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EPIDEMIOLOGY 101:
AN OVERVIEW OF EPIDEMIOLOGY
AND ITS RELEVANCE TO U.S. LAW

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Events occurring during the latter half of the twentieth century accelerated the intertwining of epidemiology, a core science discipline of public health, with the field of law, its theories, teachings, and practices. Examples of events giving rise to this interdisciplinary activity include the increasing introduction of epidemiologic data and methods into the courtroom during civil litigation; legal issues confronting epidemiologists, as well as epidemiologists' associated dependence upon legal counsel when responding to potential bioterrorism threats and when investigating other health problems for which criminal actions may have played a causal role; litigation involving the prevention of tobacco use and related

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3. Richard A. Goodman et al., Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations, 31 J.L. MED. & ETHICS 684, 688-89 (2003) ("Examples of such legal issues and questions include the law(s) surrounding the gathering of admissible evidence during public health investigations, access to premises (i.e., the law of entry), establishing and maintaining a chain of custody of evidence, disclosure of confidential health information by public health to law enforcement, and restricting a person's freedom of movement following exposure to communicable diseases.").
4. Id. at 687.
5. Id. at 688-93.
diseases, and injuries putatively associated with numerous other products; and lawsuits brought to address environmental hazards. An even more recent development is the recognition of the indispensable role of law in public health policy and program implementation, as illustrated by the conceptualization of legal frameworks to address public health problems, such as cardiovascular diseases and obesity, and to improve the public's health through healthy communities.

Developments such as the aforementioned have required epidemiologists to increase their understanding of the legal system and United States law—at the local, state, and federal levels—and, reciprocally, have impelled lawyers and law students to learn about epidemiology and other facets of public health. These issues also have underscored the practical relevance of epidemiology to the spectrum of legal lifetime professional development needs, beginning in the law school classroom and extending through continuing legal education and other postgraduate opportunities. The juxtaposition of law to epidemiology and to other public health sciences also has been the focus of initiatives to foster the introduction and incorporation of "public health literacy" within the environment of United States law schools.

This article primarily provides an overview of epidemiology for law school faculty, law students, and practicing lawyers, through a review of selected core definitions and basic concepts in epidemiology and public health practice. The article then briefly compares concepts of causation in epidemiology with causation in law. The article concludes by characterizing the increasing presence of epidemiology in the continuum of legal education and practice.

8. Id. at 94. For additional discussion regarding events in the twentieth century that have given rise to interdisciplinary activity in epidemiology and law, see SANA LOUE, CASE STUDIES IN FORENSIC EPIDEMIOLOGY (2002); SANA LOUE, FORENSIC EPIDEMIOLOGY: A COMPREHENSIVE GUIDE FOR LEGAL AND EPIDEMIOLOGY PROFESSIONALS (1999); Zita Lazzarini et al., Evaluating the Impact of Criminal Laws on HIV Risk Behavior, 30 J.L. MED. & ETHICS 239 (2002); Zita Lazzarini et al., Criminal Law and Public Health Practice, in LAW IN PUBLIC HEALTH PRACTICE, supra note 1, at 63-92.
11. Caveat lector: covering the entire complex field of epidemiology in an article such as this is impossible. For an in-depth examination of this field, readers are encouraged to consult an array of basic references on this topic, including APPLIED EPIDEMIOLOGY: THEORY TO PRACTICE (Ross C. Brownson & Diana B. Petitti eds., 2d ed. 2006); FIELD EPIDEMIOLOGY (Michael B. Gregg ed., 2d ed. 2002); LEON
I. EPIDEMIOLOGY IN PUBLIC HEALTH PRACTICE: CORE DEFINITIONS AND CONCEPTS

A. Epidemiology Defined

In the United States, public health services are provided by a workforce comprising an estimated 448,000 individuals situated primarily in government agencies at the local, state, and federal levels. The missions, functions, and powers of these agencies and their workforces are specified by law. However, decisions regarding policies and services implemented by these agencies and their workforce are informed by data developed through both public health surveillance and applications of epidemiology, the underlying quantitative science of public health practice. Epidemiology is formally defined as "[t]he study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems."13

