

Nancy A. Dreyer

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Professional Experience

Dreyer Strategies LLC	2022-
IQVIA Real-World Solutions	
Chief Scientific Officer	2018-2022
Head, Center for Advanced Evidence Generation	2016-2022
Senior Vice President & Global Chief of Scientific Affairs	2016-2022
Quintiles (merged with IMS Health to become IQVIA in 2016)	
Senior Vice President & Global Chief of Scientific Affairs	2011-2016
University of North Carolina at Chapel Hill	
Adjunct Professor of Epidemiology	2013-
Outcome Sciences Inc. (acquired by Quintiles in 2011)	
Senior Vice President & Global Chief of Scientific Affairs	2005-2011
I3 Research (formerly Ingenix), United Health Group	
Senior Vice President	1999-2005
Epidemiology Resources Inc & the New England Epidemiology Institute	1980-1999
CEO, President & Founder	1980-1999
Founder and Publisher of peer reviewed journal, Epidemiology	1990-1999

Advisory Boards, Professional Honors and Awards

Current Board Memberships & Other Leadership Positions

- Brandeis University Trustee, 2019-
- Picnic Health, Chief Scientific Advisor, 2023-
- Drug Information Association: Director 2012-2015, Scientific and Policy Advisory Council, 2018-
- Duke-Margolis Center for Health Policy Research, Member, RWE Collaborative Advisory Group, 2017-
- International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Real-World Data Steering Committee, 2021-

Previously Held Positions

- Center for International Blood and Bone Marrow Transplant Research, Data Science Advisory Com., 2020-23
- National Football League Health & Safety Committee, Standing Consultant, 2013-2019
- Health Technology: National Evaluation System for Health Technology Planning Board, Duke-Margolis Center, 2015-16; Medical Device Epidemiology Network Steering Committee/Planning, 2012-15
- Patient-Centered Outcomes Research Institute, Member, Clinical Trials Advisory Panel, 2018-2021
- Peking University Health Science Center, Beijing, China, Academic Consulting Committee, Center of Postmarketing Safety Evaluation, Dept of Epidemiology and Biostatistics, 2013-2018
- Int'l Society for Pharmacoepidemiology, VP Finance & Executive Committee, 2007-2010; Director 2010-2013

- Drug Research Group, Waltham, MA, Director, 1993-2009

Recognition and Awards

- WEQUAL Award Regulation and Innovation Finalist, Americas 2022 www.linkedin.com/in/nancy-a-dreyer-135b852/recent-activity/shares/
- PharmaVoice Red Jack Award in 2019 for sustained inspirational leadership in the life sciences. Twice recognized as one of the 100 most inspiring people in life sciences (2007, 2014)
- DIA Global Inspire Award for Author of the Year for “Advancing a framework for regulatory use of real-world evidence: When real is reliable.” 2019
- Fellow of the Drug Information Association (FDIA), 2017
- Fellow, International Society for Pharmacoepidemiology (FISPE), 2003

Recent keynote and other high-profile speaking engagements (selected examples)

- Korea Institute of Drug Safety and Risk Management, 2023
- Honored Invited Speaker, Harry Guess Memorial Lecture, University of North Carolina, 2023
- 1st Boao International Conference on Real-World Studies of Medical Products, Hainan Province, China, December, 2022, – When to trust real-world evidence and Why
- Asia Pacific Oncology Drug Development Consortium “How does real-world data transform drug development and support regulatory decision making?” September 2022
- American Statistical Association Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Keynote on Real-World Evidence with FDA, September 2022
- Amgen, Keynote address on using RWE for regulatory and other purposes
- Advanced oncology RWE programs in America – Lessons for Europe. Precision Oncology Symposium, Paris, France, November, 2021
- Astellas Global Medical Affairs Summit, 2021
- Gilead, Grand Rounds, 2020
- Boehringer-Ingelheim, Global Summit, 2020
- Takeda with Mark McClellan, former FDA Commissioner, 2020
- IQVIA Change Maker Series Speaker: London, England 2019, NY, NY 2020
- AbbVie Real-World Evidence Panel, 2019
- Lilly EXPERT Advisory Panel, 2019
- National Academy of Science, Medicine and Engineering Forum on Drug Discovery, Development, and Translation: Examining the Impact of Real-World Evidence on Medical Product Development: A Workshop Series, 2018
- University of Tokyo, Invited Speaker 2018
- Japanese Society of Pharmacoepidemiology, Kyoto, Japan, 2016
- Evidence-Based Medicine Conference, Beijing, China, 2014

