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FRAUD IN SCIENTIFIC RESEARCH AND ITS IMPLICATIONS FOR HEALTHCARE PROFESSIONAL EDUCATORS

EL FRAUDE EN LA INVESTIGACIÓN CIENTÍFICA Y SUS IMPLICACIONES PARA EDUCADORES DE LA SALUD

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ABSTRACT:

Keywords:
Research Ethics, Scientific Misconduct, Critical Thinking, Retractions.

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Background: This study aims to contribute to the reflection on the impact of fraud in medical publications and to offer suggestions to health science educators to limit the potential harm of fraudulent publications concerning scientific literature integrity and patient wellbeing. **Methods**: We analyze the retractions of Joachim Boldt and Yoshitaka Fujii, the two researchers with the most cases of retractions due to fraud. The Web of Science and Retraction Watch Database were consulted in December 5th 2023. We also carried out a bibliographic search on scientific integrity and critical thinking to identify ways for preventing fraud and mitigating its consequences. **Results**: 194 studies were obtained for Boldt and 151 for Fujii. These studies generated 5,450 citations for Boldt and 2,245 for Fujii. After filtering to include only citations from systematic reviews, 734 systematic reviews were found to have cited Boldt's retracted studies, while 140 systematic reviews cited Fujii's studies. The literature reports that several non-technical skills linked to leadership and management are important for researchers, such as effective communication, teamwork, coaching, task sharing, strategic planning, budgeting, personnel selection and evaluation, and situational awareness. **Conclusions:** All actors must work to foster a culture of integrity at all stages of the research process to prevent harm to patients. It is essential to identify appropriate pedagogical strategies to influence the skills, attitudes and behaviors of future professionals. Developing integrity and critical judgment may require the use of different methodological approaches to those traditionally used in the medical sciences.

RESUMEN:

Palabras clave:
Integridad científica, Ética de la investigación, Mala conducta científica, Pensamiento crítico, Retractaciones.

Antecedentes: Este estudio contribuye a la reflexión sobre el impacto del fraude en las publicaciones médicas y ofrece sugerencias a los educadores de ciencias de la salud para limitar el daño potencial de las publicaciones fraudulentas en la integridad de la literatura científica y el bienestar de los pacientes. **Métodos**: Se analizan las retractaciones de Joachim Boldt y Yoshitaka Fujii, los dos investigadores con el mayor número de retractaciones por fraude. Se consultaron Web of Science y Retraction Watch Database el 5 de diciembre de 2023. Se realizó una búsqueda bibliográfica sobre integridad científica y pensamiento

crítico para identificar formas de prevenir el fraude y mitigar sus consecuencias. **Resultados**: Se obtuvieron 194 estudios para Boldt y 151 para Fujii, generando 5,450 y 2,245 citas respectivamente. Se encontró que 734 revisiones sistemáticas citaron los estudios retractados de Boldt y 140 citaron los de Fujii. La literatura reporta que diversas habilidades no técnicas vinculadas al liderazgo y la gestión son importantes para los investigadores: comunicación efectiva, trabajo en equipo, acompañamiento profesional, distribución de tareas, planificación estratégica, elaboración de presupuestos, selección y evaluación de personal, y conciencia situacional. **Conclusiones**: Todos los actores deben fomentar una cultura de integridad en todas las etapas del proceso de investigación para prevenir daños a los pacientes. Es esencial identificar estrategias pedagógicas apropiadas para influir en las competencias, actitudes y comportamientos de los futuros profesionales. El desarrollo de la integridad y el juicio crítico requiere enfoques metodológicos diferentes a los tradicionalmente empleados en las ciencias médicas.

1. Introduction

Scientific research seeks explanations about reality in a rigorous and systematic way, according to the scope and methods of each science.[1] However, due to various scandals that have emerged in recent years, and the potential consequences of such fraud, scientific integrity and fraud as its most serious form of violation, are topics that are generating a great deal of interest.

Fraud is 'any intentional act or omission designed to deceive others, resulting in the victim suffering a loss and/or the perpetrator making a gain'[2], and is always an ethically reprehensible action, but in the context of medical research, it can have extremely serious consequences. A prominent case is that of Dr. Hwang, who fabricated data in publications on cloned human blastocyst-derived stem cells, which were published in Science.[3] Another widely known case was the fraud perpetrated by Andrew Wakefield,[4] who linked autism to the MMR vaccine. Although this study was later withdrawn due to conflicts of interest, data manipulation and other ethical violations, the effects of its publication continue to have a negative impact on public health worldwide due to its major impact on vaccination.[5] In addition to these cases, and due to the steady increase in retractions for suspected research fraud,[6] the scientific community has recently turned its attention to the issue of integrity.

This study aims to contribute to the reflection on the impact of lack of scientific integrity and fraud in medical publications and to offer suggestions to health science educators to limit the potential harm of fraudulent publications. To this end, we first explain the reasons why research fraud may have implications for clinical practice. Then, the fraud committed by the two authors with the highest number of retractions due to data misrepresentation are analyzed as a means to illustrate the consequences of this type of fraud. Finally, two levels of action are proposed for educators of health professionals: preventing fraud through training in scientific integrity and mitigating the consequences of fraud through training in critical thinking.

2. Scientific evidence and clinical practice

The purpose of scientific articles is to disseminate the results of research to other scientists, and they must meet the following criteria: logical rigor, replicability, clarity and conciseness of style, accuracy, comprehensive-

1 Artigas, M. *Filosofía de la ciencia*, EUNSA, Pamplona, 1999.

2 Cotton, D., Johnigan, S. y Givarz, L. *Fraud Risk Management Guide: Executive Summary*, Committee of Sponsoring Organizations of the Treadway Commission, 2016.

3 Hwang, W. S., Roh, S. I., Lee, B. C. y cols. "Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts". *Science (New York, N.Y.)* 2005; 308(5729): 1777-1783; Hwang, W. S., Ryu, Y. J., Park, J. H. y cols. "RETRACTED: Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst". *Science (New York, N.Y.)* 2004; 303(5664): 1669-1674.

4 Wakefield, A. J., Murch, S. H., Anthony, A. y cols. "Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children". *Lancet (London, England)* 1998; 351(9103): 637-641.

