

Occupational Epidemiology and the National Institute for Occupational Safety and Health

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Introduction

The major factors that propelled the development of occupational epidemiology since the 1950s have been delineated (1). They include momentum to control occupational injury that gained national prominence in the wake of the Triangle Shirtwaist Fire of March 25, 1911, in which 146 young, mostly female immigrant garment workers fell to their deaths while escaping from a fire in a locked sweat shop. This tragedy was a turning point in the nationwide adoption of state-based occupational safety regulations, workers' compensation programs, and federal safety legislation. During the 1930s, federal initiatives in occupational safety and health required contractor compliance, not only with wage and hour laws, but also with federal occupational safety and health regulations. The New Deal built state capacity by funding state industrial hygiene programs. Levenstein (1) reports a diminution of interest in occupational safety and health, except for the Atomic Energy Act in the 1950s, until the 1960s' resurgence in organized labor's political voice. Also, societal reaction to the Farmington, West Virginia, mine disaster of 1968, which killed 78 miners, led to passage of the Federal Coal Mine Health and Safety Act of 1969 and introduced federal regulation and federal inspectors to the mining industry.

To this brief history could be added the major scientific advances in the invention and commercialization of synthetic organic chemicals, such as organic dyes that caused epidemics of bladder cancer among industrial workers and anemia and leukemia among benzene-exposed workers. Interest among health-care students and the public probably was affected by growing concern about the health effects of environmental toxins communicated to the public through Rachel Carson's 1962 book, *Silent Spring* (2). This book vividly detailed the environmental consequences of pesticides and helped launch the environmental movement. In 1965, a parallel popular book by Ralph Nader, *Unsafe at Any Speed* (3), concerned the forces at play in industry and society that led to production of unsafe automobiles and failure to adopt new safety technology,

such as seat belts, which vaulted consumer safety into the public agenda. These historical tides provided fertile ground for national-level development of occupational epidemiology midway through the 20th century.

The institutional genealogy and political history of the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) through numerous government predecessor organizations has been delineated by Lynne Page Snyder (L.P. Snyder, *The National Institute for Occupation Safety and Health, 1971–1996: a brief history*. Office of the Public Health Service Historian, 1997, unpublished data). The capstone event for occupational health in the mid-20th century was passage of the Occupational Safety and Health (OSH) Act, supported by President Lyndon Johnson as part of the New Society and signed into law on December 29, 1970 by President Richard Nixon, the son-in-law of a miner who died of silicosis. Congress provided a broad delegation of authority to the Secretary of Labor to carry out the OSH Act. The OSH Act federalized regulation and enforcement, including inspections that had previously been a function of various state governments, and provided for the first time uniform national enforcement of occupational safety and health across the United States. It removed responsibility for inspection and enforcement from state governments—which sometimes were conflicted in balancing the interests of health and safety against those of commercial enterprise and local politics. The OSH Act also mandated that the federal government gather a critical mass of scientific expertise across multiple disciplines, such as medicine, epidemiology, industrial hygiene, safety, health education, and psychology, to focus exclusively on occupational disease and injury prevention.

The OSH Act also reshaped the playing field with regard to epidemiologic investigations. The first change was in providing workers or their representatives and management with experts who could assess the potential for, or occurrence of, occupational disease and injury in their workplaces. Before the

OSH Act, the playing field in many states was far from level. Employers, especially larger corporations, had the resources to provide access to occupational health consultants and epidemiologists. It would have been unusual for organized labor and much less likely for nonunion workers at smaller workplaces to have the resources to hire such experts. The OSH Act gave them access to epidemiologic consultation, which was called a Health Hazard Evaluation (HHE), and the Act was worded to give them direct access to expertise in the federal government, thereby bypassing state and local government. The impact of the NIOSH HHE program was that both workers and management gained unhindered access to multidisciplinary occupational health expertise. Workers and small employers were no longer prevented from obtaining this expertise by an inability to pay. Also, perhaps most importantly, worksite problems would now be approached by using a public health and consultative perspective.

Parallel considerations also led to inclusion in the OSH Act of research expertise in epidemiology, toxicology, and other fields. This expertise would provide unbiased information as the basis for recommendations and regulations on health and safety. To carry out independent large-scale preplanned research on worker health and safety (i.e., industrywide studies), the OSH Act gave NIOSH right of entry into private workplaces and ensured time and space for examination and interview of workers.

