

## BÖLÜM 8

# KLİNİKTE TOPLANAN GÖZLEMSİZ STANDART VERİNİN RAPORLANMASI (RECORD)

Neşe YAKŞI<sup>1</sup>

## GİRİŞ

Sağlık sistemlerinde verinin elektronik ortamda depolanabilmesi klinik olarak olumlu gelişmelere yol açmıştır (1) ve özellikle standart olarak toplanan veriler kolay ulaşılabilir olması nedeniyle son zamanlarda araştırmacılar tarafından sıkılıkla kullanılmaktadır. Standart olarak toplanan veriler herhangi bir araştırma amacı olmaksızın toplanan verilerdir. Farklı sağlık sunucularından, farklı coğrafik bölgelerden toplanan bu veriler araştırmacılar için yenilikçi, etkili ve maliyet etkin çalışmalarına imkan tanımaktadır. Bu sebeple, sağlıkta standart toplanan verilerin kullanımı ulusal idarelerce desteklenmekte ve sağlık araştırmalarının dönüşümü, sağlık hizmetlerinin iyileştirilmesi ve hasta bakımının geliştirilmesi amacıyla teşvik edilmektedir (2). Fakat veri ulaşılabilirliğinin kolay olması ve standart toplanan verilerin araştırma amaçlı kullanımının hızla yaygınlaşması, beraberinde sağlık araştırmalarının ve elde edilen bulguların yorumlanmasında bir takım kaygı ve soruları beraberinde getirmiştir (3).

RECORD (**R**eporting of **S**tudies **C**onducted **U**sing **O**bservational **R**outinely **C**ollected **D**ata), sağlık alanında yönetimsel veya klinik amaçla standart olarak toplanan hastalık ve sağlık verileri kullanılarak yapılan gözlemsel çalışmaların raporlanmasıında kullanılan bir kılavuzdur (4). Farklı disiplinlerden alanında uzman hekim, araştırmacı ve editörler tarafından 2015 yılında; gözlemsel araştırmalarda 2007 yılından bu yana kullanılan STROBE (**S**trenghthening the **R**eporting of **O**bservational **s**tudies in **E**pide*m*iology) kılavuzunun bir uzantısı olarak oluşturulmuştur (5). RECORD rehberi güncel olarak yirmiden fazla dergi tarafından desteklenmekte ve kullanımı önerilmektedir (4). Almanca, Çince, Japonca ve Fransızca dillerine çevrilmiştir (4). Türkçe çevirisi bulunmamaktadır.

<sup>1</sup> Dr. Öğr. Üyesi, Amasya Üniversitesi Tıp Fakültesi Halk Sağlığı AD, drnsyks@gmail.com

fakat daha önemli olan bu rehberlerin araştırmacılar, dergiler ve hakemler tarafından uygulanmasıdır. RECORD rehberi standart toplanan sağlık verileri ile yapılan gözlemsel çalışmaların raporlanması sırasında kullanılan, STROBE rehberinin bir alternatif değil, destekleyici ve tamamlayıcı olarak geliştirilmiş bir kılavuzdur. RECORD-PE ise standart olarak toplanan veriler ile yapılan farmakoepidemioloji alanındaki çalışmalarında kullanılmak üzere RECORD rehberinden uyarlanarak oluşturulmuştur. Diğer araştırma kılavuzlarında olduğu gibi RECORD rehberi de araştırma raporlama kalitesini artırarak okuyucuya makalenin kısıtlıkları, güclü yanları ve sonuçlarının doğruluğunu yorumlama imkanı sunmaktadır. Bununla birlikte RECORD rehberinin kullanılması araştırmaların şeffaflığı, tekrarlanabilmesi ve araştırmamanın uygun raporlanması açısından önemlidir.