5 Segura Benedicto, A. "La Supuesta Asociación Entre La Vacuna Triple Vírica y El Autismo y El Rechazo a La Vacunación". *Gaceta Sanitaria* 2012; 26(4): 366-371.

6 Leistedt, S. J. y Linkowski, P. "Fraud, Individuals, and Networks: A Biopsychosocial Model of Scientific Frauds". *Science & Justice: Journal of the Forensic Science Society* 2016; 56(2): 109-112.

ness, ethical compatibility, significance and relevance.[7] Once scientists submit the manuscript, the review process begins, which includes submitting the work to an anti-plagiarism program. This is followed by peer review, usually in a blind process and with more than one reviewer, who provide comments on the text received, which will help the authors to modify the text, ensuring the scientific quality of the article.[8]

Throughout this process, the researcher is expected to act in accordance with the ethical codes of scientific ethics, in addition to respecting some relevant guidelines, such as the World Medical Association's Helsinki Declaration on Ethical Principles for Medical Research Involving Human Participants,[9] the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-Related Research Involving Human Subjects, the Universal Declaration on Bioethics and Human Rights,[10], the Singapore Declaration,[11] the European Code of Conduct for Research Integrity,[12], among others.

On the other hand, health decision-making has been moving from a model based on tradition and authority,[13] to evidence-based medicine (EBM),[14] understood as 'the conscious, judicious and explicit use of the best evidence when making decisions regarding the care of individual patients, integrating clinical experience with the best available external evidence originating from systematic research'.[15] Thus, there is a connection between the outcome of medical research, a scientific publication, EBM and clinical practice.

Within the scientific literature, levels of hierarchy have been established, according to the 'value' or 'weight' of the evidence. Thus, animal studies and expert opinion are said to have the lowest weight, then case reports, followed by observational analytical studies (including cohort studies and case-control studies), with randomized clinical trials having the highest weight, and finally systematic reviews and meta-analyses, which carry the most weight, meaning they provide the best quality evidence.[16] However, when applying the information provided by the MBE to clinical practice, the health professional must take into account various factors, such as the differences between the population studied and the specific patient, the interventions, the follow-up, the limitations of the studies, among many others.[17] On the other hand, using the MBE, many clinical guidelines are developed to help the health professional identify the most appropriate health interventions for the treatment of patients affected by specific conditions.

3. Fraud and retractions of Joachim Boldt and Yoshitaka Fujii

Methods:

3.1. Search strategy

Unfortunately, more and more cases have come to light in which scientists alter or even fabricate their research data, which could lead to misleading recommendations by EBM and eventually clinical guidelines. As an example, the retractions of Joachim Boldt and Yoshitaka Fujii, the two researchers with the most cases

7 Lam Díaz, R. M. "La Redacción de Un Artículo Científico". *Revista Cubana de Hematología, Inmunología y Hemoterapia* 2016; 32(1): 57-69; Universia España. [On line publication] "¿Cuál Es El Proceso Para Publicar Un Artículo Científico?". 2018. https://www.uhipocrates.edu.mx/bibliotecavirtual/universia/ebook-cuales-el-proceso-para-publicar-un-articulo-cientifico.pdf [Consulted: 3/12/2022].

8 López Leyva, S. «El proceso de escritura y publicación de un artículo científico». *Revista Electrónica Educare* 2013; 17(1): 05-27.

9 The World Medical Association, 75a Asamblea General, Helsinki, Finlandia. [On line publication] "Declaración de Helsinki de La AMM – Principios Éticos Para Las Investigaciones Médicas En Seres Humanos". 2024. [Consulted: 24/11/2024].

10 UNESCO. [On line publication] "Declaración Universal Sobre Bioética y Derechos Humanos". 2005. http://portal.unesco.org/es/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html [Consulted: 29/06/2024].

11 ID22. [On line publication] "WCRI Singapore Statement". *WCRIF — The World Conferences on Research Integrity Foundation*. 2010. [Consulted: 7/03/2021].

12 European Science Foundation y All European Academies. [On line publication] *The European Code of Conduct for Research Integrity*. Estrasburgo, 2011. [Consulted: 2/08/2020].

13 Encyclopedia of Ethics. [On line publication] "Paternalism | Encyclopedia of Ethics — Credo Reference". 2001. [Consulted: 19/03/2019].

14 Schalock, R. L., Gomez, L. E., Verdugo, M. A. y Claes, C. "Evidence and Evidence-Based Practices: Are We There Yet?". *Intellectual and Developmental Disabilities* 2017; 55(2): 112-119.

15 Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B. y Richardson, W. S. "Evidence Based Medicine: What It Is and What It Isn't". *BMJ (Clinical Research Ed.)* 1996; 312(7023): 71-72.

16 Wallace, S. S., Barak, G., Truong, G. y Parker, M. W. "Hierarchy of Evidence Within the Medical Literature". *Hospital Pediatrics* 2022; 12(8): 745-750.

17 Laporte, J. R. *Principios Básicos de Investigación Clínica*, 2da ed., AstraZeneca, 2001.

of retractions due to fraud, are depicted. The scientific fraud committed by these two researchers was widely discussed both in the scientific world[18] and in the press,[19] showing the stir that these scandals generated.

For this purpose, the Web of Science (WoS) and Retraction Watch Database were consulted on December 5th, 2023. This bibliometric study does not involve human subjects, as it exclusively analyzes publicly available retracted articles and their citation patterns within academic databases. All analyzed articles were either open access publications or accessed through institutional academic library subscriptions, ensuring complete reliance on publicly available data. Since the analysis focuses solely on published scientific literature in the public domain and does not involve any identifiable individuals beyond the authors whose misconduct has been officially documented. All data analyzed were derived from peer-reviewed sources and databases, ensuring that the study maintains ethical standards while examining patterns of citation behavior in retracted scientific literature.

3.2. Eligibility criteria, data extraction and synthesis

We extract all the retractions of these two authors, excluding animal studies and studies that were not in English. The following parameters were systematically extracted: authors, title, journal of publication, and year of publication and of retraction, the time to retraction was calculated in years by determining the interval between the original publication date and the formal retraction date. Additionally, we record both the total number of citations received by each retracted article and the specific number of citations within systematic reviews, these were identified through the Clarivate Analytics system from Web of Science and PubMed Database.

Subsequently, systematic reviews that cited one or more of the retracted articles were identified by both authors. Finally, systematic reviews that cited four or more retracted articles were reviewed in full text. We decided to report our findings in the form of a narrative review.