In place of various state-specific activities that previously had led to disparities in worker protection and health, the OSH Act standardized the establishment of regulations and periodic inspection of workplaces across the United States. The Act also established a rational system to generate and apply new knowledge relevant to worker safety and health. The OSH Act led to establishment of OSHA (a regulatory body) and, in April 1971, NIOSH (a research institute). NIOSH was envisioned as a science-based center dedicated to preventing occupational disease and injury. It was to have many interrelated functions that together would serve as a system for the scientific advancement of prevention.

Early on, epidemiology was deemed central to the work of NIOSH, and it played three major roles. The role most familiar to the rest of CDC, where NIOSH is located, is field epidemiology. At the request of workers, their labor representative, management, or state health departments, NIOSH (under the HHE program) conducts field epidemiologic investigations of individual workplaces. The field teams can consist of an epidemiologist, who often is a physician, and industrial hygienists, who are highly skilled in identifying potential workplace hazards, measuring and controlling levels of exposure, and identifying appropriate control strategies.

A second role for epidemiology is the conduct of large studies, often involving multiple industrial facilities across the United States, to assess the relationship of exposure and possible adverse outcomes. Epidemiologic associations sometimes are postulated by laboratory research in toxicology (also a forte of NIOSH) and sometimes by the astute observations of workers and their health-care providers. These large multiplant studies also assess the shape of the exposure–response relationship. Understanding the exposure–response relationship is essential to assessing risk, which is essential to recommending a level of exposure at which workers will not suffer short-term or long-term illnesses as a consequence of their work (e.g., the risk for lung cancer from exposure to diesel exhaust in the trucking industry [4]). Such large-scale studies are not limited to chemical exposure but include the evaluation of best practices for preventing injuries, such as slips, trips, and falls in hospitals (5) and other hazards.

The third role for epidemiology in NIOSH's work is surveillance for occupational disease and injury. The goals of this surveillance are to estimate the magnitude and trends of occupational disease and injury, identify new occupational diseases and injuries, detect sentinel health events that signal failures of prevention, and develop strategies for targeting all-too-scarce preventive resources to industries, occupations, and locations most in need.

Occupational disease surveillance is not new. It is rooted in the astute observations of Bernardino Ramazzinni (1663–1714) (6) about the relationship of occupation and disease in the 17th century, and of Alice Hamilton, a field epidemiologist and physician (7), who negotiated access to myriad industries and occupations during World War I and later, was intent on preventing occupational disease and injury.

Occupational health exists at the border between labor and management, and government support for preventing occupational injury and disease has waxed and waned with waves of political change (1). Renewed interest is often generated by fresh societal concern after occupational disasters with large numbers of victims, such as the Triangle Shirtwaist Fire of 1911 and the Farmington Coal Mine Disaster of 1968. This *MMWR* report provides examples of how NIOSH uses epidemiology to conduct field investigations in response to requests, to carry out large-scale investigations to assess causal associations or dose response relationships, and to maintain surveillance systems for occupational health and disease.

Field Studies in Response to Requests

Example: Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant

In 2002, Kathleen Kreiss, a NIOSH scientist and former CDC Epidemic Intelligence Service (EIS) Officer, and colleagues reported an outbreak of bronchiolitis obliterans in workers at a microwave-popcorn production plant that used diacetyl as a butter flavoring agent (8). In response to a request from the Missouri Department of Health, which had received reports of eight former workers from the plant who became ill during 1993–2000, NIOSH conducted an epidemiologic field investigation and exposure assessment. In 2000, 117 current workers completing a symptom questionnaire had 2.6 times the expected rate of respiratory symptoms, twice the rate of physician-diagnosed asthma and bronchitis, and 3.3 times the rate of airways obstruction (10.8 times the rate for nonsmokers). Detailed assessment of exposures in the plant showed a strong relationship between exposure to diacetyl and current respiratory disease. As an example of the potential severity of the disease, according to NIOSH's investigation, one patient was a 40-year-old nonsmoking housewife who had begun work on the packaging line in 1993 and had become symptomatic with airway disease in 1994. At that time, her forced expiratory volume was only 24% of normal, and in 1995, she had been placed on a waiting list for lung transplant.