## KAYNAKLAR

1. Hillestad R, Bigelow J, Bower A, Girosi F, Meili R, Scoville R, vd. Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. *Health affairs*. 2005;24(5):1103-17.
2. De Coster C, Quan H, Finlayson A, Gao M, Halfon P, Humphries KH, vd. Identifying priorities in methodological research using ICD-9-CM and ICD-10 administrative data: report from an international consortium. *BMC health services research*. 2006;6(1):1-6.
3. Harpe SE. Using secondary data sources for pharmacoepidemiology and outcomes research. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*. 2009;29(2):138-53.
4. Reporting of Studies Conducted Using Observational Routinely Collected Data [İnternet]. Erişim adresi: <http://www.record-statement.org/checklist.php>
5. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandebroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Bulletin of the World Health Organization*. 2007;85:867-72.
6. Benchimol El, Smeeth L, Guttmann A, Harron K, Hemkens LG, Moher D, vd. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*. 2016;115:33-48.
7. Ioannidis JP, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, vd. Increasing value and reducing waste in research design, conduct, and analysis. *The Lancet*. 2014;383(9912):166-75.
8. Rothman KJ, Greenland S, Lash TL. Modern epidemiology. C. 3. Wolters Kluwer Health/Lippincott Williams & Wilkins Philadelphia; 2008.
9. de Oliveira Costa J, Bruno C, Baranwal N, Gisev N, Dobbins TA, Degenhardt L, vd. Variations in Long-term Opioid Therapy Definitions: A Systematic Review of Observational Studies Using Routinely Collected Data (2000-2019). *British Journal of Clinical Pharmacology*. 2021;
10. Homer CS, Thornton C, Scarf VL, Ellwood DA, Oats JJ, Foureur MJ, vd. Birthplace in New South Wales, Australia: an analysis of perinatal outcomes using routinely collected data. *BMC pregnancy and childbirth*. 2014;14(1):1-12.
11. Teece L, Gray LJ, Melbourne C, Orton C, Ford DV, Martin CA, vd. United Kingdom Research study into Ethnicity And COVID-19 outcomes in Healthcare workers (UK-REACH): a retrospective cohort study using linked routinely collected data, study protocol. *BMJ open*. 2021;11(6):e046392.
12. Prokosch H-U, Ganslandt T. Perspectives for medical informatics. *Methods of information in medicine*. 2009;48(01):38-44.
13. Haas R, Busija L, Gorelik A, O'Connor DA, Pearce C, Mazza D, vd. Protocol: Patterns of care for people presenting to Australian general practice with musculoskeletal complaints based on

- routinely collected data: protocol for an observational cohort study using the Population Level Analysis and Reporting (POLAR) database. *BMJ Open*. 2021;11(9).
14. Fonferko-Shadrach B, Lacey AS, White CP, Powell HR, Sawhney IM, Lyons RA, vd. Validating epilepsy diagnoses in routinely collected data. *Seizure*. 2017;52:195-8.
  15. Manuel DG, Rosella LC, Stukel TA. RESEARCH METHODS & REPORTING. *BMJ*. 2010;341:441.
  16. Prevention EC for D, Control. Narcolepsy in association with pandemic influenza vaccination—a multi-country European epidemiological investigation. Stockholm. 2012;
  17. Sørensen HT, Sabroe S, Olsen J. A framework for evaluation of secondary data sources for epidemiological research. *International journal of epidemiology*. 1996;25(2):435-42.
  18. Baron JA, Lu-Yao G, Barrett J, McLerran D, Fisher ES. Internal validation of Medicare claims data. *Epidemiology*. 1994;5:41-4.
  19. Benchimol El, Manuel DG, To T, Griffiths AM, Rabeneck L, Guttmann A. Development and use of reporting guidelines for assessing the quality of validation studies of health administrative data. *Journal of clinical epidemiology*. 2011;64(8):821-9.
  20. Marston L, Carpenter JR, Walters KR, Morris RW, Nazareth I, White IR, vd. Smoker, ex-smoker or non-smoker? The validity of routinely recorded smoking status in UK primary care: a cross-sectional study. *BMJ open*. 2014;4(4):e004958.
  21. Brown A, Kirichek O, Balkwill A, Reeves G, Beral V, Sudlow C, vd. Comparison of dementia recorded in routinely collected hospital admission data in England with dementia recorded in primary care. *Emerging themes in epidemiology*. 2016;13(1):1-9.
  22. Berry JG, Hall M, Hall DE, Kuo DZ, Cohen E, Agrawal R, vd. Inpatient growth and resource use in 28 children's hospitals: a longitudinal, multi-institutional study. *JAMA pediatrics*. 2013;167(2):170-7.
  23. Shahian DM, Wolf RE, Iezzoni LI, Kirle L, Normand S-LT. Variability in the measurement of hospital-wide mortality rates. *New England Journal of Medicine*. 2010;363(26):2530-9.
  24. Springate DA, Kontopantelis E, Ashcroft DM, Olier I, Parisi R, Chamapiwa E, vd. ClinicalCodes: an online clinical codes repository to improve the validity and reproducibility of research using electronic medical records. *PLoS one*. 2014;9(6):e99825.
  25. Anderson E, Raja EA, Shetty A, Gissler M, Gatt M, Bhattacharya S, vd. Changing risk factors for placental abruption: A case crossover study using routinely collected data from Finland, Malta and Aberdeen. *PLoS one*. 2020;15(6):e0233641.
  26. Weiskopf NG, Weng C. Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research. *Journal of the American Medical Informatics Association*. 2013;20(1):144-51.
  27. Van den Broeck J, Argeseanu Cunningham S, Eeckels R, Herbst K. Data cleaning: detecting, diagnosing, and editing data abnormalities. *PLoS medicine*. 2005;2(10):e267.
  28. Harron K, Goldstein H, Wade A, Muller-Pebody B, Parslow R, Gilbert R. Linkage, evaluation and analysis of national electronic healthcare data: application to providing enhanced blood-stream infection surveillance in paediatric intensive care. *PLoS one*. 2013;8(12):e85278.
  29. Bohensky MA, Jolley D, Sundararajan V, Evans S, Pilcher DV, Scott I, vd. Data linkage: a powerful research tool with potential problems. *BMC health services research*. 2010;10(1):1-7.
  30. Lariscy JT. Differential record linkage by Hispanic ethnicity and age in linked mortality studies: implications for the epidemiologic paradox. *Journal of aging and health*. 2011;23(8):1263-84.
  31. Murray J, Bottle A, Sharland M, Modi N, Aylin P, Majeed A, vd. Medicines For Neonates Investigator G, Medicines for Neonates Investigator Group. 2014. Risk factors for hospital admission with RSV bronchiolitis in England: a population-based birth cohort study. *PLoS One*. 9:e89186.
  32. Horsfall L, Walters K, Petersen I. Identifying periods of acceptable computer usage in primary care research databases. *Pharmacoepidemiology and drug safety*. 2013;22(1):64-9.
  33. Dinan MA, Curtis LH, Carpenter WR, Biddle AK, Abernethy AP, Patz Jr EF, vd. Variations in Use of PET among Medicare Beneficiaries with Non-Small Cell Lung Cancer, 1998–2007. *Radiology*. 2013;267(3):807-17.
  34. Carrara G, Scirè CA, Zambon A, Cimmino MA, Cerra C, Caprioli M, vd. A validation study of a new classification algorithm to identify rheumatoid arthritis using administrative health databases:

- case-control and cohort diagnostic accuracy studies. Results from the REcord linkage On Rheumatic Diseases study of the Italian Society for Rheumatology. *BMJ open.* 2015;5(1):e006029.
- 35. Johnson M, Rigge L, Culliford D, Josephs L, Thomas M, Wilkinson T. Primary care risk stratification in COPD using routinely collected data: a secondary data analysis. *NPJ primary care respiratory medicine.* 2019;29(1):1-6.
  - 36. Pruitt Z, Pracht E. Upcoding emergency admissions for non-life-threatening injuries to children. *The American journal of managed care.* 2013;19(11):917-24.
  - 37. McLintock K, Russell AM, Alderson SL, West R, House A, Westerman K, vd. The effects of financial incentives for case finding for depression in patients with diabetes and coronary heart disease: interrupted time series analysis. *BMJ open.* 2014;4(8):e005178.
  - 38. Brunt CS. CPT fee differentials and visit upcoding under Medicare Part B. *Health economics.* 2011;20(7):831-41.
  - 39. Nilsson F, Bonander C, Andersson R. The effect of the transition from the ninth to the tenth revision of the International Classification of Diseases on external cause registration of injury morbidity in Sweden. *Injury prevention.* 2015;21(3):189-94.
  - 40. Toh S, García Rodríguez LA, Hernán MA. Confounding adjustment via a semi-automated high-dimensional propensity score algorithm: an application to electronic medical records. *Pharmacoepidemiology and drug safety.* 2011;20(8):849-57.
  - 41. Freemantle N, Marston L, Walters K, Wood J, Reynolds MR, Petersen I. Making inferences on treatment effects from real world data: propensity scores, confounding by indication, and other perils for the unwary in observational research. *Bmj.* 2013;347.
  - 42. Marston L, Carpenter JR, Walters KR, Morris RW, Nazareth I, Petersen I. Issues in multiple imputation of missing data for large general practice clinical databases. *Pharmacoepidemiology and drug safety.* 2010;19(6):618-26.
  - 43. Benchimol EI, To T, Griffiths AM, Rabeneck L, Guttman A. Outcomes of pediatric inflammatory bowel disease: socioeconomic status disparity in a universal-access healthcare system. *The Journal of pediatrics.* 2011;158(6):960-7.
  - 44. Nassar N, Dixon G, Bourke J, Bower C, Glasson E, De Klerk N, vd. Autism spectrum disorders in young children: effect of changes in diagnostic practices. *International journal of epidemiology.* 2009;38(5):1245-54.
  - 45. Lipscombe LL, Hwee J, Webster L, Shah BR, Booth GL, Tu K. Identifying diabetes cases from administrative data: a population-based validation study. *BMC health services research.* 2018;18(1):1-8.
  - 46. Nicol A, Caruso J, Archambault É. Open data access policies and strategies in the European research area and beyond. *info@ science.* 2013;1:495-6505.
  - 47. Boutron I, Graham ID, Moher D, Glasziou P, Korevaar DA, Chalmers I, vd. Increasing value and reducing waste in biomedical research: who's listening? 2015;
  - 48. Research CI of H. Canada's Strategy for Patient-oriented Research: Improving Health Outcomes Through Evidence-informed Care. Canadian Institutes of Health Research; 2013.
  - 49. Hoffman S, Podgurski A. The use and misuse of biomedical data: is bigger really better? *American journal of law & medicine.* 2013;39(4):497-538.
  - 50. Langan SM, Schmidt SA, Wing K, Ehrenstein V, Nicholls SG, Filion KB, vd. The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE). *bmj.* 2018;363.
  - 51. Nicholls SG, Langan SM, Benchimol EI, Moher D. Reporting transparency: making the ethical mandate explicit. *BMC medicine.* 2016;14(1):1-3.