



New Data Suggest Burden of Group B Streptococcus (GBS) Infection in U.S. Adults Greater Than Previously Recognized

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A new study published in *The Journal of Infectious Diseases* showed high rates of GBS infection among the elderly, African Americans, and people with chronic conditions

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced detailed results of the first study to show the burden of both invasive and non-invasive Group B Streptococcus infections (GBS) among hospitalized adults in the United States. The study, published in *The Journal of Infectious Diseases*, estimated that 188,570 GBS-related hospitalizations (95% confidence interval [CI]: 175,290–202,710) and 5,660 deaths (95% CI: 5,260–6,080) occur each year among US adults ages 18 or older when including both invasive and non-invasive GBS infections. Previous studies describing the burden of GBS infection in adults have primarily focused on invasive disease because existing surveillance systems rely on blood culture collection. In the new study, however, non-invasive disease was 3–4 times more common than invasive disease, suggesting that adult GBS burden is considerably greater than previously recognized.

The most prevalent sites of GBS infection were the skin and soft tissue (39%), urinary tract (23%), and bone and joint (16%). Overall, 79% of infections were non-invasive and most infections (60%) identified GBS as the only pathogen.

Rates of GBS-associated hospitalization were significantly higher in adults 65 years and older, African Americans, and people with underlying chronic medical conditions such as

obesity, diabetes, chronic renal disease, and coronary artery disease. The finding that obesity and diabetes put patients at increased risk for GBS-associated hospitalization is especially noteworthy given that recent Centers for Disease Control and Prevention (CDC) reports have highlighted that the prevalence of obesity among U.S. adults is 42%¹, and that as many as 34 million American adults (roughly 13% of all U.S. adults) have diabetes, with another 88 million having pre-diabetes (roughly 35% of all U.S. adults), a condition that if not treated often leads to type 2 diabetes within five years.²

The study was conducted as a collaboration between Pfizer and the University of Louisville Division of Infectious Diseases. The University of Louisville was recently designated as the first Center of Excellence for epidemiological research of vaccine-preventable diseases by Pfizer Vaccines. This collaboration between the university and Pfizer is aimed at determining the human health burden of important infectious diseases and potential vaccine effectiveness.

“These new data suggest that the burden of GBS infection is considerably greater than previously recognized in earlier surveillance studies that only focused on invasive disease,” said Julio Ramirez, M.D., Chief of the Division of Infectious Diseases at the University of Louisville. “Importantly, we found that the rates of GBS infection in this study are comparable to that of other adult infections for which vaccines are routinely recommended, which underscores the need for developing approaches for preventing this infectious disease among an aging adult population.”

Additional findings from the study included the following:

73 in every 100,000 adults were hospitalized with GBS infection each year (95% CI: 68–78), and this annual incidence reached 100 per 100,000 in adults ages 65 or older (95% CI: 85–117) 3% of adults hospitalized with GBS infection died For every invasive GBS infection, 3.7 non-invasive infections occurred Annual rates of GBS infection in African American adults were 2.6 (95% CI: 2.2–3.1) times higher than in white adults– 157 per 100,000 vs. 60 per 100,000 Compared with the general population, annual GBS infection rates were 2 to 6 times higher among adults with underlying chronic medical conditions, including: Chronic renal disease – 421 per 100,000 Diabetes mellitus – 409 per 100,000 Coronary artery disease – 259 per 100,000 History of stroke – 171 per 100,000 Obesity – 129 per 100,000 Chronic obstructive pulmonary disorder (COPD) – 98 per 100,000 Current smokers – 98 per 100,000

“This type of study, evaluating both invasive and non-invasive GBS infections, is essential for understanding the full spectrum of GBS disease burden among adults,” said John M. McLaughlin, PhD, Global Epidemiology and Scientific Affairs Lead, Pipeline Vaccines,

Pfizer Inc., and the lead study author. “These data should aid healthcare providers with clinical decision-making. Our population-based study gives the first estimates of total annual GBS burden in the United States, emphasizing the importance of preventive efforts in the growing population of adults who are older or have chronic medical conditions, and will inform future vaccination strategies.”

In January 2020, Pfizer launched its Vaccines Division’s Centers of Excellence Network, a global program of collaborations with academic institutions to conduct real-world epidemiologic research to accurately identify and measure the burden of specific vaccine-preventable diseases and potentially evaluate vaccine effectiveness in adults. This collaborative study between the University of Louisville and Pfizer was completed prior to the university being named as Pfizer Vaccine’s first Center of Excellence site.

About the Study

Study investigators identified GBS infections among adults ≥ 18 years of age by retrospectively reviewing laboratory and medical records from six hospitals in Louisville, Kentucky between January 1, 2014 and December 31, 2016. Data describing demographic and clinical characteristics (e.g., chronic medical conditions) were collected for each patient. At the time of the study, Louisville’s population was generally similar to the United States in terms of demographics and prevalence of underlying chronic medical conditions based on data from the Behavioral Risk Factor Surveillance System (BRFSS), an annual survey conducted by the CDC that provides United States specific and Louisville Metropolitan Statistical Area specific estimates.

Among the 1,076 adults with GBS infection, the median age was 52 years, 51% were male, 73% were white, 24% were black, and 89% had ≥ 1 chronic medical condition. Patients had to have GBS isolated from culture obtained during hospitalization with (1) clinical or laboratory evidence of local signs and symptoms of infection or (2) systemic inflammatory response. Instances where GBS was isolated from culture without local or systemic evidence of infection were categorized as colonization (only) and were excluded. Pregnant women meeting criteria for GBS infection were included (except positive screening cultures from asymptomatic pregnant women).

Annual rates of GBS infection were estimated by dividing the number of GBS cases occurring among permanent residents of the catchment area (most-serious site only) identified across the five hospitals used for calculating incidence by US Census population estimates for the catchment area. For calculation of risk-group-specific incidence rates, the prevalence of chronic medical conditions in the catchment area were obtained from

the Louisville Metropolitan Statistical Area-specific BRFSS.

About Group B Streptococcus

Bacteria called Group B Streptococcus or *Streptococcus agalactiae* (Group B strep, GBS) commonly live in people's gastrointestinal and genital tracts. The gastrointestinal tract is the part of the body that digests food and includes the stomach and intestines. The genital tract is the part of the body involved in reproduction. Most of the time the bacteria are not harmful and do not make people feel sick or have any symptoms. Sometimes the bacteria invade the body and cause certain infections, which are known as GBS disease.

GBS bacteria can cause many types of infections: bacteremia (bloodstream infection) and sepsis (the body's extreme response to an infection); meningitis (infection of the tissue covering the brain and spinal cord); pneumonia (lung infection); bone and joint and skin and soft-tissue infections.

Unfortunately, experts have not identified effective ways to prevent GBS disease in people older than one week old. How people get these bacteria or spread them to others is generally unknown, as the bacteria do not spread through food, water, or anything with which people may come into contact.

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DISCLOSURE NOTICE:

The information contained in this release is as of May 4, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's results of a study to show the burden of both invasive and non-invasive GBS among hospitalized adults in the United States that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indications for Pfizer's vaccine candidate against GBS; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy, and, if approved, whether they will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer's vaccine candidate against GBS; the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

¹ Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity and severe obesity among adults: United States, 2017–2018. NCHS Data Brief, no 360. Hyattsville, MD: National Center for Health Statistics. 2020. Available at: <https://www.cdc.gov/nchs/data/databriefs/db360-h.pdf>. Accessed on April 20, 2020. ² Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human

Services; 2020. Available at: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>. Accessed on April 20, 2020.

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