Minimum Data Elements for Monitoring and Evaluation of National and International Rabies Control Programs.

Version 4, September 2023

United Against Rabies

1.0. Using this document

This document is a composition of key data elements identified from many of the most-prominent rabies guidance documents from international and national animal health and human health agencies.

This document provides a recommended structure for data collation as well suggested data collection templates, reproductions of fundamental tables from WHO and WOAH, and suggestions for how these Minimum Data Elements (MDE) should be used to support evidence-based rabies policies.

Users of this document should first evaluate if their current field programs collect these data elements (Pages 7 – 15) and if current country-level data definitions are consistent with international guidance (Pages 16 – 25).

Discrepancies in data collection methods, variables, or definitions should prompt re-consideration of the National Rabies Program policies; rabies experts with WHO, WOAH, and UAR are available to help consult at the request of National Programs.

Where relevant, this document provides links to standard definitions from the WHO and WOAH. If data is being collected in alignment with international standards and recommendations, then National Programs should next consider if the format of the data allows for completion of the suggested data templates (Pages 26 – 31).

Lastly, National Programs should submit data routinely to the WHO Global Health Observatory and WOAH WAHIS. The type of information submitted and timelines for data submission are prone to change, therefore not explicitly covered in this document. However, each country should have a national WHO and WOAH representative that is responsible for assisting with data notifications.

The United Against Rabies Forum is a community of rabies experts that are available to provide technical assistance should there be questions or concerns regarding the collection, interpretation, analysis, or international reporting of these critical data elements.

For more information, please contact globalrabiescoordinator@woah.org

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2.0. Background

Rabies, a progressive and fatal viral encephalitis, is among the most critical zoonotic threats to global health. The global control of rabies is a significant challenge, requiring the coordination of human, animal, and environmental health sectors. Many rabies endemic countries face important hurdles for rabies control, including limited understanding of local rabies epidemiology and dog populations, logistic and operational challenges, and limited resources to enact control programs.[1-4] The large majority of human rabies cases are the result of bites from domestic dogs,[1] and human rabies deaths are almost always preventable.[1,5] Most deaths occur in low and middle-income countries due to lack of access to effective post-exposure prophylaxis, not seeking professional healthcare after an exposure, or lack of awareness as to the risks of rabies. Rabies offers a unique opportunity for targeted disease elimination in dogs rather than mitigation, as demonstrated by the elimination of canine and certain wildlife rabies viruses in Western Europe and some countries in the Americas .[2,6-8] However, there are major gaps in the quality, timeliness, availability, and use of rabies data which confound the ability of national and international agencies to make evidence-based and cost-effective policies.[9,10]

One of the major challenges to track health progress towards rabies elimination is the lack of reliable surveillance data.[9,10] Rabies burden estimates vary substantially within and between countries, and there is substantial misrecognition, under-detection, and under-reporting of human rabies cases.[9,11-18] Surveillance capacity and resulting case detection rates for animal rabies are also low.[19] Data are especially challenging in low-income countries, which have severe resource constraints, limited public health and laboratory infrastructure, and competing health demands, and where often the disease is more prevalent.[9,20] A recent report by the World Health Organization (WHO) shows that a country's relative wealth is associated with availability of data and evidence-driven health policy and planning.[21] The lack of reliable data on rabies incidence hinders prevention and control efforts by reducing community support for disease control and its perceived priority among public health officials.[20,22,23] Rabies surveillance data standards are spread across numerous documents and guidance from the WHO, World Organisation for Animal Health (WOAH, founded as OIE), the Food and Agriculture Organization of the United Nations (FAO), and many non-governmental organizations that focus on rabies control and global health.[1,24-26] This document is intended to bridge these resources and provide the most critical data elements that National and International programs should collect across all aspects of a comprehensive rabies control program.

Accurate estimates of the true incidence of rabies cases, particularly in humans, are critical to track health progress and performance, assess the impact of public health programs and interventions, increase accountability, and inform policy decisions about surveillance, research, and healthcare.[27] Reliable, comparable data allows for informed course correction and improved performance. Regular production of data is also essential to track progress and improve situational awareness.[21] Therefore, a more straightforward, systematic approach to data collection and standards is necessary to improve monitoring and evaluation of dog rabies control.

Building on previous experience on disease surveillance and rabies control, this document intends to provide a realistic set of minimum essential surveillance data elements (MDE) that are essential to track health progress, ensuring comparability and accountability, while considering country resources and time constraints, and minimizing the data reporting burden. We have identified the core information needed to assess rabies health progress, allowing for reliable, comparable estimates in time and between countries. By providing a common standard for rabies data, our aim is to move towards resolving rabies-related information gaps that would improve health policy decisions globally.