4. Results

Once the repetitions were removed, 194 studies were obtained for Boldt and 180 for Fujii, but 29 animal studies were excluded for Fujii, leaving 151 for this author. Subsequently, citations were identified for each of the articles through the WoS Clari-vate Analytics system and the PubMed Database. We obtained 5,450 citations for Boldt and 2,245 for Fujii. Next, citations from systematic reviews were selected exclusively, leaving 1,307 citations for Boldt and 513 for Fujii. We then identified systematic reviews that cited one or more of the retracted articles of both authors. A total of 734 systematic reviews were found to cite Boldt's retracted studies and 140 systematic reviews cited Fujii's studies. Subsequently, to get a better idea of the impact of fraud in the systematic reviews, we proceeded to read in full text those reviews that focused on clinical topics, were available in English and cited at least 4 retracted articles from each author; the latter in order to select the papers with the highest representation of falsified data. The result of this exercise yielded 43 systematic reviews for Boldt and 29 for Fujii.

Figure 1 shows the summary of the procedure followed and the numbers obtained at each stage:

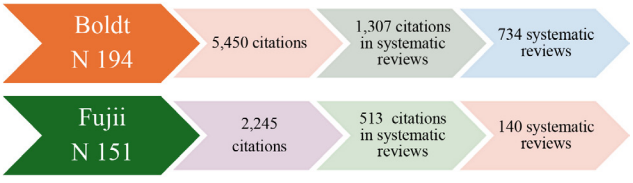

Figure 1

18 Wilkes, M. y Navickis, R. [On line publication] "The Boldt Affair: A Quandary for Meta-Analysts". *Anesthesiology News*. 2013. https://www.anesthesiologynews.com/Commentary/Article/04-13/The-Boldt-Affair-A-Quandary-for-Meta-Analysts/22877 [Consulted: 21/08/2018]; Carlisle, J. B. "A Meta-Analysis of Prevention of Postoperative Nausea and Vomiting: Randomised Controlled Trials by Fujii et al. Compared with Other Authors: A Meta-Analysis of Prevention of Postoperative Nausea and Vomiting". *Anaesthesia* 2012; 67(10): 1076-1090.

19 Blake, H. [On line publication] "Millions of Surgery Patients at Risk in Drug Research Fraud Scandal". *The Telegraph*. 3 de marzo de 2011. https://www.telegraph.co.uk/news/health/8360667/Millions-of-surgery-patients-at-risk-in-drug-research-fraud-scandal.html [Consulted: 12/08/2025]; McNeill, D. [On line publication] "Japanese Fraud Case Highlights Weaknesses in Scientific Publishing". *The Chronicle of Higher Education*. 8 de octubre de 2012. https://www.chronicle.com/article/japanese-fraud-case-highlights-weaknesses-in-scientific-publishing/ [Consulted: 12/08/2025].

4.1. Analysis of articles by Joachim Boldt

Dr. Joachim Boldt was a renowned researcher in the area of blood volume expanders, who advocated the use of hydroxyethel starch (HES) for this purpose. In the first instance, scientific journals retracted his articles because of problems with ethics committee approval,[20] but failure to comply with ethical review requirements was only the initial problem.[21] Subsequently, other more serious misconduct was discovered, such as fabrication of data, including fictitious patients and the alleged use of albumin in a hospital setting that did not have it.[22] The 194 retracted studies of J. Bold can be seen in Appendix 1 and the 734 systematic reviews citing articles by this author in Appendix 2.

These articles based on false data were widely disseminated and two of the retracted studies were cited more than 100 times in other scientific articles, one 163 times and one 109 times. In addition, one of Boldt's most cited articles appears in 38 systematic reviews and there are 734 systematic reviews citing at least one paper by this author, confirming the impact that a single retraction can have on the citation network. Of the 43 full-text reviews read, and their eventual updates, it is noteworthy that only 11 excluded Bold's retracted studies and the other 32 kept them in the analysis.

While it is true that many of the reviews that exclude retracted articles do not find a significant difference in their results after exclusion,[23] other reviews do find important differences to consider. For example, some reviews report that, after exclusion, the strength of evidence associating HES use with increased mortality rose from low to moderate.[24] The exclusion of Boldt's retracted studies has no impact on the results of several systematic reviews because of their small sample size, between 28 to 55 patients.[25] As for reviews that did not exclude papers after retraction, the conclusions may differ from the results reported by Boldt, while others agree.

Boldt's authored reviews deserve to be considered separately. In total he has 9 retracted and 13 current reviews. Not surprisingly, all of Boldt's reviews favor colloids. One of 2004 concludes that the adverse effects attributed to HES are resolved with the new products.[26] In another, Boldt states that the US Food and Drug Administration (FDA) should be less restrictive in approving new HES solutions and not require national data to support them.[27] It is interesting to note that Boldt acknowledged having received payments from the manufacturer.[28] This is why it has been suggested that journals should withdraw all narrative reviews of Boldt, given the obvious conflicts of interest.

4.2. Analysis of articles by Yoshitaka Fujii

Dr Yoshitaka Fujii was a leading researcher in the area of postoperative nausea and vomiting, promoting the use of some drugs that prevent it. Fuji's work was

20 Wilkes and Navickis, *op.cit.*

21 Inoue, Y. y Muto, K. "Noncompliance with Human Subjects' Protection Requirements as a Reason for Retracting Papers: Survey of Retraction Notices on Medical Papers Published from 1981 to 2011". *Accountability in Research* 2016; 23(2): 123-135.

22 Shafer, S. L. "Shadow of Doubt". *Anesthesia and Analgesia* 2011; 112(3): 498-500.

23 Bunn, F. y Trivedi, D. "Colloid Solutions for Fluid Resuscitation". *The Cochrane Database of Systematic Reviews* 2012; (6): CD001319; Lewis, S. R., Pritchard, M. W., Evans, D. Jw. y cols. "Colloids versus Crystalloids for Fluid Resuscitation in Critically Ill People". *The Cochrane Database of Systematic Reviews* 2018; 8: CD000567.

