



EDITORIAL

FROM EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES TO CLINICAL PROTOCOLS AND EVIDENCE SUMMARIES

One of the most common problems in hospital care is variability in clinical practice, which has been defined as “inequality in the use of health resources between different geographic areas or healthcare levels, in circumstances in which adaptation of the knowledge and resources of the system should primarily be aimed at meeting individual patient needs” (1). Obstetrics and gynecology as a field of practice has not been immune to this issue. In 2015, for example, removal of ovaries at the time of hysterectomy for benign uterine disease ranged between 50% in the United States, 30% in Australia and 12% in Germany (2). As for cesarean section, Latin America has one of the highest frequencies, with 40% of all deliveries, followed by North America with 30%, Europe with 25%, Asia with 19% and Africa with 7% (3). It is not self-evident that this wide variation in the frequency with which this surgery is performed is due to varying patient needs, but rather to different styles in the practice of medicine. The problem occurs when this variability is associated with poor health outcomes for the population in the form of an increase in adverse events, and unwarranted higher costs, or when it is the result of health inequalities among populations (1).

One example of poor results is the association which has been described between elective cesarean delivery and the increase in neonatal respiratory distress syndrome in gestations under 38 weeks and 6 days (4). Therefore, variability in obstetric practice is reflected in higher costs for healthcare services due to increased delivery costs and management of neonatal respiratory distress. As pertains to prophylactic

oophorectomy, there has been much debate regarding the benefit of lowering the risk of tubal, ovarian or breast cancer as compared to the associated risks of increases in cardiovascular disease, osteoporosis, cognitive alterations and poor quality of life, particularly when performed before 45 years of age (5). Oophorectomy could also create a greater need for hormone replacement therapy or other medical treatments for the management of secondary conditions, with the subsequent increase in out-of-pocket spending and higher costs for the health system.

Our specialty is not the only one affected by clinical variability. Clear examples are also found in other surgical specialties and procedures such as carotid revascularization, surgery for morbid obesity, peripheral vascular disease in diabetics, prostate cancer (6), or in the inadequate use of prophylactic antibiotics in pediatric surgery, increasing the risk of opportunistic infections in those who receive them (7).

Another example of clinical practice variability which falls within the framework of the definition presented above is found in this issue of the *Revista Colombiana de Obstetricia y Ginecología* (RCOG). It refers to a problem of variability in healthcare use as a clear example of inequity. The study by Martínez-Pérez et al. illustrates that one of the factors that most influence the delay in diagnosis of breast cancer in Antioquia, Colombia, is the affiliation to the social security system subsidized by the State compared to the contributory regime from the workers.

In the past, physician experience was considered the best guarantee to prevent poor health outcomes.

However, several circumstances led to a shift in this perception: the application of epidemiology to decision-making regarding individual patient care, known as clinical epidemiology (8) or modern epidemiology (9), which allowed a more direct application of frequency estimators to the concept of the risk of the disease (10); or predictions regarding who will become ill or die (11), with stronger epidemiological designs, including the development of randomized controlled trials supported by robust statistical methods for assessing intervention effects (12). This approach resulted in the development of evidence-based medicine which focused on the importance of measuring results and adequately selecting the most relevant endpoints in accordance with the underlying condition (13) and the assessment of the validity of published studies (14). This was followed later by the development of systematic reviews of interventions, which allowed a more accurate assessment of their safety and efficacy (15). This resulted in the emergence of the current thinking that informed decision-making is an option to arrive at improved health results which, together with clinical expertise, has become the corner stone of medical practice.

These methodological approaches have been used most frequently for the assessment of medical treatments and, to a lesser degree, in relation to surgical treatments, where rapidly advancing technologies have precluded the performance of randomized controlled studies (16). However, currently available electronic clinical records, coupled with the interest of practitioners, patients and payers in the therapeutic value in terms of good and bad results of the various surgical procedures carried out at a large scale, have been instrumental for gaining insight into the issue of variability. Finally, lower variability has been described in surgical specialties when learning-based methods and quality improvement process ownership by surgeons are applied in surgical services and healthcare institutions (7).