The meaning of epidemiology can be illuminated further by unpacking this definition. At its core, epidemiology is a study that relies on measurements and the quantification of health events, other population characteristics, and principles of statistics.14 Epidemiology requires that public health professionals study the distribution of frequencies and patterns of health characteristics, events, and patterns within and across different population groups.15 Epidemiology also seeks to identify risk factors, predictors, or other determinants for increased or decreased probabilities of health events in populations.16 Although epidemiology is commonly associated with infectious disease problems, in reality the science of epidemiology is used to study a broad spectrum of health-related states, including injuries, chronic diseases, occupationally acquired conditions, pregnancy and births, developmental disabilities, deaths, and others.17 When compared with clinical health care and curative medicine, epidemiology is distinguished by its focus on population groups rather than on individual patients.18 Finally, epidemiologic methods and data developed through epidemiologic study help

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14. LILIENFELD & STOLLEY, supra note 11, at 3-4.
15. Id. at 18-19.
17. Id. at 13.
18. Id. at 12.
inform the public health policy-making process, to make decisions to control and prevent health problems, and to promote desired health outcomes.19

B. Epidemiologic Methods

Both fundamentally and practically, the primary methodologic approach of epidemiologists—those in public health agencies, academics, and other settings who engage in epidemiology—is to count, divide, and make comparisons.20 Epidemiologists first count units of specified health events, such as cases of disease, injury, disability, death, or hospitalizations.21 Epidemiologists next define the size and composition of the at-risk or affected population, and compute rates of occurrence of the specified health event in that population by dividing the number of health events (the numerator) by the population (the denominator).22 Next, epidemiologists compare those rates of occurrence with rates among other populations, that are distinguished by determinants such as suspected risk factors.23 Finally, by comparing rates in different populations, epidemiologists establish a quantitative basis for making inferences about the potential causal role of suspected disease- or injury-causing agents, the mode(s) of transmission or acquisition, and other possible risk factors or determinants for the specified health event.24

Epidemiologists use a variety of study designs, which may be grouped into two fundamental categories: experimental and observational. Experimental study designs enable investigators to maintain control over all basic circumstances.25 An example of such a design is a prospective study designed to measure the efficacy of new vaccines, in which an investigator uses a method to prospectively define which study participants will receive the new vaccine prior to possible exposure to the disease-causing agent and which study participants will not.26 By contrast, an observational study typically allows data to be collected after a population has been exposed to disease- or injury-causing agents and, therefore, are not under an epidemiologist’s total control.27

Observational studies may be either descriptive or analytical studies. In a descriptive study, an epidemiologist gathers and analyzes data about a health event in a defined population and describes the data in relation to characteristics of affected individuals such as age distribution, race and/or ethnicity, sex, and

19. Id. at 14.
20. Id. at 15-16.
21. Id.
22. Id. at 92-93.
23. Id. at 94-96.
24. Id. at 96.
25. LILIENFELD & STOLLEY, supra note 11, at 151.
27. LILIENFELD & STOLLEY, supra note 11, at 151-53.
occupation; places of likely exposure including residence, workplace, recreational or vocational settings; and pertinent times of activities possibly associated with individuals’ exposures or onset of symptoms or signs. Descriptive studies and their associated data often generate clues or testable hypotheses regarding etiologic agents, causative risk factors, and modes of disease transmission.

Analytical study designs, by contrast, are used to test hypotheses regarding the occurrence of the disease or health event and, ultimately, to provide a scientifically rational basis for addressing the public health problem. Two of the most common types of analytical studies are cohort and case-control studies, as demonstrated below:

### Cohort Study Approach

<table>
<thead>
<tr>
<th>III</th>
<th>Not III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed</td>
<td>a</td>
</tr>
<tr>
<td>Unexposed</td>
<td>c</td>
</tr>
</tbody>
</table>

Relative Risk = \[
\frac{\text{Incidence in exposed}}{\text{Incidence in unexposed}} = \frac{a}{a+b} \div \frac{c}{c+d}
\]

### Case-Control Study Approach

<table>
<thead>
<tr>
<th>III (Cases)</th>
<th>Not III (Controls)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed</td>
<td>a</td>
</tr>
<tr>
<td>Unexposed</td>
<td>c</td>
</tr>
</tbody>
</table>

\[
\text{Odds Ratio} = \frac{\text{Odds of exposure in cases}}{\text{Odds of exposure in controls}} = \frac{a/c}{b/d} = \frac{ad}{b/c}
\]


29. Fontaine & Goodman, supra note 28, at 78-79.


31. LILIENFELD & STOLLEY, supra note 11, at 152.

In a cohort study, an investigator works forward from suspected risk factors to health events or disease occurrence. Specifically, an investigator begins by classifying members of a population into two groups, regardless of whether the health event of interest is present among those members, separating those who have been exposed to the suspected risk or causal factor from those who have not been exposed. An estimate of relative risk can be calculated from these data, that is, the risk of the health event occurring among individuals with the risk factor, compared with the risk among those without the risk factor.