More specifically, the United Against Rabies (UAR) Forum seeks to identify the MDE that will inform disease detection and integrated bite case management (IBCM) programs, dog vaccination programs, human bite treatment and post-exposure prophylaxis (PEP) programs, vaccine and pharmaceutical stocking and delivery, dog population management, animal rabies, and any other data consumers. MDE are organized in country profiles, including national rabies strategy, disease surveillance, public health infrastructure, and dog population.

Strengthening country capabilities for data collection, processing, and use is essential to ensure the sustainability of rabies control efforts and public health improvements more broadly. This set of MDE does not cover all aspects of rabies control, particularly MDE necessary to operate field-level programs. We encourage countries to collect more fine-grained data at the subnational level and provide appropriate incentives for a reliable, independent assessment of rabies control programs. The methods for data collection and the data itself should be available to the public to encourage accountability and good governance. Data must be used to inform policy, and incentives to increase in-country capacity for data production, management, and analysis are critical to improving health programs and interventions. Lastly, data should be submitted routinely to relevant international agencies that support global health systems, specifically the WHO Global Health Observatory and WOAH World Animal Health Information System (Figures 1 & 2). National rabies programs are strongly encouraged to work with their National Focal Points to share data and information, in accordance with international regulations and agreements.

This document is intended to provide guidance for the collection of key programmatic data for national rabies programs and submission of data to international human and animal health agencies. It lists recommended MDE to assess rabies control programs and guide policy decisions at the national and international levels. Although many countries may not be able to collect all suggested minimum data elements, this guide will provide a starting point for countries that aspire to do so and integrate into their national surveillance as they build capacity. Standardized data elements and reporting are also intended to update rabies burden estimates. Reliable, timely, and available data are essential to improve decision making regarding rabies control programs and public health investments to achieve the goal of eliminating dog-mediated human rabies deaths by 2030.[10]

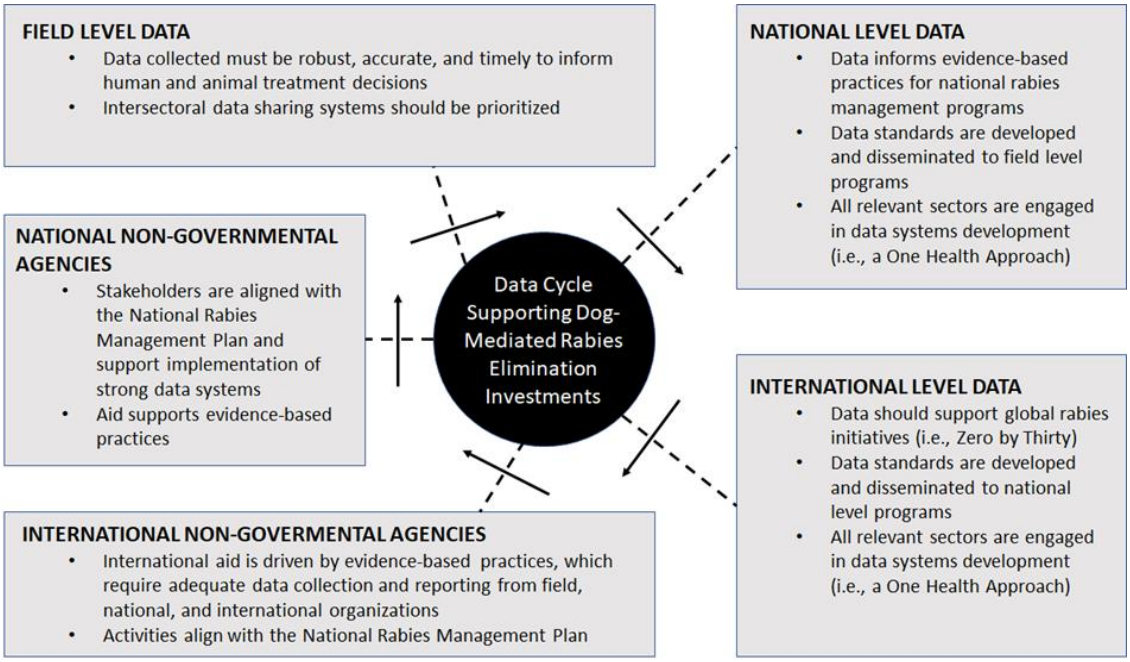


Figure 1: Data Cycle Supporting Dog-Mediated Rabies Elimination Investments. Data originates from field programs, but impacts national and international policies, which in turn impact the capacity for field level activities.