Committees and Teaching

Scientific Committees (selected examples)

- Advisor, Vanke School of Public Health, Tsinghua University for grant from the National Natural Science Foundation of China, 2023-
- Editorial Board of Chinese Journal of Pharmacoepidemiology 2016-2020
- Cardiac Safety Research Consortium Think Tank: Post Approval Cardiac Safety Assessment –Opportunities Beyond the Randomized Clinical Trial, 2016
- European Medicines Agency’s PROTECT Project for the Innovative Medicines Initiative, Steering Committee, Alternative Work Package Co-Leader 2009-2013, Work Package Co-Leader, 2014-15
- FDA Cardiac Safety Research Consortium. NOAC Reversal Agent Think Tank Follow-up: Post Approval Safety and Effectiveness. Invited Panelist. February 3, 2015
- Swedish Institute for Working Life, Umeå, Sweden: Advisor, Reference Group on Mobile Phones and Subjective Disorders, 1995-1998
- FDA, Radiopharmaceuticals Drug Advisory Committee, Consumer Representative, 1986-1990

Industry Advisory Boards

- Actelion/J&J: CARE Pulmonary Arterial Hypertension Steering Committee, 2021-2023
- Sanofi, Atopic Dermatitis Advisory Board, 2017
- Genentech Pediatric Asthma Advisory Board Member, 2016
- Allergan, Chair Publications Steering Committee for HERO Lap Band Study, 2010-2013

Teaching – Selected Examples

- Int'l Society of Pharmacoepidemiology: Pre-meeting annual course on New Frontiers in Pharmacoepidemiology: Beyond claims and EMR. 2011-
- Asia Pacific Oncology Drug Development Consortium. How does real-world data transform drug development and support regulatory decision-making? 2022
- Harvard Chan Chinese Student Alumni Association, Frontier Healthcare Cross Talk Series: Future of Clinical Trial: an RWE-supported method, 2021
- Columbia Business School, Guest speaker 2020
- DIA preconference course lead for regulatory use of real-world evidence, 2018-2020
- Univ. of North Carolina Gillings School of Global Health – topics in pharmacoepidemiology, 2013-
- FDA Center for Drug Evaluation and Research: Registry-Based Pharmacoepidemiology Studies of Long Latency Outcomes: Theory & Practice, 2014, Advanced Topics on Pharmacoepidemiology: Drug-based and Disease-based Registries, 2011

Education

University of North Carolina at Chapel Hill: PhD and MPH with a concentration in Epidemiology
Brandeis University: AB

Publications

Books

Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Conducted under Contract No. 290 2014 00004-C.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. 1st edition, 2007; 2nd Edition, 2010; Third edition, 2014. Also available in Korean (Korean National Evidence-based Healthcare Collaborating Agency, published December 2010), and in Chinese (University of Peking, published December 2012).

Gliklich RE, Leavy MB, Dreyer NA (sr eds). Registries for Evaluating Patient Outcomes: A User's Guide. 4th ed. (Prepared by L&M Policy Research, LLC, under Contract No. 290-2014-00004-C with partners OM1 and IQVIA) AHRQ Publication No. 19(20)-EHC020. Rockville, MD: Agency for Healthcare Research and Quality; September 2020. Posted final reports are located on the Effective Health Care Program search page.
<https://effectivehealthcare.ahrq.gov/products/registries-guide-4th-edition/users-guide>.

