interviews were audio recorded and transcribed verbatim.

Content analysis of interviews' transcripts

The Graneheim and Lundman's method of qualitative content analysis was adopted to interpret the interviews (14). After repeatedly reading the transcripts to immerse in the data, the researchers followed the steps of defining the transcripts' meaning units, open coding, grouping, categorizing, and abstracting of the transcripts (15). This process was reviewed to remove redundancies, and finally extract the main subcategories, categories and themes with appropriate headings describing the related content. The process was performed by two researchers to ensure inter coder credibility.

The trustworthiness of the results was evaluated through credibility, transferability, dependability, and confirmability criteria (16-18). Moreover, the interviewers built rapport with the interviewees. Thick and contextualized description was employed to ensure transferability. Dependability and confirmability were pursued through providing audit trail for coding records and coders try to set aside their assumptions.

Proposed codes of ethics for telemedicine

A preliminary draft of codes based on the outcomes of the previous steps including literature review—especially WMA statement on the ethics of telemedicine (4) — the upstream documents—namely the “Patients' Rights Charter” of Iran (12) — the “General Guide to Professional Ethics for Medical Sciences Staff” (13), and the qualitative study. To review the draft

carefully to finalize, three, two-hour focus group sessions were held where each code was reviewed and participants expressed their views on the amendments or revisions; this process continued until participants reached a consensus. Finally, the draft was reviewed by three experts in the field, in addition to the participants involved in the previous stages, to confirm its alliance with the results of content analysis and upstream documents.

Ethical considerations

This study was approved by the Ethics Committee of Tehran University of Medical Sciences (Approval No. IR.TUMS.MEDICINE.REC.1396.4329).

The researchers elaborated the purpose of the study to the interviewees and in the focused group sessions, guaranteed the confidentiality of their information, and obtained their verbal informed consent. Participants could withdraw at any time.

Result

The demographic data of the study participants were presented in table 1.

Table 1- Interviewees' characteristics

Group	Sex	Number of subject
Medical ethics specialists	Female	2
	Male	8
Medical informatics specialists	Female	7
	Male	7
Physicians	Female	4
	Male	9
Patients	Female	3
	Male	8

After the content analysis of 48 interviews' transcripts, 134 codes were extracted, which were further classified into two themes,

seven categories and 31 subcategories (table 2). The two themes included telemedicine's positive and negative aspects from ethical

perspective. Categories' descriptions and participants' statements are as follows:

Table 2- Themes, categories and subcategories of ethical concerns in telemedicine

Themes	Categories	Subcategories
<i>Positive aspects of telemedicine from ethical perspective</i>	<i>Increased autonomy and respect for dignity</i>	<i>Easier access to services More choices for provision or service usage More awareness More convenience in provision or service usage</i>
	<i>More effectiveness</i>	<i>Cost reduction Time-saving Quick access to patients' records Likelihood of 24-hour patient management Increased likelihood of documenting provided services Increased likelihood of reducing medical errors through technology's enhanced features (e.g. artificial intelligence and medical sensors)</i>
	<i>Increasing equity</i>	<i>Increased access Increased service provision to deprived and remote areas Increased service provision to individuals with disabilities Increased provision of specialists' services Decreased administrative corruption</i>
	<i>Negative aspects of telemedicine from ethical perspective</i>	<i>Impact of disturbance or insufficiency in service provision on patient management</i>
<i>Increased likelihood of medical information disclosure</i>		<i>Likelihood of hacking the transferred data Likelihood of software tools' low security Likelihood of misusing the large amount of data Increased likelihood of secret disclosure due to large number of staff involved in a telecare service</i>
<i>Increased likelihood of impersonation and deception</i>		<i>Increased likelihood of malingering Ambiguity in an avatar's identity Increased likelihood of deception Increased likelihood of being exposed to misleading advertisement</i>
<i>Ambiguities in legal and official status of telemedicine service provision</i>		<i>Ambiguity in medical errors' compensation Ambiguity in physicians' payments Ambiguity in determining the responsible body for medical errors</i>