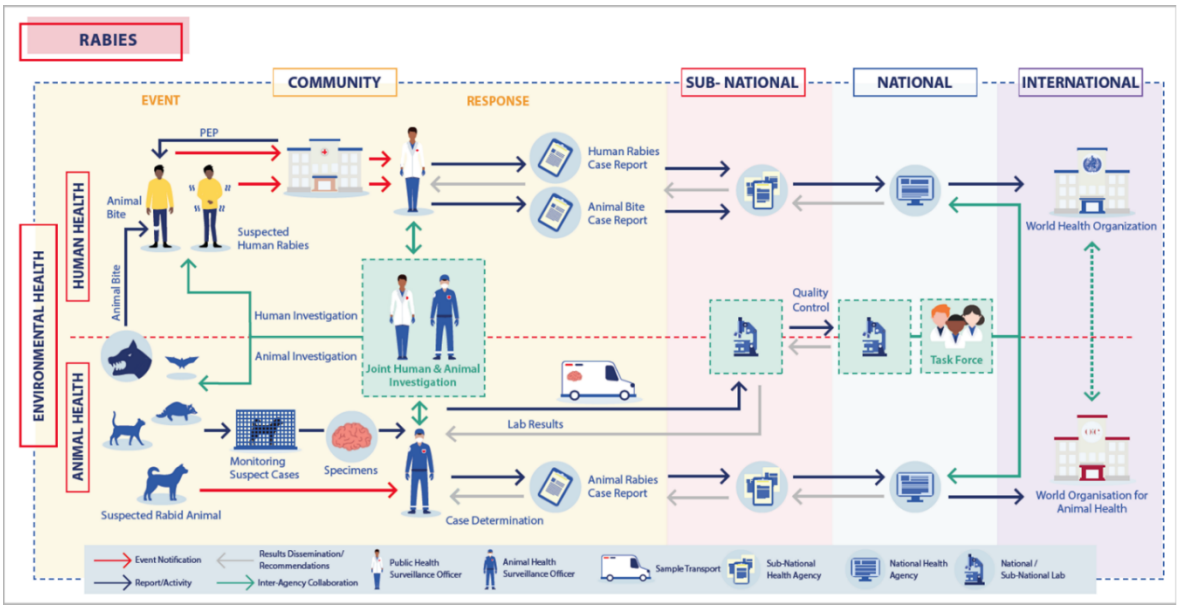


Figure 2: Generalized Pathway for Rabies Surveillance and Data Sharing. Key data elements should be shared with national and international agencies to enable evidence-based rabies control policies.

3.0. Country Rabies Situational Profile

Instructions: *This page contains important information that describes the functioning of the National Rabies Program. Many of these data elements are unlikely to change frequently, therefore it is suggested to document this information as a National Program Profile, and to notify collaborators when key functions of the National Program change.*

Background

- What is the human population in the country?
- How many rabies zones[1] are within the country?

National Strategy

- Is a national rabies control program in place?
- Does the national plan include consideration for rabies prevention in humans and animals?
- Does the national plan include legislation for rabies control?
- Does the national plan include a dog vaccination strategy?
- How many zones[1] within the country have enacted the dog vaccination strategy?

Surveillance

- Is there a system of passive public health surveillance[2] for animal rabies?
- Is there a system of active surveillance[3] for animal rabies?
- Is human rabies notifiable across the entire country?
- Is animal rabies notifiable across the entire country?
- How many zones[1] within the country regularly report rabies surveillance data to national authorities?

Post-Exposure Prophylaxis

- Who is responsible for procuring human rabies vaccines?
- Where is human rabies vaccine procured?
- At what level of government is the vaccine stored?
- Which vaccine regimen(s) are used?
- Is nerve tissue vaccine still used?
- Is PEP administered using a risk-based approach?
- What types of RIG are available?
- Who is responsible for procuring RIG?

Dog Population

- How many dogs are in country (WOAH Chapter 7.7.8)?
- What method of dog population estimation was used (WOAH chapter 7.7.8) (ICAM)?
- What year was the estimate conducted?

