Appendix

Table A.1. Variable definitions and sources

|  |  |  |
| --- | --- | --- |
| Variable name | Description | Source |
| Price | Adjusted vaccine price per dose (excluding federal excise tax) in 2014 dollars | CDC Vaccine Price List; CPI from Bureau of Labor Statistics database (used to adjust prices) |
| DirCompete1 | Binary variable equals to one if there were products (excluding the product in question) purchased by CDC in year t that of the same vaccine type but produced by a different manufacturer  | Author created based on purchase data |
| DirCompete2 | Binary variable equals to one if there were products (excluding the product in question) purchased by CDC in year t that of the same vaccine type but produced by two or more other manufacturers | Author created based on purchase data |
| IndirCompete | Binary variable equals to one if there were products that of different vaccine types but partially overlapping in providing protections and purchased by CDC in year t | Author created based on purchase data |
| ShareComp1(for combination vaccines) | Binary variable equals to one if there is at least another combination vaccine purchased by CDC in year t that shared one component with the combination vaccine in question | Author created based on purchase data |
| ShareComp2(for combination vaccines) | Binary variable equals to one if there is at least another combination vaccine purchased by CDC in year t that shared two or more components with the combination vaccine in question | Author created based on purchase data |
| Manufacturer name change | Binary variable equals to one if the manufacturer was merged by another manufacturer and changed its name in year t | CDC Vaccine Price List; Morton and Kyle (2012) |
| Name change t-1 | Binary variable equals to one if the manufacturer was merged by another manufacturer and changed its name in year t-1 | NA |
| Shortage | Binary variable equals to one if the product had a shortage or limited supply in year t | CDC Current Vaccine Shortages & Delays websites (http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm); FDA website on CBER-Regulated Products: Current Shortages (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351921.htm ) and resolved Shortages (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351943.htm); National Vaccine Advisory Committee (2003); Shrestha et al. (2010); Santibanez et al. (2012) |
| Shortage t-1 | Binary variable equals to one if the product had a shortage or limited supply in year t-1 | NA |
| Shortage\_oth | Binary variable equals to one if another product that provided the same protection had a shortage or limited supply in year t | NA |
| Shortage\_oth t-1 | Binary variable equals to one if another product that provided the same protection had a shortage or limited supply in year t-1 | NA |
| Pricecap | binary variable equals to one if the vaccine brand was price capped | 1993 CDC Vaccine Price List; Rodewald et al. (2006) |
| Age | Years since product license was approved by FDA | ACIP recommendation documents, FDA websites for List of Vaccine Approvals (<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/default.htm>), RED BOOK Online*®* |
| Thimerosal-free | Binary variable indicating whether the product was thimerosal-free | CDC Vaccine Price List |
| Aprvd doses (for non-combination vaccines) | # doses approved to be administered in a series | ACIP recommendation documents; FDA websites; CDC’s Pink book (2012) |
| Components(for combination vaccines) | # antigen components (defined as below) a combination vaccine has | Created by author |
| Combination | Binary variable equals to one if it is a combination vaccine | Created by author  |
| Antigen components |  |  |
| DTP-containing | Binary variable equals to one if it is a Diphtheria, Tetanus and Pertussis-containing vaccine | ACIP Vaccine Acronyms (2015)  |
| Hib-containing | Binary variable equals to one if it is a Haemophilus influenzae type b-containing vaccine | ACIP Vaccine Acronyms (2015) |
| Hep A-containing | Binary variable equals to one if it is a Hepatitis A-containing vaccine | ACIP Vaccine Acronyms (2015) |
| Hep B-containing | Binary variable equals to one if it is a Hepatitis B-containing vaccine | ACIP Vaccine Acronyms (2015) |
| HPV-containing | Binary variable equals to one if it is a Human Papillomavirus vaccine | ACIP Vaccine Acronyms (2015) |
| MMR-containing | Binary variable equals to one if it is a Measles, Mumps and Rubella-containing vaccine | ACIP Vaccine Acronyms (2015) |
| Men-containing | Binary variable equals to one if it is a Meningococcal-containing vaccine | ACIP Vaccine Acronyms (2015) |
| Pneumo-containing | Binary variable equals to one if it is a Pneumococcal vaccine | ACIP Vaccine Acronyms (2015) |
| Polio-containing | Binary variable equals to one if it is a Poliovirus-containing vaccine | ACIP Vaccine Acronyms (2015) |
| Rota-containing | Binary variable equals to one if it is a Rotavirus vaccine | ACIP Vaccine Acronyms (2015) |
| Var-containing  | Binary variable equals to one if it is a Varicella-containing vaccine | ACIP Vaccine Acronyms (2015) |
| T |  Linear time trend | NA |

Table A.2. Manufacturer name-changing events affecting childhood vaccines purchased by the public sector, 1996-2014