24 Zarychanski, R., Abou-Setta, A. M., Turgeon, A. F. y cols. "Association of Hydroxyethyl Starch Administration with Mortality and Acute Kidney Injury in Critically Ill Patients Requiring Volume Resuscitation: A Systematic Review and Meta-Analysis". *JAMA* 2013; 309(7): 678-688; Haase, N., Perner, A., Hennings, L. I. y cols. "Hydroxyethyl Starch 130/0.38-0.45 versus Crystalloid or Albumin in Patients with Sepsis: Systematic Review with Meta-Analysis and Trial Sequential Analysis". *BMJ (Clinical Research Ed.)* 2013; 346: f839.

25 Boldt, J., Heesen, M., Welters, I., Padberg, W., Martin, K. y Hempelmann, G. "Does the Type of Volume Therapy Influence Endothelial-Related Coagulation in the Critically Ill?". *British Journal of Anaesthesia* 1995; 75(6): 740-746; Boldt, J., von Bormann, B., Kling, D., Börner, U., Mulch, J. y Hempelmann, G. "[Volume replacement with a new hydroxyethyl starch preparation (3 percent HES 200/0.5) in heart surgery]". *Infusionstherapie Und Klinische Ernahrung* 1986; 13(3): 145-151; Boldt, J., Knothe, C., Schindler, E., Hammermann, H., Dapper, F. y Hempelmann, G. "Volume Replacement with Hydroxyethyl Starch Solution in Children". *British Journal of Anaesthesia* 1993; 70(6): 661-665; Boldt, J., Heesen, M., Müller, M., Pabsdorf, M. y Hempelmann, G. "The Effects of Albumin versus Hydroxyethyl Starch Solution on Cardiorespiratory and Circulatory Variables in Critically Ill Patients". *Anesthesia and Analgesia* 1996; 83(2): 254-261; Boldt, J., Mueller, M., Menges, T., Papsdorf, M. y Hempelmann, G. "Influence of Different Volume Therapy Regimens on Regulators of the Circulation in the Critically Ill". *British Journal of Anaesthesia* 1996; 77(4): 480-487.

26 Boldt, J. "[Hydroxyethylstarch (HES)]". *Wiener Klinische Wochenschrift* 2004; 116(5-6): 159-169.

27 Boldt, J. "Volume Therapy in Cardiac Surgery: Are Americans Different from Europeans?". *Journal of Cardiothoracic and Vascular Anesthesia* 2006; 20(1): 98-105.

28 Hartog, C. S. y Perner, A. "Narrative Reviews from a Fraudulent Author: Reasons to Retract". *Intensive Care Medicine* 2019; 45(5): 719-721.

subjected to parallel investigations requested by the former editor-in-chief of Anesthesia & Analgesia and the Japanese Society of Anesthesiologists. They concluded that 172 of 212 articles investigated were fraudulent because fabricated data were used, that the fraud was done by him alone, and that he had listed co-authors to diminish suspicions of fraud. They also concluded that studies in which he had appeared as co-author were valid and that he had been granted authorship as a professional favor.[29] Appendix 3 shows the 151 studies that were retracted, and Appendix 4 shows the 140 systematic reviews that cite articles by this author.

Although his articles are less cited than those of Boldt, the most cited being 71, the number of works that were retracted is significant. Of the 29 reviews read in full text, 3 were retracted, all by Fujii, 7 did exclude Fujii's studies, and 17 reviews never excluded the retracted studies.

In the reviews that exclude studies by this author, changes in the magnitude of the effect of granisetron[30] or in the safety profile of this drug are noted.[31] This drug is used for the treatment and prevention of nausea and vomiting caused by chemotherapy.[32] It is interesting to note that the authors of these reviews suspected irregularities in the harm reported by Fujii. For example, they report that Fujii reports exactly the same risk of adverse effects in most of his studies, or that the same center (where Dr Fujii worked) had a disproportionate weight in the effect of the drug in question.[33] These concerns led other reviews to exclude Fujii's articles even before the official retraction,[34] showing the mistrust that already existed towards this researcher.

Many of the reviews that did not exclude the data reported by Fujii do agree with Fujii's results,[35] but the fact that these fraudulent papers are included in the sample raises doubts about the validity of the conclusions. It is noteworthy that one review included articles even after their retraction,[36] which is particularly complex from the point of view of trust in medical research.

As for the reviews authored by Fujii, it is striking that in all of them he is the sole author. Of the six, four have been retracted; however, two reviews remain valid.[37]

5. Consequences of fraud

The consequences of fraud in biomedical research are difficult to quantify but are evident at different levels. On the one hand, some publishers have expressed

29 Miller, D. R. "Retraction of Articles Written by Dr. Yoshitaka Fujii". *Canadian Journal of Anaesthesia = Journal Canadien D'anesthesie* 2012; 59(12): 1081-1088.

30 J. B. Carlisle and C. A. Stevenson, "Drugs for Preventing Postoperative Nausea and Vomiting," *The Cochrane Database of Systematic Reviews*, no. 3 (July 2006): CD004125; Carlisle, "A Meta-Analysis of Prevention of Postoperative Nausea and Vomiting." Japanese Society of Anesthesiologists. [On line publication] *The Results of Investigation into Dr. Yoshitaka Fujii's Papers*. 2012. [Consulted: 9/06/2018].

31 Carlisle, J. B. y Stevenson, C. A. "Drugs for Preventing Postoperative Nausea and Vomiting". *The Cochrane Database of Systematic Reviews* 2006; (3): Kranke, P., Apfel, C. C., Eberhart, L. H., Georgieff, M. y Roewer, N. "The Influence of a Dominating Centre on a Quantitative Systematic Review of Granisetron for Preventing Postoperative Nausea and Vomiting". *Acta Anaesthesiologica Scandinavica* 2001; 45(6): 659-670.

32 MedlinePlus medicinas. [On line publication] "Granisetrón". https://medlineplus.gov/spanish/druginfo/meds/a601211-es.html [Consulted: 13/04/2023].

33 Kranke et al., *op cit.*

34 Griffiths, J. D., Gyte, G. M. L., Paranjothy, S., Brown, H. C., Broughton, H. K. y Thomas, J. "Interventions for Preventing Nausea and Vomiting in Women Undergoing Regional Anaesthesia for Caesarean Section". *The Cochrane Database of Systematic Reviews* 2012; (9): CD007579; Habib, A. S. y Gan, T. J. "Pharmacotherapy of Postoperative Nausea and Vomiting". *Expert Opinion on Pharmacotherapy* 2003; 4(4): 457-473.

