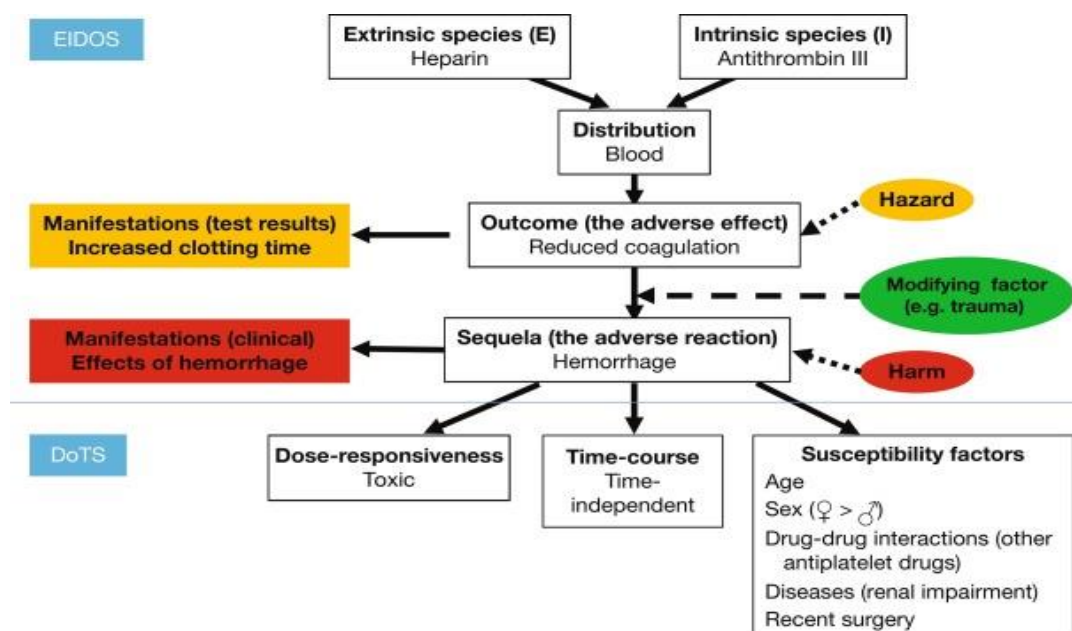


“Surveillance” in drug safety



Appendix

The main paper to which this is an appendix describes the evolution of a definition of ‘surveillance’ in pharmacovigilance, using a combination of four approaches: etymology, usage, previous definitions, and the Ramsey-Lewis method (in which the characteristics of the system being described is used to derive the definition).

Much of the material on the first two of these (etymology and usage) was omitted from the main body of the article for the sake of brevity; that material is given here.

Etymology

“Surveillance” and “monitoring”

“Surveillance” comes from Old French, sur (over) + veiller (to watch). The transitive verb from “surveillance” is the back-formation “surveil”, “to exercise surveillance over”.

The original Indo-European root of “veiller” is UEG, from which the Latin word vigor and vigilare (to watch or stay awake) derive, with their connotations of watchfulness and liveliness; indeed, “watch” and “wake” have the same root. Metathesis of vigilare gives velox, speedy, from which we derive “velocity”.

Thus, “vigilance” and “surveillance” have the same etymology; their origins imply both watchfulness and speed, warn, tell. It is defined as “overseeing; surveillance, listening in”. speedy action.

“Monitoring” derives from the Latin word *monere*, to bring to the notice of, remind, advise, recommended.

Surveillance		
	Passive	Active
Purpose	<ul style="list-style-type: none"> >To access trends >To identify risk factors for prevention and control 	<ul style="list-style-type: none"> >To validate passive surveillance systems >To loosely track new invasions
Pros	<ul style="list-style-type: none"> >Inexpensive >Can cover large areas 	<ul style="list-style-type: none"> >More accurate and complete data >Can produce early and timely data
Cons	<ul style="list-style-type: none"> >Under reporting >Incomplete data 	<ul style="list-style-type: none"> >Can be resource intensive >Methodology must be well-developed

“Active”

The word “active” derives from the Indo-European root AG, to drive, push, or do. The Greek words (*agōgē*; meaning, among other things, freight, seizure, guidance, and observance) and (*agōn*, assembly, contest, and struggle) give English words such as *pedagogue*, *demagogue*, *hypnagogue*, *agonist*, *antagonist*, and *protagonist*, in which some of these meanings are implied.

The Latin derivative, *agere*, and its supine form *actum*, give us words such as *act*, *stratagem* and *strategy*, *agenda*, and *exigency*, in which the guiding are, when relevant, essential aspects of being active. *independence*, and *compatibility*, among others. *Penance*, *aiding*”, it combines both active and passive making these qualifiers redundant. *These* etymologies and have changed little over the centuries. *etc.*” It is then.

Below we discuss the distinction between surveillance. *14th century* or which the doing aspects of the root are evident. Thus, *driving* and *guiding* are, when relevant, essential aspects of being active.

“Passive”

The word “passive” comes originally from the Indo-European root PAEN, meaning “almost”, implying near death and therefore sufferance or patience. From the Latin derivative, the deponent verb patior (I undergo, suffer, or be subjected to), and its sup form passus, we derive passion, patient repentance, and pain are also related. Thus, waiting is an essential part of being passive. In the phrase “watchful w “watchful” implies activity (see above) and “waiting” implies passivity.

If surveillance is in any sense watchful waiting, it combines both active passive elements, making these qualifiers reductants.

Usage

Etymology need not, and often does not, dictate usage. However, the usages of the words closely reflect the

“Surveillance”

“Surveillance” appeared at the end of the 18th century, meaning “watch or guard kept over a person; supervision for the purpose of direction or control, superintenden meaning has not changed since monitoring and survelliance.