The prologue to the NIOSH investigation is instructive. During 1993–1998, several plant workers were seen by two pulmonary physicians in southwestern Missouri (9). The physicians found fixed airway obstruction and viewed the patients as atypical in that they worked in the same plant, smoked minimally or not at all, and did not respond to asthma medications. The pulmonologists referred the patients separately to national referral centers and expressed concern in one of their referral letters about similar cases associated with the same plant. They wrote that they had reported the situation to OSHA; OSHA inspectors had “visited the plant but concluded no lung hazards existed” (9).

Meanwhile, the spouse of one worker identified four additional coworkers who were similarly affected. That information was referred to a lawyer specializing in workers' compensation, who consulted an occupational physician, who in turn contacted the Missouri Department of Health. Subsequently, an experienced environmental health worker called CDC, which referred the call to NIOSH. A call from the NIOSH investigator to the Missouri state epidemiologist led to a request to NIOSH for assistance in a joint investigation. After completing the investigation, NIOSH continued to contribute to the understanding

of this outbreak by conducting epidemiologic investigations at other similar plants, by conducting toxicologic studies, and by recommending regulatory and engineering solutions.

Overview

The Institute of Medicine (IOM) assessed the impact of field investigations conducted in response to requests from representatives of workers or industry (10). It described nine examples of hazards identified during 1978–2006 that resulted in “wide impacts.” One was the example of diacetyl in the microwave-popcorn plant. In another example, exposure to dibromochloropropane (a nematocide previously associated with sterility in chemical production workers) was assessed among agricultural workers in several investigations during 1977–1981. OSHA used the findings to set a standard in 1979 limiting occupational exposure. In addition, IOM noted that a large number (337) of NIOSH investigations of lead exposure during 1978–1995 “provided information about exposures and control measures, consultation, and enforcement activities.” IOM also noted 1) four investigations of silica exposure in the roofing industry that were cited as the basis for a curriculum designed to train 20,000 roofers to prevent occupational lung disease; 2) two investigations of finely ground silica, known as silica flour, that led to recommendations and regulations for control of occupational exposure; 3) eight investigations of flock made of synthetic fiber that was found to cause interstitial pneumonitis; 4) numerous investigations of musculoskeletal disorders that have informed OSHA and “stimulated major research activities within and outside NIOSH”; and 5) numerous field investigations by NIOSH demonstrating that powdered latex gloves were a risk factor for latex allergy, which played a role in replacing them with powder-free latex gloves.

Preplanned Large-Scale Studies

One of the major responsibilities assigned to NIOSH in the OSH Act is the conduct of epidemiologic studies of chronic and low-level exposure to chemicals in industry (i.e., industrywide studies). These studies are designed to detect an increased risk if it truly exists while avoiding a false negative finding resulting from small sample sizes or previously established exposure controls. Because many chronic diseases demonstrate latency between exposure and disease onset, the population studied must have sufficient years of exposure and sufficient years of follow-up to demonstrate a possible effect. To demonstrate an exposure–response relationship, which is critical to assessing causality and in establishing a level of exposure at which there is no effect, exposure must vary among cohort members.

Example: Studies of Mortality from TCDD

During the late 1970s and early 1980s, a confluence of interests led NIOSH to conduct a cohort mortality study of workers exposed to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), one of many dioxin congeners. Studies from Scandinavia were pointing to an association among chemical production workers between TCDD exposure and excess risk for soft tissue sarcoma and lymphoma. Concern existed for veterans and others exposed during the Vietnam War to TCDD, an inadvertent contaminant of the widely used defoliant Agent Orange. Toxicologic studies were also pointing to an increased risk and a physiologic mechanism for toxicity, the aryl-hydrocarbon receptor. In 1980, the U.S. Department of Defense requested assistance from NIOSH in conducting an epidemiologic study of soldiers who had served in Vietnam. A recent EIS Officer (W.H.) and the Director of NIOSH, Tony Robbins, visited the Pentagon, where they learned of the limited available records that could be used to accurately characterize the location of soldiers in Vietnam and their exposure to defoliants. They concluded that a study in civilian exposed workers was more likely to be useful than a study among soldiers. The civilian study could then be applied to Vietnam War veterans.