Gliklich R, Dreyer N, Leavy M, eds. Tools and Technologies for Registry Interoperability. Registries for Evaluating Patient Outcomes: A User's Guide. Addendum 2. AHRQ Publication No. 19(20)-EHC017-EF, October 2019

Gliklich RE, Dreyer NA, Levy M, Christian JB (eds). 21st Century Patient Registries. Registries for Evaluating Patient Outcomes: A User's Guide. EBook Addendum to Third Edition. (Prepared by L&M Policy Research, LLC, with partners OM1 and QuintilesIMS under Contract No. HHSA290201400004C.) AHRQ Publication No. 17(18)-EHC013-EF. Rockville, MD: Agency for Healthcare Research and Quality. March, 2018

Velentgas P, Dreyer NA, Nourjah P, Smith SR, Torchia MM. Developing a protocol for observational comparative effectiveness research: A user's guide. Conducted under Contract No. 290-2005-0035-I. AHRQ Publication No. 12(13)-EHC099. Rockville, MD: Agency for Healthcare Research and Quality. January 2013. Available in Chinese (University of Peking, published December 2018).

Published Articles and Book Chapters

1. Dreyer NA: Sex roles and delay behaviour. **Journal of Chronic Disease** 1978; 31:493-495.
2. Dreyer NA, Pizzo SV: Blood coagulation and idiopathic thromboembolism in fertile women. **Contraception** 1980; 22(2):123-135.
3. Dreyer NA, Woods NF, James SA: ISRO: A scale for measuring sex role orientation in women. **Sex Roles** 1981; 7(2):173-182.
4. Pizzo SV, Lewis JG, Campbell EE, Dreyer NA: Fibrinolytic response and oral contraceptive-associated thromboembolism. **Contraception** 1981; 23(2):181-186.
5. Dreyer NA, Loughlin JE, Friedlander ER, *et al.*: Choosing populations for study of human health effects of low-dose ionizing radiation. **American Journal of Public Health** 1981;71(11):1247-1252.
6. Dreyer NA, Loughlin JE, Fahey FH, Harley N: The feasibility of epidemiologic studies of cancer in people residing near Rocky Flats. **Health Physics** 1982;42(1):65-68.
7. Walker AM, Dreyer NA, Friedlander ER, *et al.*: An independent analysis of the National Cancer Institute study on non-nutritive sweeteners and bladder cancer. **American Journal of Public Health** 1982;72(4):376-381, 1982.
8. Dreyer NA, Friedlander ER: Identifying the health risks from very low-dose sparsely ionizing radiation. **American Journal of Public Health** 1982; 72(6):585-588.
9. Dreyer NA, Friedlander ER: Response to I.D.J. Bross on low-dose radiation re: study challenged. **American Journal of Public Health** 1982; 72:1301.
10. Walker AW, Loughlin JE, Friedlander ER, Rothman KJ, Dreyer NA: Projections of asbestos-related disease, 1980-2009. **Journal of Occupational Medicine** 1983; 25(5):409-425.