35 De Negri, P. y Ivani, G. "Management of Postoperative Nausea and Vomiting in Children". *Paediatric Drugs* 2002; 4(11): 717-728; Bolton, C. M., Myles, P. S., Nolan, T. y Sterne, J. A. "Prophylaxis of Postoperative Vomiting in Children Undergoing Tonsillectomy: A Systematic Review and Meta-Analysis". *British Journal of Anaesthesia* 2006; 97(5): 593-604; Balki, M. y Carvalho, J. C. A. "Intraoperative Nausea and Vomiting during Cesarean Section under Regional Anesthesia". *International Journal of Obstetric Anesthesia* 2005; 14(3): 230-241; Habib, A. S. y Gan, T. J. "Evidence-Based Management of Postoperative Nausea and Vomiting: A Review". *Canadian Journal of Anaesthesia = Journal Canadien D'anesthesie* 2004; 51(4): 326-341; Skledar, S. J., Williams, B. A., Vallejo, M. C. y cols. "Eliminating Postoperative Nausea and Vomiting in Outpatient Surgery with Multimodal Strategies Including Low Doses of Nonsedating, off-Patent Antiemetics: Is 'Zero Tolerance' Achievable?". *TheScientificWorldJournal* 2007; 7: 959-977; Holte, K. y Kehlet, H. "Perioperative Single-Dose Glucocorticoid Administration: Pathophysiologic Effects and Clinical Implications". *Journal of the American College of Surgeons* 2002; 195(5): 694-712; Aapro, M. "Granisetron: An Update on Its Clinical Use in the Management of Nausea and Vomiting". *The Oncologist* 2004; 9(6): 673-686.

36 Zhang, L., Zhu, J., Xu, L. y cols. "Efficacy and Safety of Flurbiprofen Axetil in the Prevention of Pain on Propofol Injection: A Systematic Review and Meta-Analysis". *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research* 2014; 20: 995-1002.

37 Fujii, Y. "The Utility of Antiemetics in the Prevention and Treatment of Postoperative Nausea and Vomiting in Patients Scheduled for Laparoscopic Cholecystectomy". *Current Pharmaceutical Design* 2005; 11(24): 3173-3183; Fujii, Y. "Prophylaxis of Postoperative Nausea and Vomiting in Patients Scheduled for Breast Surgery". *Clinical Drug Investigation* 2006; 26(8): 427-437.

the difficulties in assessing whether fraud has actually occurred, because often there are no objective elements to determine it, or it is a costly process.[38] This is why, despite the suspicions that existed in the cases of the authors analyzed, publishers did not take strong action and publications were initially retracted due to problems with the approval of the ethics committee; only later was the fabrication of damage confirmed.[39] In the case of Boldt, the authors' suspicions were not confirmed. In the case of Boldt, the original retraction note explicitly added: 'does not mean that the research results per se are fraudulent';[40] something similar occurred with Fujii.[41]

In addition, there is no uniformity in the way the retraction of articles is reported, so retracted articles are not easy to identify.[42] Thus, the retracted article may still be used as a reference by other researchers. One study found that, of the retractions between 1972 and 2006, almost 50% of the articles cite them as valid science.[43] In fact, it was difficult for the present study to identify retractions, as traditional meta-search engines such as Web of Science, PubMed or Scopus do not always identify retracted articles as such. In this sense, the work carried out by Retraction Watch was fundamental.

If the papers are included in systematic reviews, the harm could be greater, as these papers are often considered to be the best quality scientific evidence available and are used by clinicians for decision-making. Drs. Boldt and Fujii are cited 1,001 and 513 times in systematic reviews. The harm could be perpetuated to the extent that systematic reviews are not updated, as 74% of the reviews citing Boldt and 71% citing Fujii are. While it is true that excluding retracted papers does not always change the final result (in the case of Boldt 5 out of 6 systematic reviews found no significant difference after exclusion,[44] and in the case of Fujii, this occurred in 2 out of 3),[45] the damage to confidence in the quality of scientific publications remains. In the same vein, a study that analyzed the impact of Reuben's retractions in systematic reviews concludes that when his studies represented less than 30% of patients, the results did not suffer from differences after exclusion.[46] It is more worrying when the outcome of the systematic review is indeed influenced by fraudulent data. In the case of Boldt, 4 systematic reviews recommend the use of HES, one of them even with lower mortality.[47] The frequent inclusion of retracted articles in the analyzed systematic reviews underscores a grave threat to scientific reliability, as evidenced by 734 reviews citing Boldt's and 140 citing Fujii's retracted works despite available retraction notices. Authors must prioritize primary sources and original publication venues, where retraction statuses are reliably updated, to mitigate this issue. Reliance on secondary citations or the use of AI for literature searches exacerbate risks by propagating outdated references that overlook retractions.

Finally, it is important to consider the effects that fraudulent publications have on clinical practice, which could be mediated by the inclusion of fraudulent articles or systematic reviews in the design of clinical guidelines or drug use regulations.[48] The FDA approved HES

38 DeMaria, A. N. "Scientific Misconduct, Retractions, and Errata". *Journal of the American College of Cardiology* 2012; 59(16): 1488-1489.

39 Japanese Society of Anesthesiologists, *op cit.*

40 "Editors-in-Chief Statement Regarding Published Clinical Trials Conducted without IRB Approval by Joachim Boldt". *Minerva Anestesiologica* 2011; 77(5): 562-563.

41 Japanese Society of Anesthesiologists, *op cit*.

42 Marcus, A. y Oransky, I. "What Studies of Retractions Tell Us". *Journal of Microbiology & Biology Education* 2014; 15(2): 151-154.

43 Furman, J. L., Jensen, K. y Murray, F. "Governing Knowledge in the Scientific Community: Exploring the Role of Retractions in Biomedicine". *Research Policy* 2012; 41(2): 276-290.