Facilities

- How many facilities conduct human rabies diagnostic testing, using WHO-recognized methods?
- How many facilities conduct animal rabies diagnostic testing, using WOAH-recognized methods?
- How many government facilities provide human vaccines to persons with rabies exposures?
- How many private facilities provide human vaccines to persons with rabies exposures?
- How many facilities (government or private) provide RIG to persons with rabies exposures?

4.0. Human Rabies (7 data elements)

Instructions: *Monitoring human rabies deaths is a key programmatic indicator and the elimination of dog-mediated human rabies deaths should be a primary goal of the National Program. Data elements should be systematically collected and submitted to the WHO GHO annually. Data elements should be used as part of a monitoring and evaluation plan to inform evidence-based policies for improved health outcomes.*

Element Name	Description	Response Options	Reference	M & E Framework
Case Classification	The number of suspected human rabies cases investigated[9] during the calendar year *	- Laboratory Confirmed (#)[11] - Clinically Confirmed - Probable (#)[10] - Suspected Case (#)[9] - Ruled Out through Testing (#)	Table 13 Table 4.1	- Rabies burden - Human rabies case rate - Human rabies testing rate - Human rabies trend analysis
Source of Infection	The number of confirmed human rabies cases (clinically[10] or laboratory[11]) by the species of animal responsible for virus transmission *	- Dog (#) - Bat (#) - Terrestrial Wildlife (#) - Other Animal (#) - Unknown Animal (#)	Table 13 Table 4.1	- Dog-mediated rabies case rate - Dog-mediated human rabies trend analysis
Rabies Virus Variant	The number of confirmed human rabies cases (laboratory[11]) by the rabies virus variant *	- Dog (#) - Bat (#) - Terrestrial carnivore (Wildlife) (#) - Other (#) - Unknown (#)	Table 14.1	- Canine-rabies freedom - Terrestrial-rabies freedom
Gender	The gender of confirmed human rabies cases (clinically[10] or laboratory[11])	- Female (#) - Male (#) - Unknown (#)	Table 13	- Gender-specific risk factors

Age	The age of confirmed human rabies cases (clinically[10] or laboratory[11])	- <5 years (#) - 5 – 14 years (#) - >15 years (#) - Unknown (#)		- DALYS - Age-specific risk factors
Disease Outcome	The number of confirmed human rabies cases (clinically[10] or laboratory[11]) that died or survived	- Died (#) - Survived (#) - Unknown Outcome (#)		- Treatment outcomes - Death rate
Vaccination Status	The vaccination status of confirmed human rabies cases (clinically[10] or laboratory[11])	- Unvaccinated (#) - Deviations or Incomplete (#) - Appropriate Vaccination (#) ** - Unknown Vaccination Status (#)	Table 6 & 9	- PEP failure rate - PEP compliance

** Optional reporting stratification: Sub-national data can be submitted to support claims of rabies-free zones*
*** Additional details of vaccination failures should be reported to WHO to ensure confidence in rabies vaccines and vaccination schedules*

Africa CDC One Health Framework - Recommended program indicators:
» At least 90% of compatible human cases are investigated (see WHO Annex 11 for suggested case investigation form)

5.0. Human Rabies Exposures (4 data elements)

Instructions: *Monitoring human rabies exposures is a key programmatic indicator for understanding the epidemiology of rabies, root causes of exposures, and to anticipate demand for post-exposure prophylaxis. These data elements should be systematically collected throughout the year and submitted to the WHO GHO annually. These data elements should be used as part of a monitoring and evaluation plan, with evidence-based policies developed to improve health outcomes based on barriers identified through routine surveillance of human rabies exposures.*

Element Name	Description	Response Options	References	Monitoring and Evaluation Framework
Case Classification	The number of people with WHO category II or III exposures [12] identified through standard reporting and case investigation[4] during the calendar year, by the case classification of the offending animal	- Laboratory Confirmed Exposure (#)[5] - Clinically Confirmed Exposure - Probable (#)[6] - Suspected Exposure (#)[7] - Non-Exposure (#)[8]	Section 8.3.1 Section 9.1	- Rabies exposure rate - Modeling key rabies indicators (human rabies deaths, exposures, PEP demand) - Trend analysis
Source of Exposure	The number of WHO category II or III human rabies exposures[12] by the species of animal responsible for exposure (laboratory[5], clinically confirmed[6], or suspected[7] exposure)	- Dog (#) - Bat (#) - Terrestrial Wildlife (#) - Other Animal (#) - Unknown Animal (#)	Section 9.1	- Dog-mediated rabies exposure rate - Modeling key rabies indicators (human rabies deaths, exposures, PEP demand) - Trend analysis
Gender	The gender of WHO category II or III human rabies exposures (laboratory[5], clinically confirmed[6], or suspected[7] exposure)	- Female (#) - Male (#) - Unknown (#)		- Gender-specific risk factors