11. Dreyer NA: Analgesic-associated nephropathy: Aetiology or tautology? **Royal Society of Medicine Services International Congress and Symposium Series** 1985; 96:19-24.
12. Lanes SF, Poole C, Dreyer NA, Lanza L: Toxic shock syndrome, contraceptive methods and vaginitis. **American Journal of Obstetrics and Gynecology** 1986;154(5):989-991.
13. Walker AM, Feldstein ML, Dreyer NA, Lanza L: Gastrointestinal illness rates on passenger cruise ships, 1975-1978. **Travel Medicine International** 1986;4(3):120-124.
14. Lanes SF, Delzell E, Dreyer NA, Rothman KJ: Analgesics and kidney disease. **International Journal of Epidemiology** 1986; 15:454-455.
15. Dreyer NA, Loughlin JE, Lanes SF, Rothman KJ: Mortality among employees of a nuclear power company. **Journal of Occupational Medicine** 1988; 30:988-989.
16. Rothman KJ, Funch DP, Dreyer NA: Bromocriptine and puerperal seizures. **Epidemiology** 1990; 1(3):232-238.
17. Lanes SF, Cohen A, Rothman KJ, Dreyer NA, Soden KJ: Mortality of cellulose fiber production workers. **Scandinavian Journal of Work, Environment and Health** 1990; 16(4):247-51.
18. Wilkinson GS, Dreyer NA: Leukemia among nuclear workers with protracted exposure to low-dose ionizing radiation. **Epidemiology** 1991; 2(4):305-309.
19. Dreyer NA: Ethical Forum: Publication Rights – A Case Study. **The Epidemiology Monitor** 1992; 13(3):4.
20. Maintaining Radiation Protection Records. National Council on Radiation Protection and Measurements, Scientific Committee 46-5, NCRP Report No. 114, November 30, 1992.
21. Poole C, Kavet R, Funch DP, Donelan K, Charry JM, Dreyer NA: Depression and headaches in relation to an alternating-current electric power transmission line. **American Journal of Epidemiology** 1993; 137:318-30.
22. Walker AW, Funch D, Dreyer NA, Tolman KG, Kremer JM, Alarcón GS, Lee RG, Weinblatt ME: Determinants of serious liver disease among patients receiving low-dose methotrexate for rheumatoid arthritis. **Arthritis and Rheumatism** 1993; 36(3):329-335.
23. Funch D, Dreyer NA, Bassin LG, Crawley JA, Brickley MG, Walker AM: The validity of case reports in a pharmacoepidemiologic study. **Post Marketing Surveillance** 1993; 7:283-289.
24. Poole C, Dreyer NA, Satterfield MH, Levin LL, Rothman KJ: Kidney cancer among petroleum refinery workers. **Journal of Environmental Health Perspectives** 1993; 101(6):53-62.
25. Lanes SF, Rothman KJ, Dreyer NA, Soden KJ: Mortality update of cellulose fiber production workers. **Scandinavian Journal of Work, Environment & Health** 1993; 19:426-428.
26. Lanes SF, Rothman KJ, Dreyer NA, Soden KJ: Mortality among workers exposed to glycerol polyglycidyl ether. **American Journal of Industrial Medicine** 1994; 25(5):689-696.