Theme 1: Positive aspects of telemedicine from ethical perspective

Increased autonomy and respect for dignity: According to the interviewees, a greater

variety of services can be accessible remotely to both service providers and recipients, and access to internet and feasibility to provide valid information increase recipients' awareness. An

interviewee said: *“This wide range of tele-services brings autonomy and respects human dignity. When you are at home or office, you can easily access the services.”* [Participant No.6]

More effectiveness: Participants believed that telemedicine can reduce costs and save time, as well as can provide quick access to patients' records and 24-hour patient management. A participant said: *“Telemedicine seems to reduce service latency and bring places closer together. Provided telemedicine services can be easily documented with the use of technology. In addition, medical errors may occur less if advanced technologies, such as artificial intelligence and medical sensors, are used properly “.* [Participant No.22]

Another participant said: *“Technologies such as artificial intelligence can help resolve some telecare issues leading to malpractice. Medical sensors are great, and help a lot in this regard.”* [Participant No.18]

Increasing equity: Telemedicine increases access to healthcare services for all, including residents of deprived areas and patients with disabilities. In the absence of specialists, telemedicine is a sensible solution to provide a wide range of services. In addition, due to telemedicine's convenient documentation and clarity of the process, less administrative corruption may occur compared to face-to-face systems. A participant stated: *“Less administrative corruption in telecare is beneficial for both people and government and guarantees justice.”* [Participant No.37]

Theme 2: Negative aspects of telemedicine from ethical perspective

Impact of disturbance or insufficiency in service provision on patient management: Telemedicine relies on technological tools that may not always be the most advanced ones, and technological tools may be exposed to malfunction or shortcomings. Low quality images and digital files as well as lack of palpation physical exam may negatively affect diagnosis and treatment process, which may lead to medical errors. Furthermore, physicians and patients may be more stressed during telemedicine services, especially when they have not already become familiar with this service type. A participant said: *“Technical problems can disrupt telecare services due to causing stress in both parties and affecting the care quality”.* [Participant No.8]

Furthermore, a participant, with telemedicine experience, said: *“High levels of stress in patients may result in incorrect or inaccurate symptoms”.* [Participant No.18]

The need to adapt to the new method of physician-patient communication for both parties may be another reason for the failure or insufficiency in services.

Increased likelihood of medical information disclosure: Software tools may have low security and be prone to hacking, and hence extensive data collected from patient records may be misused in telemedicine. As more staff are involved in telemedicine process, such risks may increase. An interviewee said: *“Big data that is transferred during healthcare service should be protected*

carefully. There are serious concerns regarding maintaining security of patients' information." [Participant No.14]

Increased likelihood of impersonation and deception: Hiding the real identity and using misguiding avatars can occur on internet virtual spaces, and hence malingering and deception are among unethical behaviors that should be prohibited in telecare. A participant said, "Impersonation is more likely to occur in telecommunication, but safe systems can minimize the risks". [Participant No.32]

Misleading advertisement for delivering or receiving services is another concern in telemedicine. A participant addressed this issue: "Telemedicine providers should have a well-defined process for evaluating the advertisements published on their systems because patients trust them as much as they trust the board of a clinic". [Participant No.4]

Ambiguities in legal and official status of telemedicine service provision: Ambiguity in compensation of medical errors, physicians' payments and determining the responsible body for medical errors fall into this category. A participant said: "Insurance agencies and legal bodies haven't developed appropriate frameworks for telemedicine. No defined regulation supports this emerging type of service". [Participant No.20]

Preliminary draft of codes of ethics for telemedicine

The preliminary draft included a preface and 34 statements. Four codes were merged into other statements and five codes were labeled as considerations in the focus group sessions. Finally, the team agreed on a version included a preface, five ethical concerns and 25 ethical codes' statement (table 3).