Age	The age of human rabies exposures (laboratory confirmed[5], clinically confirmed[6], or suspected[7] exposure)	- <5 years (#) - 5 – 14 years (#) - >15 years (#) - Unknown (#)		- Age-specific risk factors - Trend analysis

Africa CDC One Health Framework - Recommended program indicators:
» Minimum of 80% of WHO Category III human rabies exposures are investigated by a veterinary professional to determine case status of the animal.
» Minimum of 90% of probable rabies cases (where a sample is available) are tested and results reported to health officials and exposed persons.

6.0. Post-Exposure Prophylaxis (3 data elements)

Instructions: *Monitoring rabies biologics is a key programmatic indicator for understanding and anticipating demand for vaccines and rabies immunoglobulin as well as barriers to accessing these biologics. These data elements should be systematically collected throughout the year and submitted to the WHO GHO annually. These data elements should be used as part of a monitoring and evaluation plan, with evidence-based policies developed to improve health outcomes based on barriers identified through routine monitoring of post exposure prophylaxis procurement, distribution, and administration.*

Element Name	Description	Response Options	References	Monitoring and Evaluation Framework
Exposure Case Classification	The number of people who received rabies PEP during the calendar year, by the case classification of the offending animal	- Laboratory Confirmed Exposure (#)[5] - Clinically Confirmed Exposure - Probable (#)[6] - Suspected Exposure (#)[7] - Non-Exposure (#)[8]	Section 9.1	- Rate of PEP initiation - Efficiency of PEP utilization
Source of Exposure	The number of people who received rabies PEP by the WHO Exposure Category[12]	- Category I (#) - Category II (#) - Category III (#) - Unknown Category (#)	Section 8.3.1	- Efficiency of PEP utilization
Rabies Immuno-globulin	The number of people with Category III exposures who received rabies immunoglobulin	- #		- Rate of RIG availability

Africa CDC One Health Framework - Recommended program indicators:

» Ensure that only cell-cultured human rabies vaccines are used (no nerve-tissue vaccines).
» Ensure that at least 50% of residents have easily accessible human rabies vaccine.
» 100% of people with suspected, probable or confirmed rabies exposures receive PEP.
» >90% of PEP regimens are documented and reported to health officials.

7.0. Animal Rabies (5 data elements)

Instructions: *Monitoring animal rabies cases is a key programmatic indicator for understanding the epidemiology of rabies, risks to the public, and measuring the impact of interventions such as dog vaccination. These data elements should be systematically collected throughout the year and submitted to the WHO GHO and WOAH WAHIS annually. These data elements should be used as part of a monitoring and evaluation plan, with evidence-based policies developed to improve health outcomes based on barriers identified through routine monitoring of animal rabies cases.*

Element Name	Description	Response Options	References	Monitoring and Evaluation Framework
Dogs	The number of suspected[7] rabies cases in dogs investigated[4] during the calendar year *	- Laboratory Confirmed (#) [5] - Clinically Confirmed - Probable (#) [6] - Suspected Case (#)[7] - Laboratory - Negative (#) - Passed Quarantine – Negative (#)	Section 9.1	- Dog-mediated rabies burden - Dog-mediated rabies case-detection rate - Laboratory testing rate - Dog-mediated rabies freedom - Trend analysis
Livestock	The number of suspected[7] rabies cases in livestock investigated[4] during the calendar year *	- Laboratory Confirmed (#) [5] - Clinically Confirmed - Probable (#) [6] - Suspected Case (#)[7] - Laboratory - Negative (#)	Section 9.1	- Laboratory testing rate - Trend analysis - Economic impact
Bats	The number of suspected[7] rabies cases in bats tested during the calendar year *	- Laboratory Confirmed (#) [5] - Laboratory - Negative (#)		- Laboratory testing rate - Trend analysis
Other Species	The number of suspected[7] rabies cases in other species tested during the calendar year *	- Laboratory Confirmed (#) [5] - Laboratory - Negative (#)		- Laboratory testing rate - Trend analysis

Rabies Virus Variant	The number of confirmed[5] animal rabies cases (laboratory confirmed) by the rabies virus variant *	- Canine (#) - Bat (#) - Terrestrial carnivore (#) - Other (#) - Unknown (#)	Table 14.1	- Dog Rabies Freedom - Terrestrial Rabies Freedom - Rabies Freedom

** Optional reporting stratification: sub-national data can be submitted to support claims of rabies-free zones*

Africa CDC One Health Framework - Recommended program indicators:
» Minimum of 50% of suspect reported dogs are investigated by veterinary professional to determine case status of the animal.
» Minimum of 90% of probable rabies cases (where a sample is available) are tested and results reported to health officials.