27. Dreyer NA: An epidemiologic view of causation: How it differs from the legal. **Defense Counsel Journal** 1994; 61(1):40-44.
28. Lanza LL, Walker AM, Bortnichak EA, Dreyer NA: Peptic ulcer and gastrointestinal hemorrhage associated with NSAID use in patients under 65 years of age: a large health maintenance organization cohort study. **Archives of Internal Medicine** 1995; 155:1371-1377.
29. Lanza LL, Walker MA, Bortnichak EA, Gause DO, Dreyer NA: Incidence of symptomatic liver function abnormalities in a cohort of NSAID users. **Pharmacoepidemiology & Drug Safety** 1995; 4:231-237.
30. Lanza LL, Dreyer NA, Schultz N, Walker AM: Use of insurance claims in epidemiologic research: identification of peptic ulcers, GI bleeding, pancreatitis, hepatitis and renal disease. **Pharmacoepidemiology & Drug Safety** 1995; 4:239-248.
31. Walker AM, Funch DP, Sulsky SI, Dreyer NA: Patient factors associated with strut fracture in Björk-Shiley 60° convexo-concave heart valves. **Circulation** 1995;92(11):3235-3239.
32. Walker AM, Funch DP, Sulsky SI, Dreyer NA: Manufacturing characteristics associated with strut fracture in Björk-Shiley 60° convexo-concave heart valves. **Journal of Heart Valve Disease** 1995;6(4):640-648.
33. Rothman KJ, Loughlin JE, Funch DP, Dreyer NA: Overall mortality of cellular telephone customers. **Epidemiology** 1996; 7:303-305.
34. Funch DP, Rothman KJ, Loughlin JE, Dreyer NA: Utility of telephone company records for epidemiologic studies of cellular telephones. **Epidemiology** 1996; 7:299-302.
35. Lanes SF, Birmann BM, Walker AM, Sheffer AL, Rosello RA, Lewis BE, Dreyer NA: Characterization of asthma management at Fallon Community Health Plan, 1988-1991. **Pharmacoeconomics** 1996;10(4):378-385.
36. Lanes SF, Sulsky S, Walker AM, Isen J, Grier CE, Lewis BE, Dreyer NA: A cost density analysis of benign prostatic hyperplasia. **Clinical Therapeutics** 1996; 18(5):993-1004.
37. Rothman KJ, Lanza L, Lal A, Peskin EG, Dreyer NA: Incidence of pelvic inflammatory disease among women treated for gonorrhea and chlamydia. **Pharmacoepidemiology & Drug Safety** 1996; 5(6):409-414.
38. Lanes SF, Lanza LL, Radensky PW, Yood YA, Meenan RF, Walker AM, Dreyer NA: Resource utilization and cost of care for rheumatoid arthritis and osteoarthritis in a managed care setting: the importance of drug and surgery costs. **Arthritis and Rheumatism** 1997; 40(8):1475-1481.
39. Walker AM, Sznke P, Bianchi LA, Field LF, Sutherland LR, Dreyer NA: 5-aminosalicylates, sulfasalazine, steroid use, and complications in patients with ulcerative colitis. **American Journal of Gastroenterology** 1997; 92(5):816-820.
40. Loughlin JE, Dreyer NA: In defense of the Social Security Administration Death Master File. **Epidemiology** 1997; 8(6):690-691.
41. Loughlin JE, Rothman KR, Dreyer NA: Lymphatic and haematopoietic cancer mortality in a population attending school adjacent to styrene-butadiene facilities, 1963-1993. **Journal of Epidemiology and Community Health** 1999; 53:283-287.
42. Dreyer NA, Loughlin JE, Rothman KJ: Epidemiologic safety surveillance of cellular telephones in the U.S. **Radiation Protection Dosimetry** 1999; 83(1-2):159-163.
43. Walker AM, Sznke P, Weatherby LB, Dicker LW, Lanza LL, Loughlin JE, Yee CL, Dreyer NA: Evaluating the risk of serious cardiac side effects among cisapride users in the United Kingdom and Canada. **American Journal of Medicine** 1999; 107:356-362.
44. Maradit Kremers H, Funch DP, Robson RA, Nalesnik MA, Ebrahim S, Cecka MJ, Opelz G, Dreyer NA, Walker AM: A combination study design to examine mycophenolate mofetil (MMF) and PTLTD in renal transplant patients. **Pharmacoepidemiology & Drug Safety** 1999; 8:509-518.
45. Dreyer NA, Loughlin JE, Rothman KJ: Cause-specific mortality in cellular telephone users. **JAMA** 1999;282(19):1814-1816.
46. Dreyer NA: Accessing third party data for research: Trust me? Trust me not? **Pharmacoepidemiology and Drug Safety** 2001; 10:385-388.
47. Funch DP, Brady J, Ko HH, Dreyer NA, Walker AM: Methods and objectives of a large US multicenter case-control study of post-transplant lymphoproliferative disorder in renal transplant patients. **Recent Results Cancer Research** 2002; 159:81-88.
48. Rothman KJ, Funch DP, Alfredson T, Brady J, Dreyer NA: Randomized Field trial of vaginal douching, Pelvic Inflammatory Disease, and Pregnancy. **Epidemiology** 2003; 14:340-348.
49. Dreyer NA: Relative risk and statistical significance: Epidemiology 101 for lawyers. **Defense Research Institute**, March 19, 2004