In 1981, NIOSH began efforts to identify plants in the United States that produced chemicals contaminated with TCDD (11). In all, 5,172 workers at 12 plants were included in a cohort mortality study. An extensive effort was made to characterize workers' potential exposure to TCDD at these plants from job assignment records. TCDD was measured in serum from a subset of 253 workers. Cause of death on a death certificate was used as the outcome of interest. Vital status was ascertained as of the last day of 1987. The duration of exposure of the cohort members varied: 54% had <1 year of exposure; 29% had 1–5 years; 13% had 5–15 years; and 4% had ≥15 years. The latency from first exposure was substantial: >20 years for 61%. The analysis of all workers did not substantiate an excess risk for lymphoma but found a nonsignificant increase in soft tissue sarcomas. The analysis of workers with >1 year of exposure and 20 years of latency indicated a significant increase in death from lung cancer and soft tissue sarcoma, and an analysis of all cancers combined also showed a significant increase. In an updated analysis that extended determination of vital status and cause of death through 1993 (12), excess mortality from all cancers was still in excess—a 60% increase for workers in the highest exposure group. Estimated exposure for this group was 100–1,000 times higher than for the general population and similar to doses used in experimental animal studies that showed cancer excess. The original study (11) has been cited >400 times and the later study (12) 175 times. Both studies have been used in risk assessments of national

and international importance, in decisions on compensation of veterans, and for other reasons.

Overview

Only one study—unpublished—has attempted to systematically evaluate the impact of NIOSH's large-scale epidemiologic studies (Mary K Schubauer-Berigan. NIOSH, personal communication, 2009). The International Agency for Research on Cancer has determined that 108 of 900 candidate agents were known human carcinogens. Schubauer-Berigan reviewed the literature cited by the International Agency for Research on Cancer for each occupational metal and fiber to identify the studies conducted by NIOSH. For epidemiologic studies, the results were as follows: chromium: three (8%) of 38 studies were conducted by NIOSH; cadmium: four (13%) of 30; crystalline silica: seven (28%) of 25; asbestos: 15 (9%) of 160; beryllium: all of eight.

The spectrum of diseases that NIOSH has studied is broad. Although a systematic census of studies is not available, examples include studies of cancer of various anatomic sites, cardiovascular disease, neurotoxicity, reproductive disorders, infectious diseases, and dermatitis. Many of these studies have been used in part as the basis for risk assessments and standard setting—for example dioxin, radon, beryllium, silica, and ethylene oxide and diesel exhaust. Another major focus of NIOSH studies has been respiratory disease, including those arising from the mining of coal, uranium, hard rock, cotton dust, vermiculite, and fibers. Traumatic injury, a major cause of occupational mortality and morbidity, also has been a major focus; such injuries include falls, electrocutions, amputations and violence. Industrywide studies also have focused on occupational sectors, such as construction, agriculture, and child labor.

Surveillance

Surveillance for NIOSH, as for the rest of CDC, follows a modified version of the definition established by Alexander D. Langmuir, the first chief epidemiologist of CDC: for NIOSH it is the systematic collection, analysis, and dissemination of health-related information for the purposes of prevention or control of disease or injury (13). NIOSH emphasizes that occupational surveillance information extends beyond mortality and morbidity to information about injuries, hazards, and exposures.

NIOSH surveillance studies developed in the 1970s and 80s under the guidance of Todd Frazier. Frazier and a former colleague from earlier days at Harvard, David Rutstein, and other NIOSH epidemiologists developed the concept of the Sentinel Health Event (occupation) or SHE(O) (14). A SHE(O) is “a

disease, disability, or untimely death, which is occupationally related and whose occurrence may: provide the impetus for epidemiologic or industrial hygiene studies; or serve as a warning signal that materials substitution, engineering control, personal protection, or medical care may be required.” The SHE(O) list in 1983 comprised 50 conditions linked to occupational exposure. Rutstein coincidentally was a classmate in residency with Langmuir at Boston City Hospital, and both were employed after residency in an epidemiology training program in New York state. The concept of the SHE(O) led directly to an invigorated effort to involve selected state health departments in occupational disease and injury surveillance and investigation, the Sentinel Event Notification System for Occupational Risk (SENSOR) Program, which focused on the surveillance of selected persistent occupational diseases such as silicosis and lead poisoning. SENSOR was championed by Edward Baker upon his return to NIOSH in 1987 as Deputy Director.