Table 3- The codes of ethics for telemedicine in Iran

Preface	
<i>Advances in computer sciences and communication technologies have affected all aspects of human life. Moreover, ongoing progress of the biomedical sciences has introduced interdisciplinary disciplines such as telemedicine. Providing telemedicine services requires compliance with well-defined guidelines including ethical guidelines. Initial draft for telemedicine's codes of ethics was prepared based the experts' consensus and the upstream documents, namely the Charter of Patients' Rights in Iran and the General Code of Ethics for Medical Professionals. In compiling the codes, the following principles of professional medical ethics were considered: justice in healthcare, health services recipients' right to choose service type, honesty and integrity, maintaining confidentiality and respect for privacy, patient safety, prioritizing the interests of health service recipients, respect for colleagues' rights, and necessity of providing standard services.</i>	
Concerns	
1	<i>Telemedicine providers must consider general ethical concerns surrounding the physician-patient relationship, which are not necessarily specific to telemedicine.</i>
2	<i>Communication tools increase the interactions between service providers and service recipients; hence, these tools should be used appropriately to protect the clients' rights as well as respect and improve community's health and safety.</i>
3	<i>When necessary, the presence of health care providers at the patient's bedside is primarily preferred.</i>
4	<i>Telemedicine dose not substitute in-person services; it can improve service quality and complement in-person services.</i>
5	<i>Telemedicine services can be widely delivered, even with minimum equipment, namely phones or social</i>

media. This guideline aimed at systematizing these services and inspecting their ethical aspects.

Ethical codes

- 1 *Telemedicine service providers should be aware of the benefits and limitations of this technology-based practice.*
- 2 *Telemedicine service providers should be aware of the relevant legal, technical, and ethical aspects.*
- 3 *Telemedicine service providers should receive necessary licenses from the authorities. They should use licensed telemedicine tools if available, and avoid using unofficial and unlicensed tools to the possible extent.*
- 4 *In case of emergencies, when public communication tools are used as means of interaction, service providers should make every effort to save patient's life.*
- 5 *When using informal and unlicensed environments and tools, telemedicine service providers should ensure clients' privacy, confidentiality, and safety.*
- 6 *Telemedicine service providers should not collaborate with telemedicine platforms where unscientific and unprofessional medical advertising occurs.*
- 7 *Telemedicine service providers should be aware of the ethnicity, culture and sensitivities of the clients receiving telemedicine services and pay attention to these considerations when providing services. Health care providers should choose the best service option according to the customer's circumstances. Providing services through telemedicine can be considered when it does not cause restrictions or problems for the clients; In case of limitations, telemedicine is the best possible choice considering the client's conditions. When in-person visit is feasible, the healthcare provider is responsible for not being at the patient's bedside on time.*
- 9 *Telemedicine service providers should fully identify themselves, state their type of specialty and declare their affiliation (if there is any).*
- 10 *Telemedicine service providers should ensure the identity of the clients.*
- 11 *Telemedicine service providers should provide clients with the necessary information about the telemedicine process and ensure that customers have an appropriate understanding of it.*
- 12 *Telemedicine service providers must obtain the informed consent of the service recipients, and document service details in accordance with the services provided. Written consent is required if high-risk interventions are to be performed.*
- 13 *Client's voluntarily contacting with telemedicine's service providers is considered informed client consent. If telemedicine services are delivered by a team of providers, the primary care physician or supervisor should ensure that the colleagues have sufficient mastery of the telemedicine's technical, legal, and ethical aspects.*
- 14 *Telemedicine service providers should ensure that the service delivery process is documented. If the employed telemedicine tools do not record the client's necessary information and documents, they should record the relevant important items themselves to be accountable for future enquiries.*
- 15 *Telemedicine service providers should carefully observe privacy and confidentiality in disseminating information on cyberspace and official and unofficial telemedicine tools, requiring obtaining clients' informed consent. Furthermore, information related to clients' identity should not be published without their informed consent.*
- 16 *Telemedicine service providers should record images of the client's sensitive body parts only if necessary for providing appropriate services. In such circumstances, the minimum possible number of images should be recorded. The client (or companions only if the client is unaware) must be explicitly informed and express their consent.*
- 17 *Telemedicine service providers are responsible for ensuring the accuracy of the educational content and information they provide on telemedicine tools and platforms.*
- 18 *Telemedicine service providers should support the clients who cannot properly use telemedicine tools, and, if necessary, train them or their companions to use the tools.*
- 19 *Telemedicine service providers should inform the clients or their companions about the method and timing of the subsequent communications or follow-ups to prevent the client from abandoning future services.*
- 20 *In both emergencies and non-emergencies, telemedicine service providers should arrange for the clients' follow-up and visits and notify them.*
- 21 *If follow-up or in-person visits are required, telemedicine service providers should explicitly state the situation and warn the clients or their companions.*
- 22 *Telemedicine service providers should report technical, security, and operational deficiencies of telemedicine tools and software to the relevant authorities (licensing or regulatory) and keep a written*

