

Kristine E. Shields MSN, DrPH

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— OBJECTIVE —

To contribute my clinical, public health, and pharmaceutical industry experience, knowledge and passion to promote excellence in public health, health research, and health programs.

— CLINICIAN, RESEARCHER, WRITER —

Women's health nurse practitioner, pharmaceutical company executive, drug safety researcher, and book author known for leadership skills, management competence, communications expertise, and collaborative abilities across divergent stakeholders.

Areas of Expertise

- Academic, Clinical, and Pharmaceutical Research and Writing
- Communications
- Pharmacovigilance and Drug Safety
- Public Health and Corporate Ethics
- Reproductive Health and Justice

— PROFESSIONAL EXPERIENCE —

Shields' Medical Writing & Consulting, LLC

Current

Principal – Consulting, writing, and research to advance health knowledge and practice. Consultant pharmaceutical company drug safety advisory board chair. Writing support to international programs in maternal health. Clients include Teva, United Biosource Corporation (UBC), the Bill & Melinda Gates Foundation, UNC faculty.

U.S. Food and Drug Administration (FDA)

Current

Consumer representative to the Bone, Reproductive, & Urologic Drugs Advisory Committee

STI (Sexually Transmitted Infections): a BMJ (British Medical Journal)

Current

Perspectives Panel Editor - ongoing review of recent peer-reviewed literature, identifying publications that have immediate or potential impact on clinical practice, producing short interpreted summaries; team leadership, reviewing, editing and approving draft content to meet production timelines.

Pregistry, LLC

1.5 years

Entrepreneur: Cofounder and Chief Operating Officer of innovative pregnancy research start-up company aiming to provide comprehensive collection, analysis, and communication of medication and vaccine exposure information to pregnant women, health care providers, regulatory agencies, and pharmaceutical companies.

Merck & Co., Inc. **15 years**
Global Compliance Organization, Office of Ethics – Associate Ethics Officer
 Create, implement, and hold management and employees accountable for compliance with, company code of conduct, values and standards, corporate responsibility.
Global Safety – Director, Risk Management and Business Process Lead
 Department representative for Merck-Schering Plough merger, interdepartmental support for implementation and compliance with regulatory agency standards.
Clinical Risk Management and Safety Surveillance – Associate Director, Director
 People and program management, operations, budget, hiring, staff development.
Worldwide Product Safety & Epidemiology – Research Associate/Senior Epidemiologist
 Expert in all aspects of pharmacovigilance and drug safety.

Correctional Healthcare Solutions, Inc. **1 year**
Coordinator, Quality Management Services for over 20 correctional facilities in eight states

Medical College of Pennsylvania **2 years**
OB/GYN Nurse Practitioner, Caring Together Perinatal Addictions Program

Planned Parenthood Federation of America Nurse Practitioner Program **2 years**
Clinical instructor for the advanced practice of nursing in the women’s health care specialty

Planned Parenthood Southeastern Pennsylvania **8 years**
Quality Assurance Coordinator and Clinician in ambulatory women’s health care

Hospitals and clinics in and around Philadelphia, PA **3 years**
Staff Nurse, Assistant Head Nurse, in Obstetrics, Gynecology, Newborn Nursery

— EDUCATION —

School	Major	Degree
University of North Carolina at Chapel Hill	Health Administration and Policy	DrPH
Drexel University	Public Health: Epidemiology	MPH
Drexel University	Advanced Practice Nursing	MSN
University of Pennsylvania	Nursing	BSN

Theses

DrPH: *The Inclusion of Pregnant Women in Clinical Trials: Implications for the US Pharmaceutical Industry*
 MPH: *The Inclusion of Women and Minorities in Research Studies at an Academic Research Center*
 MSN: *Correctional Health Care Nurses’ Attitudes toward Inmates*

Selected Academic Honors

- Academic Achievement Award (Highest honor)
Drexel University School of Public Health (MPH)
- High Honors (4.0/4.0)
Drexel University School of Nursing (MSN)
- Magna Cum Laude (3.7/4.0)
University of Pennsylvania School of Nursing (BSN)

— VOLUNTEER EXPERIENCE —

Darkness to Light, AuthorAid (International)
Unite for Sight (Chennai, India), Jubilee House (Managua, Nicaragua)
Worthwhile Wear and Freedom Boutique, Pipersville Library
Bucks County Medical Reserve Corps

— PUBLICATIONS —

Books:

The Vulva Owner's Manual: Finding Your Best Option for Contraception. (Blackfox Communications, 2020) ISBN: 978-1-7353742-1-5