44 Bunn, F. y Trivedi, D. *op cit*.; Mutter, T. C., Ruth, C. A. y Dart, A. B. "Hydroxyethyl Starch (HES) versus Other Fluid Therapies: Effects on Kidney Function". *The Cochrane Database of Systematic Reviews* 2013; (7): CD007594; Henry, D. A., Carless, P. A., Moxey, A. J. y cols. "Anti-Fibrinolytic Use for Minimising Perioperative Allogeneic Blood Transfusion". *The Cochrane Database of Systematic Reviews* 2011; (3): CD001886; Perel, P., Roberts, I. y Ker, K. "Colloids versus Crystalloids for Fluid Resuscitation in Critically Ill Patients". *The Cochrane Database of Systematic Reviews* 2013; (2): CD000567; Zhong, J. Z., Wei, D., Pan, H. F. y cols. "Colloid Solutions for Fluid Resuscitation in Patients with Sepsis: Systematic Review of Randomized Controlled Trials". *The Journal of Emergency Medicine* 2013; 45(4): 485-495.

45 Carlisle, J. B. y Stevenson, C. A. *op cit.*

46 Marret, E., Elia, N., Dahl, J. B. y cols. "Susceptibility to Fraud in Systematic Reviews: Lessons from the Reuben Case". *Anesthesiology* 2009; 111(6): 1279-1289.

47 Shi, X. Y., Zou, Z., He, X. Y., Xu, H. T., Yuan, H. B. y Liu, H. "Hydroxyethyl Starch for Cardiovascular Surgery: A Systematic Review of Randomized Controlled Trials". *European Journal of Clinical Pharmacology* 2011; 67(8): 767-782.

48 Moore, R. A., Derry, S. y McQuay, H. J. "Fraud or Flawed: Adverse Impact of Fabricated or Poor Quality Research". *Anaesthesia* 2010; 65(4): 327-330.

in 2007,[49] but with conditions in populations with severe sepsis and children undergoing cardiac surgery, and it is estimated that it has been administered to at least 30 million patients.[50] Both the FDA and the European Medicines Agency (EMA) conducted extensive investigations into the safety of this substance in 2012, which led to changes in doses, indications, adverse effects and precautions.[51] In fact, in January 2018, the EMA recommended the suspension of the manufacturing of HES, but in July of the same year decided to maintain authorization under severe conditions.[52] In addition, the National Institute for Health and Care Excellence in England clearly indicates that tetrastarch should not be used for resuscitation.[53]

Changes in research and scientific publication policies have also been observed. For example, the emergence of audit committees within research institutions has been facilitated,[54] and there are new requirements from scientific journals, such as requesting ethics committee approval, or the signature of all authors attesting that they had access to the original data.[55]

6. Implications for educators

The existence of fraud in medical research should prompt serious reflection for the scientific and academic community, including educators of health science professionals. On the one hand, in order to reduce the incidence of scientific fraud, the way in which concepts of ethics and integrity are taught should be reviewed; on the other hand, given that these problems are likely to continue to occur, future professionals must critically apply scientific evidence to clinical practice, which requires competencies linked to critical thinking.

6.1. Training in scientific integrity

Despite increased scrutiny of scientific research, retractions continue to increase.[56] This is a symptom that vigilance and sanctions are not sufficient. The old adage 'prevention is better than cure' is probably more relevant than ever to address this problem. The focus must be on the training of researchers, which includes strengthening the moral character and identification of the intrinsic value of their profession in society.[57] Given the persistent rise in retractions despite enhanced oversight, there is a compelling need to integrate innovative bioethics training as a core component in under— and postgraduate programs for healthcare professionals. This new formative process should explicitly cover ethics in scientific research and publication, including the various forms of fraud (e.g., fabrication, falsification, and plagiarism), their profound risks to scientific validity and patient safety, and targeted preventive measures such as adherence to reporting guidelines and institutional oversight. Such structured education would equip future researchers with the foundational tools to uphold integrity from the outset of their careers.

The traditional emphasis is often on deontology and education about expected behaviors, current national and international regulations and the procedures that the researcher must follow. This approach is quite simple, since all that is required is the provision of information on the established guidelines on research ethics. However, they often remain at the level of theoretical knowledge and do not adequately address the skills and attitudes that are essential to influence the behavior of

49 Food and Drug Administration. [On line publication] "HIGHLIGHTS OF PRESCRIBING INFORMATION". 2007. https://www.fda.gov/media/72764/download [Consulted: 26/02/2021].

50 Wilkes, M. y Navickis, R. *op cit.*

51 Wiedermann, C. J. y Eisendle, K. "Comparison of Hydroxyethyl Starch Regulatory Summaries from the Food and Drug Administration and the European Medicines Agency". *Journal of Pharmaceutical Policy and Practice* 2017; 10.

52 European Medicines Agency. [On line publication] "Human Medicines — Hydroxyethyl Starch Solutions for Infusion". https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0 [Consulted: 5/12/2023]

53 National Institute for Health and Care Excellence. [On line publication] "Intravenous Fluid Therapy in Adults in Hospital | Guidance | NICE". 5 de mayo de 2017. [Consulted: 14/02/2021].

54 Redman, B. K. y Caplan, A. L. "Improving Research Misconduct Policies: Evidence from Social Psychology Could Inform Better Policies to Prevent Misconduct in Research". *EMBO Reports* 2017; 18(4): 511-514.

55 Wise, J. "Boldt: The Great Pretender". *BMJ (Clinical Research Ed.)* 2013; 346: f1738.

56 Furman, J. L., Jensen, K. y Murray, F. *op.cit.*; Grieneisen, M. L. y Zhang, M. "A Comprehensive Survey of Retracted Articles from the Scholarly Literature". *PloS One* 2012; 7(10): e44118

57 Cairns, A. C., Linville, C., Garcia, T. y cols. "A Phenomenographic Study of Scientists' Beliefs about the Causes of Scientists' Research Misconduct". *Research Ethics* 2021; 17470161211042658; Pizzolato, D. y Dierickx, K. "Stakeholders' Perspectives on Research Integrity Training Practices: A Qualitative Study". *BMC Medical Ethics* 2021; 22(1): 67.

future health professionals.[58] Despite their importance, the real benefit of various research ethics training programs has not been demonstrated[59] and they may be ineffective or even deleterious.[60] Many researchers believe that ethics training programs are not seen as relevant by participants and therefore fail to change researcher behavior.[61] The KAP (Knowledge, Attitudes, Practices) approach, widely used in health care since the 1950s,[62] can help us better understand why these programs are ineffective. One study reports that researchers explain the unethical behavior of their colleagues (practice) by internal problems (profit, convenience, moral deficiency, personal biases) or external problems (pressure, fear), more linked to attitudinal issues, and less to ignorance, which is closer to knowledge.[63] Thus, it is not surprising that researchers under the pressure to 'publish or perish' may end up not respecting the rules, seen as external to their personal values, and engage in practices contrary to integrity.