record of the deficiencies for documentation.

- 24 *In the event of a harm or medical error, telemedicine service providers have the same responsibility as in-person service providers.*
- 25 *Telemedicine service providers have full responsibility for all interventions, recommendations, and consultations they provide in telemedicine, and this responsibility dose not differ from that of in-person service providers.*

Discussion

In this study, the ethical considerations of telemedicine in Iran were studied from the related stakeholders' perspectives, and a draft of codes of ethics through a participatory process was developed. Content analysis of interviews with stakeholders resulted in two themes, namely positive aspects of telemedicine from ethical perspective (including increased autonomy and dignity, more effectiveness, and increasing equity), and negative aspects of telemedicine from ethical perspective (including impact of disturbance or insufficiency in service provision on patient management, increased likelihood of medical information disclosure, increased likelihood of impersonation and deception, and ambiguities in legal and official status of telemedicine service provision. The final draft of codes of ethics consisted of a preface, five ethical concerns and 25 ethical codes' statement.

A review on articles from 2012 to 2017 shows classification of the ethical issues in telemedicine into four categories: technology, physician-patient relationship, confidentiality and security, and informed consent (19). Another study in 2020 identified ethical concerns of telemedicine by reviewing publications over a 25-year period, namely accessibility, effectiveness,

continuity of care and training (20). Telemedicine codes of ethics should address these concerns; hence the present study interpreted its outcomes based on the above-mentioned categories.

Technology

Technical issues included the quality of digital files and security. Physicians are accountable for the quality of provided care and should report technological malfunctions to the authorities (19), highlighted in this draft (code no. 23) (table 3). In addition, secured and approved tools or websites should be used for providing telecare (21), and hence, according to code no. 3, using official licensed tools are preferred in providing telecare to guarantee security and official issues (table 3).

Patient-physician relationship

Creating a respectful and trusting environment between physician and patient is important for deciding on appropriate care and treatment (19) using the following strategies: transparency in obtaining informed consent, clearly describing the telecare process to the patient, and elaborating the patient's right to withdraw from telemedicine (20). The final draft's code no. 9 and code no. 11 (table 3) covered the above-mentioned ethical issues.

Confidentiality, privacy and security

Patients are often concerned about the confidentiality of their information, especially in asynchronous tele-services (20, 22). Therefore, both patients and staff should be trained to follow security protocols (23), and service providers should be aware of the security standards of the telemedicine tools (10, 19); in the final draft, concern no. 2 and codes no. 5, 16 and 17 cover confidentiality, privacy and security, respectively. Furthermore, code no. 10 stated that providers must ensure patients' personal identity (table 3) to prohibit malingering and deception.

Informed consent

Patients should be aware of the benefits and drawbacks of telemedicine, and such informed autonomy allows them to decide on the service type according to their personal values and therapeutic goals (8, 9). Physicians must be transparent with patients and detail tele-service process before any medical intervention (4, 10, 19). In the final draft, codes no. 12 and 13 addressed obtaining informed consent (table 3).

Accessibility

Although telemedicine service providers are responsible for the fair distribution of resources (9), they cannot solve all access problems (e.g., patients' internet access). Additionally, they should undertake caring for patients who are unfamiliar with telemedicine and do not know how to work with telemedicine tools until they have sufficient familiarity and suitable access (20). Code no. 19 of the final draft addressed this responsibility of service providers (table 3).