In a case-control study, an investigator works conceptually backward from the health event or effect to the suspected causative risk factor. The investigator begins by identifying, within the population of interest, those individuals with the health event (cases) and those individuals without the health event (controls). These data permit calculation of an “odds ratio,” which—by comparing the odds of the risk factor’s presence among cases and controls—also provides an estimate of the influence of the suspected risk factor on the presence of the health event.

C. Epidemics and Epidemiologic Field Investigations

The various methodologic approaches in epidemiology all relate directly to one of the most well-known applications in this field of science, the epidemiologic field investigation, used to characterize and solve patterns of public health problems such as epidemics, outbreaks, and clusters. An epidemic is the occurrence of cases of disease or other health conditions in excess of what is usually expected in a specific place and/or among a group of individuals for a given period of time. Confusion may arise between the terms epidemic, outbreak, and cluster, primarily because the meanings of these terms overlap. Although epidemic and outbreak are nearly synonymous terms, epidemic commonly is used in reference to problems that are geographically widespread, while outbreak is reserved for problems affecting smaller numbers of individuals or problems that are more sharply defined in terms of areas of occurrence. The third term, cluster, is sometimes used incorrectly as a synonym for epidemic or outbreak; instead,
clusters are groups of cases of disease occurring in specific places and during given times that may or may not be greater than expected levels of occurrence.\textsuperscript{43} Two other related terms are endemic, a high background rate of disease,\textsuperscript{44} and pandemic, which indicates disease occurrence on a global or other widespread level.\textsuperscript{45}

Epidemiologic field investigations often are conducted in response to occurrences of epidemics, outbreaks, and other acute public health problems. When outbreaks occur, there is an urgent need to identify key factors, including the etiologic agent or cause, the source of the agent, and the mode of spread. Identifying these factors is crucial to establishing a scientifically rational basis for recommending control and preventive measures, and for informing affected communities or populations about the need to accept the recommended public health measures. Guidelines and steps for conducting epidemiologic field investigations have been developed to reflect the needs for urgency and development of practical recommendations.\textsuperscript{46} However, epidemiologic field investigations often are subject to conditions and challenges that "constrain the ideal use of scientific methods," including, for example, a reliance on data sources—office medical record notes, for example—that were never intended for scientific studies\textsuperscript{47} and biases in information provided by interviewed persons as a result of media coverage and publicity focused on the disease outbreak.\textsuperscript{48}

II. CAUSATION IN EPIDEMIOLOGY AND LAW

Although both law and science seek to discover truth, there are essential differences in each discipline’s approach to conceptualizing and establishing truth, as well as in the methods used to discover the truth.\textsuperscript{49} The United States Supreme Court succinctly articulated some of these basic differences in \textit{Daubert v. Merrell Dow Pharmaceuticals, Inc.}:

It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.\textsuperscript{50}

\begin{itemize}
\item \textsuperscript{43} Id.; Ross C. Brownson, \textit{Outbreak and Cluster Investigations, in Applied Epidemiology: Theory to Practice, supra} note 11, at 68, 69.
\item \textsuperscript{44} Brownson & Hoehner, \textit{supra} note 40, at 16; FRIIS & SELLERS, \textit{supra} note 16, at 20.
\item \textsuperscript{45} FRIIS & SELLERS, \textit{supra} note 16, at 20.
\item \textsuperscript{46} Michael B. Gregg, \textit{Conducting a Field Investigation, in Field Epidemiology, supra} note 11, at 62, 64-77 (describing "ten basic tasks" in a field investigation).
\item \textsuperscript{47} Goodman & Buehler, \textit{supra} note 39, at 4-5.
\item \textsuperscript{48} Id. at 5-6; Brownson & Hoehner, \textit{supra} note 40, at 14.
\item \textsuperscript{49} Richard A. Goodman et al., \textit{Epidemiology and the Law, in Applied Epidemiology: Theory to Practice, supra} note 11, at 289, 301-10.
\item \textsuperscript{50} Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596-97 (1993).
\end{itemize}
Professor Lawrence Gostin echoes this perspective, in part, but also has provided a more practical contrast of the legal and scientific disciplines’ views of the meaning of truth and the methods used to establish truth:

While law seeks finality and closure, scientific inquiry is continuous; while law in civil litigation makes decisions by the preponderance of evidence (greater than 50 percent), science uses statistical significance (greater than 95 percent, with a confidence limit that does not include 1.0); while law follows an adversarial method, science embraces the experimental design (the “scientific” method); while legal evidence is testimonial, scientific evidence is empirical.51

This contrast provides particularly instructive insights regarding the legal and scientific disciplines’ respective approaches to causation, including how causation is established and, once established, how causation is used.