50. Dreyer, NA: Tap into a global community of care. Web-based registries for orphan diseases. **Good Clinical Practice Journal**, 17-19 December, 2005.
51. Dreyer NA, Bertagna M, Gliklich RE: Designing and assessing registries to evaluate the safety of medical products. **The Monitor**. Association of Clinical Trials Professionals 2007; 21(4):47-50.
52. Eljovich L, Dreyer NA, Van Den Bos J, Johnston SC: Under-treatment and outcomes of non-traumatic subarachnoid hemorrhage by hospital volume: A multi-state study. **Stroke** 2008; 39:536-536.
53. Dreyer NA, Sheth N, Trontell A, Gliklich RE: Good practices for handling adverse events detected through patient registries. **Drug Information Journal** 2008; 42(5):421-428.
54. Dreyer NA, Garner S: Registries for robust evidence. **JAMA** 2009; 302(7):790-791.
55. Dreyer NA, Schneeweiss S, McNeil B, Berger ML, Walker A, Ollendorf D, Gliklich RE: GRACE Principles: Recognizing high-quality observational studies of comparative effectiveness. **American Journal of Managed Care** 2010; 16(6):467-471.
56. Adisasmito W, Chan PKS, Lee N, Oner AF, Gasimov V, Aghayev F, Zaman M, Bamgboye E, Dogan N, Coker R, Starzyk K, Dreyer NA, Toovey S: Effectiveness of antiviral treatment in human influenza H5N1 infections: analysis from a global patient registry. **Journal of Infectious Disease** 2010; 202(8):1154–1160.
57. Dreyer NA, Tunis SR, Berger M, Ollendorf D, Mattox PW, Gliklich RE: Why observational studies should be among the tools used in comparative effectiveness research. **Health Affairs** 2010; 29(10): 1818-1825.
58. Setoguchi S, Shrank WH, Liu J, Lee JC, Saya U, Winkelmayer WC, Dreyer NA. Angiotensin Receptor Blockers and Angiotensin-Converting Enzyme Inhibitors: Challenges in comparing effectiveness of angiotensin receptor blockers vs. angiotensin-converting enzyme inhibitors for hypertension in Medicare data. **Clinical Pharmacology & Therapeutics** 2011; 89(5):674-82.
59. Dreyer NA. Making observational studies count: shaping the future of comparative effectiveness research. **Epidemiology** 2011; 22(3):295-297.
60. Li Q, Glynn RJ, Dreyer NA, Liu J, Mogun H, Setoguchi S. Validity of Claims-based Definitions of Impaired Left Ventricular Systolic Function in Medicare Patients. **Pharmacoepidemiology and Drug Safety** 2011; 20(7); 700-708.
61. Zaman M, Toovey S, Dreyer NA. An extended review of human infection with influenza H5N1 virus in North West Frontier Province (NWFP), Pakistan in 2007. **Emerging Infectious Diseases** 2011; 17:1056-1059.
62. Berger ML, Dreyer N, Anderson F, Towse A, Sedrakyan A, Normand, SL. Prospective observational studies to assess comparative effectiveness: ISPOR good research practices task force report. **Value in Health** 2012;15(2):217-30.
63. Gliklich R, Glennie J, Mattox PW, Graff JS, Garner S, Marrone CM, Shaya FT, Hansen J, Lewin J, Blackburn S, Berger M, Dreyer NA. Survey of Real-World Research Workforce, Training, and Education: Report from the DIA Real-World Outcomes Task Force. **Drug Information Journal** 2012; 26:185-191.
64. Dreyer NA, Velentgas P. Registries. In *Pharmacoepidemiology*, Strom B, Kimmel S, Hennessy S, Eds. Fifth edition, John Wiley & Sons Ltd., 2012
65. Oner AF, Dogan N, Gasimov V, Adisasmito W, Coker R, Chan PKS, Lee N, Tsang O, Hanshaoworakul W, Zaman M, Bamgboye E, Swenson A, Toovey S and Dreyer NA: H5N1 Avian Influenza in Children. **Clinical Infectious Disease** 2012; 55:26-32.
66. Gliklich RE, Leavy MB, Velentgas P, Dreyer NA, Tunis SR, Mohr P, Messner DA, Moloney RM, Karkare Su, Dubois RW, Graff JS: Incorporating Stakeholder Perspectives in Developing a Translation Table Framework for Comparative Effectiveness Research. **Journal of Comparative Effectiveness Research** 2012; 1(3):281-292.
67. REGISTER Group (Campbell B, Patrick H, Dreyer NA, Grilli R, Franklin GM, Lee Robin SH, Maddern G, Tunis S, Lyratzopoulos G). International collaboration in the use of registries for new devices and procedures. **British Journal of Surgery** 2012; 99: 744–745.
68. Chan PKS, Lee N, Zaman M, Adisasmito W, Coker R, Hanshaoworakul W, Gasimov V, Oner AF, Dogan N, Tsang O, Phommasack B, Touch S, Bamgboye E, Swenson A, Toovey S, Dreyer N: Determinants of Antiviral Effectiveness in H5N1 Avian Influenza. **Journal of Infectious Disease** 2012; 206: 1359-66.
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70. Dreyer NA, Toovey S, Oner AF, Bamgboye E, Dogan N, Zaman M, Gasimov V, Adisasmito W, Coker R, Chan PKS, Lee N, Tsang O, Hanshaoworakul W, Phommasack B, Touch S, Swenson A, Reddy D.