Effectiveness, beneficence and adaptability

Effectiveness, beneficence, and adaptability of the provided remote services, for the patients and society, are among telemedicine' major challenges (9). If the patient is not the main beneficiary in receiving services, telemedicine is not the treatment of choice (20); for example, when physicians must perform hand-on physical examinations or other types of nonverbal communication must be employed (8, 10). Although other solutions may be available (e.g., having a qualified physician colleague at the patient bedside) (22), physicians are responsible for professionally judging whether telemedicine or in-person visits is the best choice for a given patient (4, 10, 20). Then, they should decide on the appropriate type of remote services for the patients considering clinical manifestations, facilities, needs, preferences, and other individual variations (1, 10). Such decision-makings become more challenging when providing telecare is needed in emergencies (21). Moreover, physicians are required to ensure that adequate and appropriate documentation is provided, and if the employed telemedicine tools do not have the options for recording, physicians must record all details themselves (4). In the final draft, concerns no. 3 and 4, and codes no. 4, 5, 6, 15 and 22 cover the aforementioned requirements (table 3).

Continuity of care

Due to a relatively constant access to technology, patients may misguidedly think that they have permanent access to telecare providers, causing problems as such

permanent access is infeasible (21). Moreover, physicians should not abandon the patients, should clarify the follow-up plan, and should share contact information with the patients (4, 10, 20). Codes no. 20 and 21 in the final draft addressed continuity of care (table 3).

Training and being well-informed

Physicians should become updated with telemedicine techniques, associated research, limitations, and benefits, as well as related legal and ethical aspects (10, 21, 24). Furthermore, supervisor physicians are responsible for ensuring that the service provider team is qualified to provide decent, ethical and safe services (24). The importance of training was covered in the final draft's codes no. 1, 2 and 14 (table 3). Moreover, patients should become familiar with the telemedicine process and technological tools. Physicians' duty to ensure the accuracy of the provided information and training were addressed in codes no. 6 and 18 of the final draft (table 3).

Responsibilities in case of medical errors

The final draft included 5 concerns and 25 codes, and all were explained in the previous subsections except concern no.1, codes no.24, and code no.25. Concern no. 1 addressed telecare providers' responsibility to follow the general ethical guidelines, even if they were not specifically developed for remote communications (e.g., telemedicine), as highlighted in the WMA statement for telemedicine (4). Moreover, code no. 24 and code no. 25 emphasized the full

responsibility of health service providers in case of medical errors or misguide, in line with in-person medical care that was supported by the interviewees' opinions and related literature (20).

Study strengths and limitations

Consensus development methods, recommended in the literature (2,12), were employed in this study.

This study had several limitations. Telemedicine has not yet been widely used in Iran; and, in many cases, tele-services are provided on non-official platforms (e.g., social networks), where maintaining high standard ethical rules is unmanageable. Hence, this study aimed at developing the codes of ethics supporting real, and standard telemedicine practices; however, these codes should be gradually revised to adapt changes in telemedicine in Iran. Moreover, more patients with various types of tele-service experiences and more physicians with various specialties and diverse experiences of telecare practices should be interviewed. Variety in interviewees' experiences can provide more accurate expression of ethical concerns. Furthermore, ethical considerations in telemedicine are not the sole responsibility of service providers, and telemedicine needs coordination among different professions as well as active commitment of relevant organizations and appropriate training and support (23).

Conclusion

Given the importance of ethical concerns in telemedicine, ethical guidelines or codes should be developed to provide a framework

for the practitioners. Thus, this work aimed at developing codes of ethics for telemedicine through a stakeholders' participatory process. Cultural and contextual differences should be considered in drafting code of ethics. The drafted code of ethics can be fulfilled by individual service providers. This draft needs to undergo the legitimization process to be

nationally approved as a reference.

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Conflicts of Interests

The authors declare that they have no conflict of interests.

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