Civil lawsuits in tort are one specific example of the legal discipline’s approach to, and its requirements for, establishing and using causation in law. Consider a plaintiff’s burden of proving the basic elements of a claim, including the defendant’s duty, the defendant’s breach of that duty, the existence of both causation in fact and proximate cause, and evidence of damages.52 In particular, consider the requirements for and implications of establishing proximate cause—evidence of a close nexus between the defendant’s actions and the plaintiff’s injuries, as well as establishing the defendant’s foreseeability of the plaintiff, the manner in which the breach of duty occurred, and the result.52 Different models of causation may be implicated, depending upon the type of tort case brought by the plaintiff and the jurisdiction in which the case is brought.54

Within epidemiology broadly, the establishment and use of determinations of causation can be illustrated in the context of epidemiologic field investigations of acute public health events, such as disease outbreaks or clusters. As previously noted, because of the acute nature of many disease outbreaks, epidemiologic field investigations frequently require that, before public health officials can implement countermeasures to terminate the problem, they first must make rapid determinations about the causative agents, modes of spread, and groups of individuals at the highest risk.55 These determinations rest on scientific evidence for causation.56

52. E.g., Kellner v. Budget Car & Truck Rental, Inc., 359 F.3d 399, 403 (6th Cir. 2004).
53. See, e.g., id. at 406 (identifying foreseeability as an element of proximate cause); Henry v. Merck & Co., 877 F.2d 1489, 1495 (10th Cir. 1989) (discussing the nexus between defendant’s actions and plaintiff’s injuries).
55. Gregg, supra note 46, at 62-64.
56. Id. at 64.
In epidemiology specifically, as in science more generally, determinations of causation—whether a population’s exposure to risk factor X resulted in disease outcome Y among the members of that population—conventionally are not considered as being absolutely proven.\(^{57}\) Rather, there is a continuum in the levels of certainty about the nature of relationships between exposure to putative risk factors and the occurrence of public health outcomes.\(^{58}\) This continuum reflects, in part, the extent to which evidence can be developed and amassed in support of, or against, hypotheses offered to explain these observations.\(^{59}\) Evidence developed in a given investigation may be evaluated by applying a set of criteria that include temporality, whether the putative cause preceded the effect or outcome;\(^{60}\) the strength of association, whether there is a statistically significant association between the putative exposure and the public health outcome;\(^{61}\) biologic gradient, whether there is a dose-response effect, such as a direct relation between the intensity of exposure and risk or severity of disease;\(^{62}\) consistency, whether a similar association was observed in different populations at different times;\(^{63}\) and plausibility, whether the explanation makes sense biologically.\(^{64}\) Evaluation of causation also may employ a rigorous assessment of the methodologic components of the investigation, including, for example, the appropriateness of the study design selected by the investigating epidemiologists.\(^{65}\)

In addition to distinguishing law and epidemiologic science on the basis of their respective approaches to establishing causation, the legal and scientific disciplines also differ, as suggested by the Supreme Court and reinforced by Professor Gostin, with regard to their views of and requirements for an endpoint in seeking truth.\(^{66}\) While scientific inquiry is a continually ongoing process, law aims for finality.\(^{67}\) For example, by law, statutes of limitations place discrete boundaries on time periods during which civil suits or criminal cases may be initiated, regardless of the status of pertinent facts, knowledge, or evidence.\(^{68}\) Moreover, owing to the principle of res judicata for civil actions, once courts have rendered

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57. Dicker, supra note 28, at 11-12.
58. See Rothman, supra note 11, at 45.
61. Id. at 295-96.
62. Id. at 298.
63. Id. at 296-97.
64. Id. at 298.
67. Daubert, 509 U.S. at 597; Gostin, supra note 51, at 282-83.
decisions in specific matters, cases cannot be retried even if new, pertinent knowledge develops following courts' decisions.\textsuperscript{69}

Finally, legal and epidemiologic approaches to determining and using causation can be distinguished by their requirements for "adherence to basic ethical tenets."\textsuperscript{70} Lawyers must represent clients "zealously within the bounds of the law," but may not mislead or misrepresent cases in the course of such representation.\textsuperscript{71} Epidemiologists also must adhere to ethical tenets, as illustrated by circumstances in which an epidemiologist might be asked by a plaintiff's counsel to serve as a consulting expert.\textsuperscript{72} Although counsel might ask the epidemiologist to identify and analyze only those studies that support causation necessary to prove the plaintiff's case, the epidemiologist's search must include all relevant studies, as well as their strengths and weaknesses.\textsuperscript{73} Otherwise, by restricting their review and analysis to include only those studies supporting proximate causation, epidemiologists would produce misleading effects regarding the state of knowledge about the nature of the causal relation.\textsuperscript{74}