“Active”

The Latin terms “activus” and “passivus” are found in Anglo-Saxon and early English texts. However, the earliest written examples of the English forms date from the century. “Active” originally meant “given to outward action rather than inward contemplation or speculation”, and soon afterwards “opposed to passive: originating OR communicating action, exerting action upon others; acting of its own accord, spontaneous” Shakespeare used it to mean “abounding in action; energetic, lively, agil nimble; diligent, busy, brisk”, and its meanings have hardly ch e, anged since then, apart al usages, such as in grammar and physics. en m e, “of ammar, law, immunology, chemistry, s, and psychology. blished ive subject, encourage the sale of from some technical usages such as in grammer and physics

“Passive”

Since its appearance in written English at the end of the 14th century, “passive” has be used to refer to something “that is acted upon or is capable of being acted upon fro outside”. At the start of the 17th century it came to mean “not acting, working, or operating on anything else; not exerting force or influence; inert, quiescent” and “that makes no response or offers no resistance; yielding readily

to external force or influence or to the will of another; submissive”. Later (19th century) it acquired the meaning movement or motion of (part of) the body: produced by an external agency” (for example, passive movements). No other general meanings have emerged since, although there are many specialized uses in fields such as gr electronics, banking, linguistic

“Active surveillance”

The term “active surveillance” was **originally used in political contexts**, dating from the 19th century, for example in an 1828 Lancet annotation: “There has been esta in Paris a journal [La Clinique], [one] object of which is ... to exercise an active surveillance on the medical officers of [Parisian hospitals]”.

An early reference, albeit political, to adverse drug effects occurred in an 1893 pamphlet on the effects of opium: “The Bombay opium officials, who seem to drive their trade hard, and to keep an act surveillance over the opinions of medical men on the s children’s pills at the Government opium shops”.

“Active surveillance” in epidemiology and pharmacovigilance

Active surveillance of infectious diseases (cholera and tuberculosis) was first ment in the 1890s [ioned ntil erm “active 0 s; it g 986 term “active surveillance” was used in relation to a 95, ption of in the UK to detect an oses . However, the term “surveillance” was not used in drug safety u the 1950s and 1960s, with different nuances of meaning. The t surveillance” in this context was introduced soon afterwards; in one example it was contrasted with spontaneous reporting of adverse drug reactions. After that, apart from a single instance of active surveillance of neonates in a 197 French paper, the term first appears in a PubMed search in 1979 in relation to surveillance for infection. Papers on active surveillance of toxic shock syndrome in relation to tampons or barrier contraceptives appeared in the 1980 is not surprising that this was an early application, since almost all of the previous work on active surveillance had involved infectious diseases. Active surveillance for drug effects was mentioned in a review of the beneficial effects of antiepileptic drugs in and active surveillance for adverse effects in a Bulgarian paper in 1987.

Other sporadic reports of the use of active surveillance appeared in 1993 on the adverse respiratory effects of shoe sprays and injuries related to fireworks, but the first occasion on which the specific therapeutic drug was in 1994, in a description of adverse events in elderly patients taking digitalis.

Active surveillance for the adverse effects of vaccines was first reported in 19 again illustrating the importance of infectious diseases in the history of the ado this term in describing the detection of adverse drug reactions. The authors had

previously described the failure of passive surveillance unacceptably high risk of aseptic meningitis with measles/mumps/rubella (MMR) vaccines that contained the Urabe mumps strain.

In addition to studies on vaccines, studies on appetite suppressants, missed doses of medications, general adverse drug reactions in hospital, and the safety of cyproterone acetate followed in the 1990s.

The terms “active surveillance” and “pharmacovigilance” both appeared in the same paper for the first time in 1996.

“Passive surveillance”

The term “passive surveillance” has been in use in different areas for many years, since at least the 1950s.

However, it was not used in the context of drug therapy or vaccines until the 1980s. I identified by searching Pubmed for “passive surveillance”; about 18% deal with surveillance of the drug (from the Dutch) as “the y for the g s were contrasted. activities relating to the detection, assessment, understanding and prevention of . Most of the papers yie surveillance” are about infectious diseases and adverse effects of vaccines.

In only about 20% of cases were active and passive surveillance mentioned in the same paper.

Postmarketing surveillance

The term “postmarketing surveillance” first appeared in the 1960s and was attributed to Bill Inman , who defined it as “techniques for detecting and measuring the incidence of adverse drug reactions... [including] all kinds of schemes for generating or testing hypotheses”.

It has also been defined (translat systematic surveillance [toezicht] and scientific study of all intended and unintended effects of medicines on human health, after their release for marketing”,

which in effect circularly defines “surveillance” as “surveillance”.

Postmarketing surveillance refers to analysis of data accumulated typically purpose of detecting adverse effects after a medicinal product has been given a marketing authorization by a regulatory body.

The term normally refers to the processes of signal detection and signal evaluation, but it may be confused with the term “pharmacovigilance”, which first appeared in French in the late 1960s, when the term “pharmacovigilance intensive” and “pharmacovigilance spontanée” In fact, the World Health

Organization's definition of pharmacovigilance is "the science and act adverse effects or any other possible drug-related problems".

Spontaneous reporting in postmarketing surveillance

Spontaneous reporting a term that emerged in the 1960 in relation to adverse drug reactions, is accepted as referring to adverse events or suspected adverse drug reaction submitted voluntarily by a reporter to a centralized organisation that focus on receipt data cleaning and structuring, analysis, follow up of reports with the aim of the value of the enclosed data, and further dissemination of the data or the results of analysis.