Research ethics encompasses the set of norms that regulate this activity, and the researcher is expected to adhere to the rules. Scientific integrity implies, on the one hand, knowledge of these norms and the ability to behave in accordance with them, it also implies the researcher's assessment of the value of science and his or her own role as a scientist. His or her attitudes and behaviors ultimately reflect this assessment. To achieve substantive ethical transformation beyond mere compliance with norms, training must delve into philosophical anthropology and the essence of human nature. Understanding innate tendencies toward self-deception, ambition, or moral rationalization reveals the deeper causes of fraudulent publications and points to remedies like cultivating virtues of truth-seeking and epistemic humility. Without this foundational anthropological perspective, efforts risk superficiality, failing to foster a lived ethic that genuinely aligns research practices with human dignity and societal trust. Moreover, it is a challenge to train in professional integrity, when we consider that there is still no shared and accepted definition by the scientific community of what is understood by this concept[64] and 66 different codes referring to integrity in research have recently been identified.[65] It is necessary to progress in the better conceptualization of this competence, which requires the work of bioethicists and educators.[66] This work is of paramount importance, because the teaching of research integrity is not effective and only with clear guidelines will it be easier to establish the most appropriate pedagogical strategies for the transmission of this type of knowledge,[67] addressing both theoretical and attitudinal aspects.

Echoing the way in which some authors propose to analyze ethical issues,[68] it has been proposed that scientific integrity develop in four distinct phases, which could be considered competences or meta-competences:

— Awareness or sensitivity, in which potential problems of integrity are identified.

— Reasoning, in which the available information is organized for decision making.

— Motivation, in which the researcher takes into account the reasons that lead him or her to behave, or not, in an integral way.

— Action, in which the researcher uses the resources available to him/her to act in accordance with reasoning and motivations.[69]

On the other hand, some skills and values associated with integrity have been identified. Among the former are metacognitive competencies, the ability to draw on the use of tools, and the basics of statistics and research

58 Pizzolato, D. y Dierickx, K. *op.cit.*

59 Crean, D., Gordijn, B. y Kearns, A. J. "Teaching Research Integrity as Discussed in Research Integrity Codes: A Systematic Literature Review". *Accountability in Research* 2023: 1-24.

60 Cairns et al., *op.cit.*

61 Ibid.

62 Andrade, C., Menon, V., Ameen, S. y Praharaj, S. K. "Designing and Conducting Knowledge, Attitude, and Practice Surveys in Psychiatry: Practical Guidance". *Indian Journal of Psychological Medicine* 2020; 42(5): 478-481.

63 Cairns et al., *op.cit.*

64 Patrão Neves, M. C. "On (Scientific) Integrity: Conceptual Clarification". *Medicine, Health Care, and Philosophy* 2018; 21(2): 181-187.

65 Crean et al., *op.cit.*

66 Pizzolato, D. y Dierickx, K. *op.cit.*

67 Crean et al., *op.cit.*

68 Rest, J. R. *Moral Development: Advances in Research and Theory*, Praeger, 1986.

69 Crean, D., Gordijn, B. y Kearns, A. J. "Impact and Assessment of Research Integrity Teaching: A Systematic Literature Review". *Science and Engineering Ethics* 2024; 30(4): 30.

methodology, and among the latter, the love of truth, intellectual humility and epistemic responsibility.[70] The competencies described are probably more relevant during the awareness, reasoning and action stages, while the values are more relevant for motivation.

In terms of practical aspects for improving education in research ethics and scientific integrity, better identification of target audiences and the creation of discipline— and level-specific programs, the design of hybrid (as opposed to online-only) training programs, and the use of mentoring have been proposed.[71]

On the other hand, there are some meta-competencies that, while valuable in themselves, could help researchers to behave with more integrity, which also deserve to be analyzed. Researchers often have to perform multiple tasks in parallel, with the help of research teams.[72] This could be relevant, as many of the integrity problems could be explained by inadequate management of the research teams, without necessarily being due to researchers' bad intentions.[73] These findings were confirmed in a recent study, which describes some factors linked to integrity violations, such as lack of supervisory capacity, lack of time (often due to inadequate time management), fatigue (linked to inadequate task allocation and understaffing), communication problems within the team, among others.[74] Thus, in order to better equip researchers to avoid breaches of scientific integrity, it should be necessary to provide them with specific competencies linked to leadership and management, such as effective communication, teamwork, coaching, task sharing, strategic planning, budgeting, personnel selection and evaluation, and situational awareness.[75] There is much evidence from other disciplines on the most effective methodologies for teaching these competences, but the work of analyzing how to apply these pedagogical strategies to the field of scientific research has not yet been done.[76] Another challenge closely linked to the above is the use of assessment tools that enable the level of performance of these competences to be analyzed. However, there are already some instruments that appear to be promising in this respect, which measure the ability to foster relationships and conduct risky research by means of a validated questionnaire.[77]

6.2. Critical thinking training

The progressive importance of evidence-based medicine has allowed standardization of patient care practices, maximizing the benefit that scientific progress brings to patients. However, as discussed above, it has limits that need to be taken into account. In addition to being very cautious when applying the results of scientific research produced in a context other than the one being worked on, the quality of the research itself must be assessed, considering the possibility that the articles may have used poor quality data or even falsified data. The editorial policies of scientific journals seek to safeguard the quality of the articles they publish, as well as the validity of their data; but, as illustrated by the cases discussed in this article, it is not always feasible to detect falsified data. While it was noted by some authors that it was indeed suspicious that a small number of researchers produced most of the data on a single topic,[78] this did not prevent Boldt and Fujii from maintaining their fraudulent practices for many years. This is why critical thinking skills, including the analysis of scientific literature, are indispensable if we want to ensure that health professionals make correct use of scientific evidence and clinical guidelines.

70 Allard, A. y Clavien, C. "Teaching Epistemic Integrity to Promote Reliable Scientific Communication". *Frontiers in Psychology* 2024; 15.