**CONCLUSION: EPIDEMIOLOGY IN THE CONTINUUM OF LEGAL EDUCATION AND PRACTICE**

Despite a burgeoning relationship between the field of public health, including its core discipline of epidemiology, and the practice of law, public health and epidemiology are conspicuously underrepresented disciplines within the continuum of legal education and practice.\textsuperscript{75} These limitations are particularly puzzling, given that epidemiologic concepts inhere in the foundational subjects of tort law and criminal law and are readily implicated in other foundational legal subjects, such as constitutional law, property law, and evidence, as well as in many additional basic and specialty areas of legal education.\textsuperscript{76}

Tort law is particularly illustrative of the intertwining of the legal and epidemiologic disciplines, as well as the potential gains to accrue by incorporating

\textsuperscript{69} See, e.g., Federated Dep't Stores, Inc. v. Moitie, 452 U.S. 394, 398 (1981) (explaining that, pursuant to the well-established principle of res judicata, "[a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action" (citing Commissioner v. Sunnen, 333 U.S. 591, 597 (1948); Cromwell v. County of Sac, 94 U.S. 351, 352-53 (1877))).

\textsuperscript{70} Goodman et al., supra note 49, at 303.

\textsuperscript{71} Id.

\textsuperscript{72} Id.

\textsuperscript{73} Id.

\textsuperscript{74} Id.

\textsuperscript{75} Richard A. Goodman et al., Other Branches of Science Are Necessary to Form a Lawyer: Teaching Public Health Law in Law Schools, 30 J.L. MED. & ETHICS 298 (2002); Wendy E. Parmet & Anthony Robbins, A Rightful Place for Public Health in American Law, 30 J.L. MED. & ETHICS 302 (2002); Parmet & Robbins, supra note 10, at 701.

\textsuperscript{76} Parmet & Robbins, supra note 10, at 703-04 (discussing the role of epidemiology in the famous tort case of Stubbs v. City of Rochester, 124 N.E. 137 (N.Y. 1919)).
epidemiologic causation and other perspectives within the continuum of legal education and practice. The case of *Robinson v. Lindsay* typifies cases involving bodily injury to plaintiffs and may be used to present the elements of negligence, or cases that are illustrative of other injury-related cases that may be used to demonstrate elements of intentional torts or strict liability.\(^7\) In *Robinson*, a standard of care case, the plaintiff sued to recover damages for an injury incurred by a snowmobile operated by a minor.\(^8\) At issue was whether a minor engaged in an inherently dangerous activity could be held to a lesser standard of care, or should be held to an adult standard of care.\(^9\) Although this case has been used to teach about the principle of standard of care,\(^10\) a potentially important consideration—for theoretical reasons and for practical purposes for both plaintiffs’ and defendants’ counsel—is the epidemiologic context for this case. Why? Because, as I have suggested in this article, only the illumination of the epidemiologic context for and the epidemiologic study of a larger sample of such injuries or health events can provide an objective, quantified estimate of the level of risk, and, therefore, contributing causal factors related to the defendant’s breach of duty and the plaintiff’s resultant injuries. Beyond providing a factual basis for context, risk, and causation for plaintiffs’ and defendants’ counsel, epidemiologic science may be applied in tort law by scholars to examine even more fundamentally relevant questions, such as whether and to what extent theories of and suits in tort actually serve to deter the frequency and level of tortious actions giving rise to lawsuits.

While this article has sought to present core concepts of the public health science of epidemiology, and to only briefly compare the core concepts of causation in epidemiologic science with causation in law, there are numerous other facets to the relationship between epidemiology and the continuum of legal education and practice of law. Pervasive linkages between certain categories of litigation—especially suits involving defective products and potentially associated injuries—and epidemiology are a prime illustration of these relationships. Subsequent analyses, scholarship, and practice efforts should examine and attempt to strengthen the under-recognized nexus between public health and epidemiology and the continuum of legal education, beginning in law school and extending through continuing education requirements for practitioners, members of the judiciary, and even law school faculty.

\(^7\) Robinson v. Lindsay, 598 P.2d 392 (Wash. 1979).
\(^8\) Id. at 392.
\(^9\) Id.