Pregnancy and the Pharmaceutical Industry: The Movement Towards Evidence-Based Pharmacotherapy for Pregnant Women (Elsevier Academic Press, 2019) ISBN: 978-0-12-818550-6

Published Papers:

Shields K, Tan RKJ, Rusconi S, Chen XS. Research news in clinical context. *Sex Transm Infect* 2020;0:553-554. doi:10.1136/sextrans-2019-054276

Tucker JD, Shields K, Villa G. Research news in clinical context. *Sex Transm Infect* 2020;96:313-314. <http://dx.doi.org/10.1136/sextrans-2019-054272>

Shields, Kristine. Zika-related birth defects: Conservative policies increase American babies' risk. *Ms Magazine Blog*, 31 October 2016. <https://msmagazine.com/2016/10/31/zika-related-birth-defects-conservative-policies-increase-american-babies-risk/>

Wyszynski D, Shields KE. Frequency and type of medications and vaccines used during pregnancy. *Obstetric Medicine* 2015, 9(1):21-27. doi: [10.1177/1753495X15604099](https://doi.org/10.1177/1753495X15604099)

Shields KE, Lyerly AD. Exclusion of pregnant women from industry-sponsored clinical trials. *Obstetrics & Gynecology* 2013; 122(5):1077-1081. doi: 10.1097/AOG.0b013e3182a9ca67

Nelsen L, Shields KE, Smugar S, Philip G. Maternal asthma medication use and selected birth defects: additional data from a large cohort study. *Pediatrics*; Letter to the Editor, 26Feb2012.

Nelsen LM, Shields KE, Cunningham ML et al. Congenital anomalies among infants born to women receiving montelukast, inhaled corticosteroids, and other asthma medications. *Journal of Allergy and Clinical Immunology*, 2012; 129(1):251-254. doi.org/10.1016/j.jaci.2011.09.003

Haas DM, Gallauresi B, Shields KE, et al. Pharmacotherapy and pregnancy: Highlights from the Third International Conference for Individualized Pharmacotherapy in Pregnancy. *Clinical and Translational Science*, 2011, 4(3):204-209. doi: [10.1111/j.1752-8062.2011.00280.x](https://doi.org/10.1111/j.1752-8062.2011.00280.x)

Dana A, Buchanan KM, Goss MA, Seminack MM, Shields KE, Korn S, Cunningham ML, Haupt RM. Pregnancy outcomes from the pregnancy registry of a human papillomavirus type 6/11/16/18 vaccine. *Obstetrics & Gynecology* 2009; 114(6):1170-8. doi: [10.1097/AOG.0b013e3181c2a122](https://doi.org/10.1097/AOG.0b013e3181c2a122)

Wilson E, Goss MA, Marin M, Shields KE, Seward J, Rasmussen SA, Sharrar RG. Varicella vaccine exposure during pregnancy: Data from ten years of the pregnancy registry. *Journal of Infectious Diseases*, 2008; 197(s2): S178-84. DOI: [10.4236/health.2010.22022](https://doi.org/10.4236/health.2010.22022)

Lehman LH, Chen J, Gould AL, Kassekert R, Beninger PR, Carney R, Goldberg M, Goss MA, Kidos K, Sharrar RG, Shields KE, Sweet A, Wiholm BE, Honig PK. An evaluation of computer-aided disproportionality analysis for post-marketing signal detection. *Clinical Pharmacology & Therapeutics*, 2007; 82 (2):173-80.

Tilson HH, Doi PA, Covington DL, Parker A, Shields KE, White A. The Antiretrovirals in Pregnancy Registry: A fifteenth anniversary celebration. *Obstetrical and Gynecological Survey*, 2007; 62(2): 137-48. DOI: [10.1097/01.ogx.0000253377.14647.80](https://doi.org/10.1097/01.ogx.0000253377.14647.80)

Pollack PS, Shields KE, Burnett DM, Osborne MJ, Cunningham ML, Stepanavage ME. Pregnancy outcomes after maternal exposure to simvastatin and lovastatin. *Birth Defects Research: Part A*, 2005; 73(11):888-896. doi.org/10.1002/bdra.20181

Fiore M, Shields KE, Santanello NC, Goldberg MR. The Merck & Co., Inc., United States pregnancy registry for rizatriptan: Post-marketing experience through 30-June-2004. *Cephalalgia*, 2005; 25(9):685-688.

