

• EDITORIAL •

COVID-19 and ethical research in Iraq

Mohammed Al-Musawi*

The New England Journal of Medicine (NEJM) has published recently the short-term results of a nonblinded, randomized trial comparing antibiotic therapy with appendectomy (with most procedures performed laparoscopically) in 1552 adults who were treated at academic health centers across the United States.¹ Trial showed that, for the treatment of appendicitis, antibiotics were noninferior to appendectomy based on results of a standardized measure of general health status, at least in the short term. In the antibiotics group, nearly 3 in 10 participants had undergone appendectomy by 90 days, and there were more emergency department visits and hospitalizations after the index treatment than in the appendectomy group. An alternative perspective is that, in the antibiotics group, more than 7 in 10 participants avoided surgery, many were treated on an outpatient basis, and participants and caregivers missed less time at work than with appendectomy. In the antibiotics group, participants with an appendicolith were at a higher risk for both appendectomy and complications than participants without an appendicolith. These data may be particularly relevant during the Covid-19 pandemic, as patients and clinicians weigh the benefits and risks of each approach, considering individual characteristics, preferences, and circumstances.²

It is important here to say that this research required all the scientific efforts to ensure study design which is based on reviewing current most updated knowledge. Not only that, it required review and approvals from each and every ethical committee at academic health

centers across the United States where the study was conducted. The study design included all the necessary measured to ensure patient safety if anything goes wrong while they are on the study. Patient safety is number one when it comes to clinical research.³

This clinical trial is a prove how well-designed research can change practice even if that practice was unshakable golden standard. It is a good opportunity here to emphasize the difference between a good doctor who is clinically skilled and follows the good clinical practice guidelines and only provides what is agreed upon. Those good doctors do not attempt to give a nonstandard medication or intervention. Also they don't run a clinical research without having the necessary research training, academic qualifications and resources (labs, personnel, funds). During the COVID 19 pandemic we started to see few Iraqi clinicians who proposed therapies or prophylactic measures to manage or to curb the viral infection. Unfortunately, when we listen to their talk, we discover the lack of the basic research knowledge and lack of scientific facts. Moreover, they are using social media to promote false ideas to the public by using their image as clinicians. Other than the fact that none of them is a specialist in the field of virology or infectious diseases, they gave themselves to practice their nonstandard medicines on patients without any scientific or ethical approval. What is even more disheartening is that while they are causing more damage to the patients and encouraging people to avoid practicing social distancing and wearing the face mask. The important question here is

how to stop that and how to prevent this now malpractice in the future.

It is very important that the Ministry of Health and Ministry of higher education should have clear and strict rules and regulations for how to conduct research on human beings based on the work of Geneva convention and international laws.⁴ It is their responsibility that they are protecting the patients in our population from these nonscientific and harmful practices. There should tough consequences on those who violates these rules to ensure public safety. Doctors should accept the fact that being a clinician does not mean to do a research on patients without their approval and without the right knowledge and qualifications. Yet they can be brought together if the clinician get the researcher qualification in the right pathway. Only then the clinician can practice it clinical research under strict institutional rules and regulations to ensure public safety.

REFERENCES

1. Flum DR, Davidson GH, Monsell SE, Shapiro NI, Odom SR, Sanchez SE, et al. A Randomized Trial Comparing Antibiotics with Appendectomy for Appendicitis. CODA Collaborative. *N Engl J Med* 2020; 383:1907-1919. doi: 10.1056/NEJMoa2014320.
2. Jacobs D. Antibiotics for Appendicitis - Proceed with Caution. *N Engl J Med*. 2020; 383:1985-1986. DOI: 10.1056/NEJM2029126
3. US Food & Drugs administration. Institutional Review Boards Frequently Asked Questions. Guidance for Institutional Review Boards and Clinical Investigators. January 1998. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions>. Accessed October/20/2020
4. History.com Editors. Geneva Convention. On History. Publisher A&E Television Networks. 2017 [Last updated August 21, 2018; Cited 2020 November 10]. Available from: <https://www.history.com/topics/world-war-ii/geneva-convention>.