One of the goals of applying quality improvement methods in health is to reduce variability among

interventions. Centers of excellence are recognized as places where a particular medical procedure is delivered in a single way and under a patient-centered approach, for example in the case of breast disease or hip surgery (17). These centers of excellence produce very good health outcomes and operate at lower costs (18).

Steps taken to reduce variation in inpatient services include evidence-based clinical practice guidelines (CPGs). CPGs are statements that contain recommendations designed to optimize patient care. They are based on a systematic review of the evidence and the assessment of the harm and benefit of alternative options. Characteristically, they contain a protocol, several questions that prompt a systematic search of the available medical evidence, an appraisal of the certainty regarding the effects found in the evidence, and recommendations for application, built by a multi-disciplinary team based on risks, benefits, preferences and costs, and which are periodically updated (19). Examples include the guidelines published in 2013 by the Colombian Ministry of Health and Social Protection for the management of premature rupture of membranes (20). However, there is considerable variation in adherence to CPGs. For example, a survey conducted to assess adherence to the guidelines for antenatal use of corticosteroids (ANC) in New Zealand showed that 52% of the respondents prescribed an initial course of ANC at ≥ 35 weeks, 93% reported having prescribed ANC at ≥ 35 weeks before elective cesarean section, and 29% exceeded the recommendations regarding the number of repeat courses (21). On the other hand, adherence to thromboprophylaxis guidelines in cancer ranges between 19 and 70% according to various studies (22). There are several reasons that explain this low adherence, including entrenched habits among physicians, lack of awareness regarding the guidelines, low credibility attached to the guidelines, the view that each patient needs to be approached individually, or the complexity of the organization or implementation of the guidelines (22). In the area of postpartum hemorrhage, one of the

factors described as associated with poor maternal outcomes is the lack of clarity in the CPG or that these are not sufficiently known. Finally, in many specific situations, CPGs have been found to be too broad and general in their approach and, therefore, not respond appropriately to the particular needs of the medical community regarding information and technical indications relevant to the proper performance of medical or surgical procedures

Therefore, clear, credible and easy-to-use alternatives to CPGs in specific conditions are required in order to improve identification of key recommendations. Several such alternatives have been suggested, as is the case with clinical pathways, procedure-specific plans and evidence summaries. Clinical pathways, also known as evidence-based clinical protocols, have been defined as “clinical management tools that organize and determine the sequence and duration of all types of interventions carried out by healthcare staff and hospital services in relation to a condition or a specific procedure” (24). In general, they describe recommendations and the supporting activities (many of them known), some of them based on evidence and others based on the organization’s past experience. They also describe responsibilities and follow a sequence of administration times and places (surgical services) (25). Evidence based procedure-specific plans, on the other hand, provide evidence-based practical recommendations, focusing on specific situations or conditions. They follow systematic methodologies for literature searches, as well as the use or construction of systematic reviews of the literature regarding interventions based on controlled clinical trials or systematic reviews for specific procedures, which are interpreted by consensus meetings of healthcare workers interested in making sure that the procedure is of the highest quality while increasing benefits and reducing the risks (26). Groups of anesthesiologists specializing in pain management have been at the forefront of the development of procedure-specific ways (27,28). Evidence-based summaries are the last of these alternatives. They are short articles addressed to healthcare professionals that summarize

the existing international evidence regarding medical care interventions and common care processes in specific clinical areas. They are based on structured literature searches focusing on specific problems, and they are drafted after a critical quality appraisal and are subject to peer review designed to ensure that they meet certain requirements. They are aimed at informing and guiding decision-making regarding clinical policy and practice (29).