Shields KE, Wiholm BE, Hostelley LS, Striano LF, Arena SR, Sharrar RG. Monitoring outcomes of pregnancy following drug exposure: A company-based pregnancy registry program. *Drug Safety* 2004; 27(6):1-15. DOI: [10.2165/00002018-200427060-00001](https://doi.org/10.2165/00002018-200427060-00001)

Wise RP, Braun MM, Seward JF, Mootrey GT, Shields KE, Salive ME, & Krause PR. Pharmacoepidemiologic implications of erroneous varicella vaccinations in pregnancy through confusion with varicella zoster immune globulin. *Pharmacoepidemiology & Drug Safety*, 2002; 11:651-654.

Shields KE, Galil K, Seward J, Sharrar R, Cordero J, Slater E. Varicella vaccine exposure during pregnancy: data from the first 5 years of the pregnancy registry. *Obstetrics & Gynecology*, 2001; 98(1):14-19.

Shields KE and DeMoya D. Correctional healthcare nurses' attitudes toward inmates. *Journal of Correctional Healthcare*, 1997; 4(1):37-59.
<http://www.ncjrs.gov/App/publications/abstract.aspx?ID=171861>

— PRESENTATIONS —

Shields KE. Industry Perspective on Liability, Incentives and Regulatory Issues. Invited oral presentation at the Conducting Sexually Transmitted Infection Research in Women of Reproductive Age: An Interdisciplinary Discussion of Experience, Strategies & Policies to Advance the Field, Rockwell, MD; virtual presentation April 27-28, 2021.

Shields KE. The Inclusion of Pregnant Women in Clinical Trials. Oral presentation at the Advancing Ethical Research Conference, Boston, MA; November 18-20, 2019.

Shields KE. Implementing New FDA Policy to Include Pregnant Women in Drug Trials to Achieve Evidence-based Pharmacotherapy. Poster presentation at the American Public Health Association Annual Meeting, Philadelphia, PA; November 2-6, 2019.

Dana A, Buchanan KM, Goss MA, Seminack MM, Shields KE, Korn S, Haupt R. Updated data from the pregnancy registry for Gardasil® (human papillomavirus types 6/11/16/18 vaccine). Poster presentation at the 26th International Papillomavirus Congress, Montreal, Canada; July 3-8, 2010.

Shields KE. Pregnancy Registries' Contribution to Informed Clinical Practice. Invited oral presentation at the Third Annual International Conference for Individualized Pharmacotherapy in Pregnancy, Indianapolis, IN; June 7, 2010.

Dana A, Buchanan KM, Goss MA, Seminack MM, Shields KE, Haupt RM. Pregnancy outcomes from the pregnancy registry for Gardasil® (human papillomavirus types 6/11/16/18 vaccine), 49th Annual Meeting of the Teratology Society, Rio Grande, Puerto Rico, June, 2009. Abstract: *Birth Defects Research (Part A)*, 85:463 (2009).

Dana A, Buchanan KM, Goss MA, Seminack MM, Shields KE, Haupt RM. Updated data from the pregnancy registry for Gardasil (human papillomavirus types 6/11/16/18 vaccine). Presentation at: Obstetrics and Gynaecology 21st Biennial European Congress, Antwerp, Belgium, May 5-8, 2010.

Shields KE, The HPV Vaccine - Examining the Safety Profile of Gardasil. Invited oral presentation at the Nurse Practitioners in Women's Health Post-Graduate Seminar – Atlantic City, NJ, February 2009.

Shields KE, New FDA Pregnancy Labeling - How it will inform your clinical practice. Invited oral presentation at the Nurse Practitioners in Women's Health Post-Graduate Seminar – Atlantic City, NJ, February 2009.

Shields KE, Informed consent processes in pregnancy registries. Invited oral presentation at the 48th Annual Meeting of the Teratology Society, Monterey, CA, July 2008. Abstract: *Birth Defects Research (Part A)*, 82(5):336 (2008).

Shields KE, Pharmaceutical safety surveillance and evaluation. Invited oral presentation at the University of Pennsylvania School of Graduate Education 680 Seminar: Evaluation of Policies, Programs and Projects. Philadelphia, PA, 11 December 2007.

Goss MA, Leitmeyer JE, Mathew V, Lehman H, Chen J, Shields KE. An evaluation of data mining by high level terms (HLTs). Poster presentation at the 23rd Annual International Conference on Pharmacoepidemiology & Therapeutic Risk Management; Quebec City, Canada, 19-22 August 2007. Abstract: *Pharmacoepidemiology and Drug Safety*, 16 (2): S258 (2007).