NIOSH also established programs for state-based surveillance for occupational injuries, called the Fatality Assessment and Control Evaluation (FACE), which completed 2,202 investigations in seven targeted topic areas of concern, including electrocutions, confined spaces, falls from elevations, machinery, child labor, migrant agricultural worker conditions, and roadway work zones. NIOSH also created the National Traumatic Occupational Fatality (NTOF) Surveillance System, a national surveillance system that has provided comprehensive national data used to target research and prevention efforts, monitor trends, and identify previously unrecognized risks for occupational trauma. For example, during the 1980s, NTOF recognized occupational homicides as a leading cause of death, accounting for 13% of work-related traumatic deaths (15).

Example: Lead Poisoning in Adults

In 1983, Paul Seligman was assigned to NIOSH as an EIS officer. To satisfy a training requirement, he evaluated the potential of the Ohio workers' compensation system as a source of information to track the Healthy People 1990 objective to eliminate occupational lead poisoning (16). At that time, the incidence of occupational lead poisoning was unknown. Seligman was concerned that state-based surveillance that relied on physician reporting led to a woefully undercounted incidence of lead poisoning in adults. Around this time, evidence was increasing that lower levels of lead exposure in young children resulted in cognitive and neurobehavioral effects. As a result, CDC, the Council of State and Territorial Epidemiologists (CSTE), and Association of State and Territorial Health Officials had pushed to institute or amend state childhood lead poisoning reporting laws nationwide

that required reporting of elevated blood lead levels (BLLs) in children to the state health departments.

Seligman recalls one of those vibrant moments of profound insight when he realized that, since all testing for blood lead in adults had to be done in one of just 70 OSHA-certified laboratories, using laboratory reporting as the foundation of surveillance for occupational lead poisoning was very feasible. Whereas most states focused on childhood lead poisoning, by 1981, four states (California, New Jersey, New York, and Texas) had required that all laboratories performing blood lead assays must report all elevated BLLs in children and adults to the state health department. In 1986, Seligman worked with these four states to publish an article in *MMWR* analyzing the states' data on elevated BLLs in adults, the vast majority of which came from workplace exposures.

To get states to expand their lead reporting requirements to include adults, Seligman worked with Henry Falk of CDC's National Center for Environmental Health to get the issue of adult lead surveillance on the agenda at meetings of CSTE and the Association of State and Territorial Health Officials. Armed with data from the four states and the support of articulate and persuasive allies in Linda Rudolph (California), Alice Stark (New York), Dennis Perotta (Texas), and Martha Stanbury (New Jersey), Seligman and Falk made a strong case for expanding the reporting of elevated BLLs to include everyone, not just children. In 1987, NIOSH and CSTE chose state-based lead poisoning surveillance as the first SENSOR condition for surveillance by using Seligman's idea for laboratory-based reporting. The system was called the Adult Blood Lead Epidemiology and Surveillance (ABLES).

NIOSH supported states using ABLES through cooperative agreements and required reporting of data by laboratories and health-care providers for adults with elevated BLLs. Supplementary data were subsequently gathered through interviews of workers, employers, and physicians. ABLES spread to 18 states by 1992, and is now active in 40 states. With the advent of ABLES, for the first time, data became available on the incidence, trends, and distribution of occupational lead poisoning. ABLES allowed estimates of the magnitude of lead poisoning and its distribution and trends over time and helped to identify high-risk industries, occupations, and specific workplaces in need of control measures. For example, ABLES reported a total of 9,871 cases of occupational lead poisoning for 2007(17), a decline from 14 per 100,000 employed adults in 1994 to 7.8 in 2007. Among the 40 participating states, prevalence rates ranged from 0.8 to 36.4 per 100,000 in the general population. Exposure at work accounted for about 80% of cases in adults. Industries with high rates included manufacturing of storage batteries and mining. Nonoccupational exposure accounted for about 5% of prevalent cases. NIOSH

and participating states were able to accomplish cooperatively all the goals of occupational disease and injury surveillance: estimating the magnitude and trend of disease, describing its distribution, identifying risk factors, and systematically collecting information useful for informing and providing preventive measures at specific worksites.