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Affected vaccine type | Affected vaccine brand | Year | Manufacturer name before merger | Manufacturer name after merger |  |
| DTAP | Tripedia | 2000 | Connaught | Aventis Pasteur |  |
| DTAP | Infanrix | 2001 | SmithKline | GSK |  |
| DTAP | Daptacel | 2005 | Aventis Pasteur | Sanofi Pasteur |  |
| DTAP | Tripedia | 2005 | Aventis Pasteur | Sanofi Pasteur |  |
| DTAP-HIB | TRIHIBIT | 2000 | Connaught | Aventis Pasteur |  |
| DTAP-HIB | TRIHIBIT | 2005 | Aventis Pasteur | Sanofi Pasteur |  |
| DTP-HIB | ActHIB/DTP | 2000 | Connaught | Aventis Pasteur |  |
| IPV | IPOL | 2000 | Connaught | Aventis Pasteur |  |
| IPV | IPOL | 2005 | Aventis Pasteur | Sanofi Pasteur |  |
| HEP A | Havrix Pediatric | 2001 | SmithKline | GSK |  |
| HIB | ActHIB | 2000 | Connaught | Aventis Pasteur |  |
| HIB | ActHIB | 2005 | Aventis Pasteur | Sanofi Pasteur |  |
| TD | Decavac | 2005 | Aventis Pasteur | Sanofi Pasteur |  |

Source: Events were identified by name changes in manufacturers of studied vaccines and confirmed based on Table 12.4 from “Markets for Pharmaceutical Products” by Fiona Scoot Morton and Margaret Kyle (2012), Chapter 12 in M.V. Pauly, T.G. Mcguire, and P.O. Barros, editors, Handbook of Health Economics Volume 2 (Elsevier), pp. 763-823.

Table A.3. Shortages in childhood vaccines purchased by the public sector, 1996-2014

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Event | Vaccine type | Vaccine brand(s) | Shortage period | Affected year | Manufacturer | Reason |
| 1 | DTaP | Infanrix, Treipedia, Deptacel | Mar 2001 - Jul 2002 | 2001-02 | GSK, Aventis Pasteur, Sanofi Pasteur | Manufacturing process updates, requirement to remove preservative. |
| 2 | DTaP | Daptacel | Apr 2012-Jul 2014 | 2012-14 | Sanofi Pasteur | Manufacturing delay |
| 3 | DTaP-IPV | Kinrix | Oct 2010-Jul 2011 | 2011 | GSK | Unknown |
| 4 | DTaP-IPV-Hib  | Pentacel | Apr 2012- Jul 2014 | 2012-14 | Sanofi Pasteur | Manufacturing delay |
| 5 | Hep B-Hib | Comvax | Dec 2007-Aug 2010 | 2008-10 | Merck | Recall due to potential equipment sterility issue |
| 6 | Hib | PedvaxHIB | Dec 2007-Jul 2009 | 2008-09 | Merck | Recall due to potential equipment sterility issue |
| 7 | MMR | MMRII | Oct 2001-Jul 2002 | 2002 | Merck | Manufacturing process updates (voluntary renovations at a vaccine filling suite which affected multiple vaccines) |
| 8 | MMRV | ProQuad | Jun 2007-Oct 2012 | 2008-12 | Merck | Unknown |
| 9 | PCV7 | Prevnar | Aug 2001-May 2003 | 2002-03 | Wyeth/Lederle | Fill line problems |
| 10 | PCV7 | Prevnar | Dec 2003-Sep 2004 | 2004 | Wyeth/Lederle | Fill line problems |
| 11 | Tdap | Adacel | Aug 2013-Jul 2014 | 2014 | Sanofi Pasteur | Increased demand |
| 12 | Var | Varivax | Oct 2001-Aug 2002 | 2002 | Merck | Manufacturing process updates (voluntary renovations at a vaccine filling suite which affected multiple vaccines) |

Sources: 1. Shrestha et al. 2010. Modeling the national pediatric vaccine stockpile: Supply shortages, health impacts and cost consequences. Vaccine 28(38): 6318-6332. 2. Santibanez et al. 2012. Effects of a nationwide Hib vaccine shortage on vaccination coverage in the United States. Vaccine 30(5): 941-947. 3. U.S. Food and Drug Administration. CBER-Regulated Products: Current Shortages (Feb, 2014): <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351921.htm>. 4. Trunong. 2012. The pediatric vaccine stockpiling problem. Vaccine 30(43): 6175-6179. 5. CDC Current Vaccine Shortages & Delays. 6. National Vaccine Advisory Committee, 2003. Strengthening the supply of routinely recommended vaccines in the United States. JAMA 290(23): 3122-3128. 7. U.S. Food and Drug Administration. CBER-Regulated Products: Resolved Shortages (Oct, 2014): <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351943.htm>. 8. American Academy of Family Physicians website <http://www.aafp.org/news/health-of-the-public/20120507sanofidtapshortage.html> 9. http://www.ashp.org/menu/DrugShortages/CurrentShortages/bulletin.aspx?id=1051 July 28, May 20, 2015, University of Utah, Drug Information Service.