Cole AJ, Doherty M, Nelsen LM, Shields KE, Walker AM. Surveillance of asthma-related drugs during pregnancy using a health insurance claims database. Poster presentation at: 22nd Annual International Conference on Pharmacoepidemiology & Therapeutic Risk Management; Lisbon, Portugal, 24-27 August 2006. Abstract: *Pharmacoepidemiol Drug Safety* 15(8):S85-S86 (#181) 2006.

Lehman HP, Chen J, Gould AL, Kassekert R, Beninger PR, Carney R, Goldberg MR, Goss MA, Kidos K, Shields KE, Sweet AR, Wiholm B, Sharrar RG. An evaluation of computer-aided disproportionality analysis for post-marketing signal detection. Poster presentation at: 22nd Annual International Conference on Pharmacoepidemiology & Therapeutic Risk Management; Lisbon, Portugal, 24-27 August 2006.

Wilson E, Goss MA, Shields K, Beninger P, Marin M, Seward J. Varicella Vaccine Exposure During Pregnancy: Data from the First 10 Years of the Pregnancy Registry. Poster presentation at the International Conference on Emerging Infectious Diseases, Atlanta, GA, 16-18 March 2006.

Shields KE. Pregnancy registries as risk management tools. Invited oral presentation at PEA's 4th Annual Risk Management Conference, Philadelphia, PA, 25-26 October 2005.

Shields KE. Sources of pregnancy exposure information – U.S. and worldwide. Invited oral presentation at the Teratology Society 45th Annual Meeting, St. Pete's Beach, FL, 25-30 June 2005.

Lehman, HP & Shields KE. Pregnancy Exposure Registries – Before and After the 2002 FDA Guidance to Industry. Invited oral presentation at the CBI's 3rd Fall Forum on Patient Registries, Philadelphia, PA, 22-23 September 2004.

Wiholm BE, Shields KE, Strauss A. Delivery outcome after the use of anti-asthma medication in early pregnancy: An analysis from the Swedish Medical Birth Register (SMBR). Oral presentation at the International Society for Pharmacoepidemiology 20th International Conference. Aug 22-25, 2004.

Galea SA, Sweet AR, Shields KE, Etzel LE, Sharrar RG, Wiholm BE. An evaluation of norfloxacin use during pregnancy. Poster presentation at the International Society for Pharmacoepidemiology 20th International Conference. Aug 22-25, 2004.

Shields KE. A Pregnancy Registry Program in a Regulatory Environment. Invited oral presentation at the DIA symposium, Pregnancy Exposure Registries: Evaluating the Teratogenic Potential of Pharmaceutical Products Used at Clinical Doses, Washington DC, May 24-25, 2004.

Burnett DM, Shields KE, Striano LF, Stepanavage ME, Pollack, PS. Pregnancy outcomes after maternal exposure to simvastatin and lovastatin. Poster presentation at the 1st International Conference on Therapeutic Risk Management and the 19th International Conference on Pharmacoepidemiology, Philadelphia, PA, August 22, 2003.

Shields KE, Galil K, Sharrar RG, Seward, J, Wiholm BE. Industry/CDC collaboration: The Pregnancy Registry for VARIVAX. Poster presentation at the First CDC Conference on Birth Defects and Developmental Disabilities: Charting the Course. Atlanta, GA, September 19, 2002.

McGhee K, Shields KE, Benson J, Beninger P, Sharrar RG. Five-year review of maternal – fetal outcomes in patients exposed to indinavir sulfate during pregnancy. Poster presentation at the 9th Conference on Retroviruses and Opportunistic Infections, Seattle, WA, February 24 - 28, 2002.

Shields KE, Bold T, Sharrar, RG. Pregnancy Registry for Singulair: Three year analysis of data. Oral presentation at the World Asthma Meeting, Chicago, IL, July 14, 2001.

Shields, KE. The Merck Pregnancy Registry Program. Invited oral presentation at Drug Information Association 11th Annual Symposium on Medical Communications, Washington, DC, March 2000.

Shields, KE. Pregnancy registries: Your role in drug safety assessment. Oral presentation at the Nurse Practitioners in Women's Health Post-Graduate Seminar – Philadelphia, PA, February 2000.

Shields, KE; Galea, S; Sweet, A; & Seward, J. Three-Year Results from the Pregnancy Registry for VARIVAX®. Poster presentation, DIA Canada – Quebec, June 1999.

Kishel L, Crawford J, Shields K, Fishman D. The Caring Together Perinatal Addictions Program. Panel presentation, New Frontiers in Maternal Child Nursing, Philadelphia, PA, May 1995.