Overview

By working with states and other federal agencies, NIOSH has helped create an effective patchwork quilt of surveillance systems for the prevention of occupational disease and injury. State-based surveillance conducted in 23 states in cooperation with NIOSH as part of SENSOR now report statistics on 19 occupational health indicators, such as burns, amputations, and pneumoconiosis. Some states also conduct in-depth surveillance on silicosis, pesticide poisoning, occupational asthma, musculoskeletal disorders, sharps injuries in hospital workers, injuries among truckers, and fatal injuries among adults and teens. Surveillance for other conditions is conducted by NIOSH itself, including cardiovascular disease deaths and traumatic injury among firefighters, radiographic evidence of coal workers' pneumoconiosis, death from various pneumoconioses and malignant mesothelioma. NIOSH also collaborates with the Consumer Product Safety Commission in surveillance for occupational injuries in a sample of U.S. hospitals reported in the National Electronic Injury Surveillance System.

The Future

In 40 years, NIOSH has developed an extraordinary capacity to carry out 1) field studies in response to requests—in the tradition of shoe-leather epidemiology 2) large-scale multisite epidemiologic studies to understand more subtle causal relationships and establish dose–response relationships essential for assessing risk and recommending safe limits on exposure; and 3) surveillance for occupational diseases and injuries of national interest. Tribute for this accomplishment goes to the scores of epidemiologists whose careers have been spent in these efforts, to the leaders of NIOSH and CDC through the decades who understood that effective prevention of occupational disease and injury needs strong epidemiologic capacity in NIOSH, to Executive Branch and Congressional leaders who facilitated these efforts, and to progressive leaders of organized labor and industry.

Major challenges remain in epidemiology's contribution to preventing occupational disease and injury. One challenge is how to ensure the safety of new advances in commerce. For example, NIOSH is playing a leadership role in innovating an epidemiologic strategy for the advances in nanotechnology.

Such anticipatory planning has not always been done in the past before the widespread adoption of new industrial technologies. For example, if the dangers of asbestos had been recognized before it was widely used, many major health consequences could have been avoided. Today, the early use of epidemiologic investigations can help reduce uncertainty about risks for occupational diseases and injuries as new industrial methods advance, even when adverse consequences of new technologies prove unfounded (e.g., early speculation about the possibility of cataracts or spontaneous abortion after using video display terminals).

A second challenge relates to NIOSH's role within the larger framework of prevention of occupational disease and injury in the United States. In contrast to the U.S. system for preventing infectious diseases, in which CDC's state partners have substantial resources, states have only marginal resources in the occupational health arena. Through a century of NIOSH and its predecessors, the federal government has been key to providing resources to enable states to develop capacity for occupational health and safety (L.P. Snyder. *The National Institute for Occupation Safety and Health, 1971–1996: a brief history*. Office of the Public Health Service Historian, 1997, unpublished data).

A third challenge is development and distribution of expertise. To understand this challenge, one can go back to Langmuir's original conceptualization of the EIS. One goal was enhancement of federal epidemiologic expertise. Another was to salt academic and health-care centers across the country with EIS graduates who would enhance disease prevention locally through the use of epidemiology. To be effective nationally in preventing occupational injury and disease, NIOSH must continue to be able to support a system for training experts, who will migrate to schools of medicine and public health and state and local health departments and who will train others. In addition, to sustain trainers, a robust support system is needed to sustain careers outside of NIOSH.

A fourth major challenge is expressed in a fundamental principle espoused by former CDC Director William Foege—that the world is a lifeboat inhabited by all peoples of all nations. With globalization, many industries and their inherent hazards to workers have moved overseas, often to countries where occupational safety and health are not considered important. Increasingly, the United States is accepting a role in ensuring that imported products are made to be safe, not just for U.S. consumer, but also for the workers who manufacture them overseas. One method to ensure health and safety is by developing international training programs, particularly in occupational epidemiology and industrial hygiene.

The ultimate challenge for NIOSH is to not only effectively control occupational diseases and injuries that are the

remnants of the last century, but also to preempt new hazardous exposures and conditions from gaining a foothold in the new century.

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