This issue of RCOG features evidence-based summaries for central venous catheter (CVC) insertion and maintenance. We decided to publish them considering that many of our obstetric patients suffer serious pregnancy-related complications such as severe pre-eclampsia, postpartum hemorrhage, obstetric sepsis or pulmonary embolism, requiring placement of these medical devices. Moreover, our colleagues are increasingly being called to be part of the multi-disciplinary team in charge of managing these patients in intensive care units. Also, one of our objectives is to publish manuscripts focused on the health of women in all stages of life. We believe that these types of documents that focus on specific problems and provide valid information in a simple, clear and concise manner are needed in emergency and inpatient services to enhance the safety and quality of their interventions. We invite specialists in our area in this country and in the wider region to develop and submit these types of short documents based on the best available evidence, for the benefit of our healthcare workers and the health of our Latin American women.

Hernando Gaitán-Duarte, MD, MSc.

Editor

REFERENCES

1. Molina Arias M. Análisis de las causas de la variabilidad en la práctica médica. *Evid Pediatr.* 2011;7:21
2. Hammer A, Rositch AF, Kahlert J, Gravitt PE, Blaakaer J, Sjøgaard M. Global epidemiology of hysterectomy: Possible impact on gynecological cancer rates. *Am*

- J Obstet Gynecol. 2015;213(1):23-9. <https://doi.org/10.1016/j.ajog.2015.02.019>
3. Betrán AP, Ye J, Moller AB, Zhang J, Gülmezoglu AM, Torloni MR. The increasing trend in caesarean section rates: Global, regional and national estimates: 1990-2014. *PLoS One*. 2016;11(2):e0148343. <https://doi.org/10.1371/journal.pone.0148343>
 4. Hansen AK, Wisborg K, Uldbjerg N, Henriksen TB. Risk of respiratory morbidity in term infants delivered by elective caesarean section: Cohort study. *BMJ* 2008;336:85-7. <https://doi.org/10.1136/bmj.39405.539282.BE>
 5. ACOG Committee Opinion No. 774. Summary: Opportunistic salpingectomy as a strategy for epithelial ovarian cancer prevention. *Obstet Gynecol*. 2019;133(4):842-3. <https://doi.org/10.1097/AOG.0000000000003165>
 6. The Dartmouth Atlas of Health Care. Variation in the care of surgical conditions. A Dartmouth Atlas of Health Care Series. Available in: https://www.dartmouthatlas.org/downloads/atlas/Surgical_Atlas_2014.pdf
 7. Sandora TJ, Fung M, Melvin P, Graham DA, Rangel SJ. National variability and appropriateness of surgical antibiotic prophylaxis in US children's hospitals. *JAMA Pediatr*. 2016;170(6):570-6. <https://doi.org/10.1001/jamapediatrics.2016.0019>
 8. Spitzer WO. Clinical epidemiology. *J Chronic Dis*. 1986;39(6):411-5. [https://doi.org/10.1016/0021-9681\(86\)90107-4](https://doi.org/10.1016/0021-9681(86)90107-4)
 9. Rothman K, Greenland K. *Modern Epidemiology*. 2 ed. Philadelphia: Lippincot-Raven; 1998.
 10. Feinstein AR. Misguided efforts and future challenges for research on "diagnostic tests". *J Epidemiol Community Health*. 2002;56(5):330-2. <https://doi.org/10.1136/jech.56.5.330>
 11. Feinstein AR. An additional basic science for clinical medicine: I. The constraining fundamental paradigms. *Ann Intern Med*. 1983;99(3):393-7. <https://doi.org/10.7326/0003-4819-99-3-393>
 12. Weiss N. Clinical epidemiology. En: Rothman K, Greenland K. *Modern Epidemiology*. Philadelphia: Lippincot-Raven; 1998.
 13. Guyatt GH, Oxman AD, Kunz R, et al. GRADE guidelines: 2. Framing the question and deciding on important outcomes. *J Clin Epidemiol*. 2011;64(4):395-400. <https://doi.org/10.1016/j.jclinepi.2010.09.012>
 14. Oxman AD, Sackett DL, Guyatt GH. Users' guides to the medical literature. I. How to get started. The Evidence-Based Medicine Working Group. *JAMA*. 1993;270:2093-5. <https://doi.org/10.1001/jama.1993.03510170083036>
 15. Green S, Higgins JPT, Alderson P, Clarke M, Mulrow CD, Oxman AD. Chapter 1. Introduction. In: Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* (updated March 2011). The Cochrane Collaboration, 2011. <https://doi.org/10.1002/9780470712184.ch1>
 16. McCulloch P, Taylor I, Sasako M, Lovett B, Griffin D. Randomised trials in surgery: Problems and possible solutions. *BMJ*. 2002;324(7351):1448-51. <https://doi.org/10.1136/bmj.324.7351.1448>
 17. Advisory Board. Why is a 'center of excellence' different from an institute?. 2011 Available in: <https://www.advisor.y.com/research/market-innovation-center/the-growth-channel/09/what-is-the-difference-between-a-center-of-excellence-and-an-institute>
 18. Mehrotra A, Sloss EM, Hussey PS, Adams JL, Lovejoy S, Soohoo NF. Evaluation of centers of excellence program for knee and hip replacement. *Med Care*. 2013;51(1):28-36. <https://doi.org/10.1097/MLR.0b013e3182699407>
 19. Institute of Medicine (US). Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Graham R, Mancher M, Miller Wolman D, et al., editors. *Clinical Practice Guidelines We Can Trust*. Washington: National Academies Press; 2011. Available in: <https://www.ncbi.nlm.nih.gov/books/NBK209538/>
 20. Amaya-Guío J, Rubio-Romero JA, Arévalo-Mora L, Osorio-Castaño JH, Edna-Estrada F, Ospino-Guzmán MP. Guía de práctica clínica para la prevención, detección temprana y tratamiento de las complicaciones del embarazo, parto y puerperio: sección 3. Infecciones en el embarazo: ruptura prematura de membranas