71 Pizzolato, D. y Dierickx, K. *op.cit.*

72 Antes, A. L., Mart, A. y DuBois, J. M. "Are Leadership and Management Essential for Good Research? An Interview Study of Genetic Researchers". *Journal of Empirical Research on Human Research Ethics: JERHRE* 2016; 11(5): 408-423.

73 DuBois, J. M. "Is Compliance a Professional Virtue of Researchers? Reflections on Promoting the Responsible Conduct of Research". *Ethics & Behavior* 2004; 14(4): 383-395.

74 McIntosh, T., Antes, A. L., Schenk, E., Rolf, L. y DuBois, J. M. "Addressing Serious and Continuing Research Noncompliance and Integrity Violations through Action Plans: Interviews with Institutional Officials". *Accountability in Research* 2024; 31(8): 991-1023.

75 Antes, A. L., Mart, A. y DuBois, J. M. *op.cit.*

76 Antes, A. L., Mart, A. y DuBois, J. M. *op.cit.*

77 Antes, A. L., English, T., Solomon, E. D. y cols. "Leadership, Management, and Team Practices in Research Labs: Development and Validation of Two New Measures". *Accountability in Research* 2024: 1-28.

78 Moore et al., *op.cit.*

The term critical thinking has been used for many years, especially in nursing education.[79] In 1990 it was defined as 'the process of intentional, self-regulated judgement, resulting in interpretation, analysis, evaluation, and inference, as well as explanation of the conceptual, methodological, criterion-logical or contextual considerations on which that judgement is based'.[80] In the current context, where information of varying quality abounds, this skill is very important, not only for health professionals, but for the entire population.[81] As illustrated by the cases discussed above, this is particularly true when evaluating the use of scientific evidence for application to clinical practice.

Among the characteristics of critical thinking have been named:[82]

— making explicit the type of cognitive processing used (type 1, an intuitive process, and type 2, an analytical process)
— recognition of cognitive biases and uncertainty
— use of inductive reasoning
— use of 'how' or 'why' questions, rather than 'what' questions
— feedback through reflective practice.

There are a number of methodological strategies that have been used in the past.

There are various methodological strategies that have been used to teach critical thinking, such as journals or portfolios, concept maps, vignettes to stimulate discussion, role-playing, case studies and imagery,[83] among others. All of them emphasize the importance of repeated personal experience and reflective practice, often accompanied by feedback adapted to the level of training.[84] A systematic review shows that so-called non-traditional methods are better than traditional ones, highlighting the usefulness of concept mapping as an effective strategy.[85] In contrast to scientific integrity, critical thinking has more evidence on the most appropriate methodologies for its teaching, however, recent work shows that there is still work to be done to ensure that it is taught effectively in training curricula.[86]

Just as leadership and management are instrumental meta-competences for promoting integrity, critical thinking also requires other competences in order to be accomplished. One of these is the ability to speak up. In a powerful testimony by Ungern-Sternberg, this researcher describes a situation she was exposed to, which clashed with her own scientific integrity, and the long process that followed the complaint, which was full of difficulties.[87] Testimonies such as this one should make us reflect on the importance of training health professionals who are not only competent from a technical and integrity point of view, but who also have the assertiveness to denounce situations that could directly or indirectly (as in the case of breaches of scientific integrity) put patients' health at risk.

Arguably, scientific integrity and critical thinking, as well as leadership, management and assertiveness, are all necessary competencies for future health professionals, who must first and foremost look after the well-being of patients.

7. Conclusion

Fraud in medical research represents a significant challenge to scientific integrity, undermines trust in research and can have serious consequences for people's health if fraudulent evidence is applied to clinical medicine. The

79 Staib, S. "Teaching and Measuring Critical Thinking". *The Journal of Nursing Education* 2003; 42(11): 498-508.

80 Facione, P. *Critical Thinking: A Statement of Expert Consensus for Purposes of Educational Assessment and Instruction. Research Findings and Recommendations*, Vol. 315, American Philosophical Association, 1990.

81 Holmes, N. G., Wieman, C. E. y Bonn, D. A. "Teaching Critical Thinking". *Proceedings of the National Academy of Sciences of the United States of America* 2015; 112(36).

82 Hayes, M. M., Chatterjee, S. y Schwartzstein, R. M. "Critical Thinking in Critical Care: Five Strategies to Improve Teaching and Learning in the Intensive Care Unit". *Annals of the American Thoracic Society* 2017; 14(4): 569-575; Sullivan, A. M., Hayes, M. M., Beltran, C. P. y cols. "Do We Teach Critical Thinking? A Mixed Methods Study of Faculty and Student Perceptions of Teaching and Learning Critical Thinking at Three Professional Schools". *Medical Teacher* 2024; 46(11): 1494-1501.

83 Staib, *op.cit*.

84 Holmes et al., *op.cit*.

85 Lee, J., Lee, Y., Gong, S., Bae, J. y Choi, M. "A Meta-Analysis of the Effects of Non-Traditional Teaching Methods on the Critical Thinking Abilities of Nursing Students". *BMC Medical Education* 2016; 16(1): 240.

86 Sullivan et al., *op.cit.*

87 Ungern-Sternberg, B. S., Regli, A., Stepanovic, B. y Becke-Jakob, K. "Authorship Misconduct: Professional Misconduct in Editorial Handling of Authorship". *British Journal of Anaesthesia* 2024; 133(6): 1134-1136.

exposure of researcher fraud in this area raises alarm bells. Cross-cutting efforts are needed to ensure that medical research is reliable, rigorous and beneficial to society as a whole. All actors, including educators of health professionals, must work to foster a culture of integrity at all stages of the research process to prevent harm to patients. For the latter, reflection on ways to teach scientific integrity and critical thinking is recommended.

Being an educator of future health science professionals is a great responsibility, because they will have everyone's life and health in their hands. It is essential to identify appropriate pedagogical strategies to influence the skills, attitudes and behaviors of future professionals. Developing integrity and critical judgement may require the use of different methodological approaches to those traditionally used in the medical sciences, and it is not surprising that this work is in its early stages for many of these competencies. In addition to methodologies, it is necessary to keep in mind the stage of training that is intended to be developed in each instance, planning based on clear objectives, the development of structured assessments and a long-term outlook.

Declarations

Availability of data and materials: All data generated or analysed during this study are included in this published article and its supplementary information files.

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