- Investigating outbreaks of novel infectious disease: an international case study. **Journal of Clinical Studies** 2013; 5(2):52-53
71. Dreyer NA. Using observational studies for comparative effectiveness: Finding quality with GRACE. **Journal of Comparative Effectiveness Research** 2013; 2(5):413-418.
 72. Dreyer NA, Dixon JB, Okerson T, Finkelstein EA, Globe D. Prevalence of Comorbidities and Baseline Characteristics of LAP-BAND AP® Subjects in the Helping Evaluate Reduction in Obesity (HERO) Study. **PLOS One** 2013; 8(11): e78971. doi:10.1371/journal.pone.0078971
 73. Mack CD, Dreyer NA, Bosco J, Fabre A. Using real-world evidence to inform decision making. **Chinese Journal of Pharmacoepidemiology** 2014; 24: 17-28.
 74. Velentgas P, Dreyer NA, Wu AW. Outcome definition and measurement. In Velentgas P, Dreyer NA, Nourjah P et al., eds. *Developing a Protocol for Observational Comparative Effectiveness Research. A User's Guide*. Rockville, MD: Agency for Healthcare Research and Quality. 2013: Chapter 6, pp. 71-92.
 75. Dreyer NA, Velentgas P, Westrich K, Dubois R. The GRACE Checklist for Rating the Quality of Observational Studies of Comparative Effectiveness: A Tale of Hope and Caution. **Journal of Managed Care & Specialty Pharmacy** 2014; 20(3):301-08.
 76. Cleeland CS, Mayer M, Dreyer NA, Yim YM, Yu E, SuZ, Mun Y, Sloan JA, Kaufman PA. Impact of symptom burden on work-related abilities in patients with locally recurrent or metastatic breast cancer: Results from a substudy of the VIRGO observational cohort study. **Breast** 2014; 23(6): 763-769. doi: 10.1016/j.breast.2014.08.004.
 77. Mendelsohn AB, Dreyer NA, Mattox PW, Su Z, Swenson A, Li R, Turner JR, Velentgas P. Characterization of missing data in clinical registry studies. **Therapeutic Innovation & Regulatory Science** 2014; 48(5): 574-582.
 78. Dreyer NA. Generating real-world evidence for using drugs and devices: delivering the right approach for the right question. **SCRIP Regulatory Affairs**, March, 2014.
 79. Dreyer NA, Duggirala HJ, Samsa G, Stang P, Velentgas P. Registry Design. In Gliklich R, Dreyer N, Leavy M, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014: Chapter 3, pp 47-72.
 80. Dreyer NA, Gliklich RE, Sheth N, Trontell AE. Adverse Event Detection, Processing, and Reporting. In Gliklich R, Dreyer N, Leavy M, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014: Chapter 12, pp 277-290.
 81. Dreyer NA, Eloff BC, Kirklin JK, Naftel DC, Toovey S. Public-Private Partnerships. In Gliklich R, Dreyer N, Leavy M, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014: Chapter 24, pp 215-230.
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 83. Mack, CD, Su Z, Mendelsohn AB, Dreyer NA. Prevention, examination and treatment of missing data in nonexperimental pharmacoepidemiologic studies. **Chinese Journal of Pharmacoepidemiology** 2015; 24(1): 14-22.
 84. Dreyer N, Blackburn S, Hliva V, Mt-Isa S, Richardson J, Jamry-Dziurla A, Bourke A, Johnson R. Balancing the Interests of Patient Data Protection and Medication Safety Monitoring in a Public-Private Partnership. **JMIR Medical Informatics** 2015; 3(2):e18 doi:10.2196/medinform.3937
 85. Lao W-L, Malone DC, Armstrong EP, Voellinger D, Somers S, Jin J, Dreyer N, Globe D. Effect of adjustable gastric banding on quality of life and weight loss in the Helping Evaluate Reduction in Obesity (HERO) registry study: 2-year analysis **Current Medical Research & Opinion** 2015; 31(8): 1451-1460 Posted on-line July 8, 2015. doi: 10.1185/03007995.2015.1059802 Informa Healthcare, 2015/8/3

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