- (RPM). *Rev Colomb Obstet Ginecol.* 2015;66(4):263-86. <https://doi.org/10.18597/rcog.293>
21. Tuohy JF, Harding JE, Crowther CA, Bloomfield FH. Reported adherence to current antenatal corticosteroid guidelines in Australia and New Zealand. *Aust N Z J Obstet Gynaecol.* 2019;59(3):416-21. <https://doi.org/10.1111/ajo.12890>
22. Mahé I, Chidiac J, Helfer H, Noble S. Factors influencing adherence to clinical guidelines in the management of cancer-associated thrombosis. *J Thromb Haemost.* 2016;14(11):2107-213. <https://doi.org/10.1111/jth.13483>
23. Woiski MD, Belfroid E, Liefers J, Grol RP, Scheepers HC, Hermens RP. Influencing factors for high quality care on postpartum haemorrhage in the Netherlands: Patient and professional perspectives. *BMC Pregnancy Childbirth.* 2015;15:272. <https://doi.org/10.1186/s12884-015-0707-9>
24. Zander K. Critical pathways. En: Melum MM, Sinioris MK, editors. *Total quality management.* AHA, Chicago: The Health Care Pioneers; 1992.
25. Romero M, Soria V, Ruiz P, Rodríguez E, Aguayo JL. Guías y vías clínicas, ¿existe realmente diferencia? *Cir Esp.* 2010;88(2):81-4. <https://doi.org/10.1016/j.ciresp.2010.03.021>
26. Lee B, Schug SA, Joshi GP, Kehlet H, Prospect Working Group. Procedure-specific pain management (Prospect) - An update. *Best Pract Res Clin Anaesthesiol.* 2018;32(2):101-11. <https://doi.org/10.1016/j.bpa.2018.06.012>
27. Prospect: Evidence-based, procedure-specific post-operative pain management. Available in: <https://esraeurope.org/pain-management/>
28. Kehlet H, Wilkinson RC, Fischer HB, Camu F; Prospect Working Group. Prospect: Evidence-based, procedure-specific postoperative pain management. *Best Pract Res Clin Anaesthesiol.* 2007;21(1):149-59. <https://doi.org/10.1016/j.bpa.2006.12.001>
29. Stephenson M. Implementation Science Team. The Joanna Briggs Institute Scientific Writer Handbook. 2018. Available in: http://joannabriggs-webdev.org/assets/docs/scientificWriters/JBI%20Scientific%20Writer%20Handbook_July%202018.pdf