8.0. Dog Population Management (3 data elements)

Instructions: *Monitoring dog population management efforts is a key programmatic indicator for understanding the dog population characteristics, designing effective dog vaccination campaigns, and promoting a healthy dog-human bond. These data elements should be systematically collected throughout the year and submitted to the WHO GHO and WOAH WAHIS annually. These data elements should be used as part of a monitoring and evaluation plan, with evidence-based policies developed to improve program outcomes.*

Element Name	Description	Response Options	References	Monitoring and Evaluation Framework
Vaccination	How many dogs were vaccinated against rabies during the calendar year? * / **	- Owned-Confined (#) - Owned-Roaming (#)[13] - Community (#)[14] - Unknown (#) - Total Dog Population (#) **	WOAH 7.7.8	- Dog vaccination coverage - Free-roaming dog vaccination coverage - Trend analysis - Dog-mediated rabies freedom
Vaccination Method	What method(s) of dog rabies vaccination were practiced during the calendar year (select all that apply, provide numbers vaccinated by each method if available)?	- Private Veterinary Clinics (Y/N) - Fixed Point Mass Vaccination (Y/N) - Door to Door Vaccination (Y/N) - Capture-Vaccinate-Release (Y/N) - Oral Rabies Vaccination (Y/N) - Other (Y/N)		- Free-roaming dog vaccination coverage - Effectiveness of vaccination strategies
Sterilization	The number of dogs that were sterilized within the calendar year *	- Male (#) - Female (#) - Unknown (#) **		- Proportion of dogs sterilized - Trend analysis - Sterilization effectiveness

** Optional reporting stratification: sub-national data can be submitted to support claims of rabies-free zones*
*** This is the minimum data element for this question. If stratified values are not available, just complete this variable*

9.0. Glossary

[1] **Zone** is a part of a country defined by the Veterinary Authority, containing an animal population or subpopulation with a specific animal health status with respect to an infection or infestation for the purposes of international trade or disease prevention or control (WOAH Terrestrial Code).

[2] **Passive public health surveillance systems** (PPHSSs) are programs that integrate both veterinary and human health components to evaluate and test suspected rabid animals involved in a human exposure (WOAH Technical Review, WHO Laboratory Manual Chapter 4).

[3] **Active rabies surveillance** is based on identifying rabies-suspected animals through targeted sampling of animals that act abnormally, are found dead, or are gathered as roadkill (WOAH Technical Review, WHO Laboratory Manual Chapter 4).

[4] An **investigation** is any attempt by a health authority to evaluate the health status of the suspected rabid animal or human for the purposes of ascribing a final case determination consistent with WHO and WOAH criteria: non-case, suspect, probable, confirmed rabid. Investigations may be conducted by phone, computer, or in-person and may result in a clinical (symptomatic) or laboratory final case determination (see also, Annex A, Annex B).

[5] For the purposes of rabies surveillance, the WHO and WOAH defines a **confirmed rabid animal** as a suspect or probable rabid animal confirmed using a standard diagnostic test as defined by WHO or WOAH (see also, Annex A) (WHO TRS, WOAH Terrestrial Code 8.15.12).

[6] For the purposes of rabies surveillance, the WHO and WOAH defines a **probable rabid animal** as a suspect rabid animal with a history of bite from another suspected rabid animal or a suspected rabid animal that is killed, dies, or disappears within 5 days of illness onset (see also, Annex A) (WHO TRS, WOAH Tech. Rev. Sci.).

[7] For the purposes of rabies surveillance, the WHO and WOAH defines a **suspected rabid animal** as a susceptible animal that shows any change in behaviour consistent with the following clinical signs: hypersalivation, paralysis, lethargy, abnormal aggression, abnormal vocalisation, diurnal activity of nocturnal species (see also, Annex A) (WHO TRS, WOAH Terrestrial Code 8.15.12).

[8] For the purposes of rabies surveillance, the WHO and WOAH defines a **non-rabid animal** as a suspect or probable rabid animal where rabies is ruled out by laboratory testing or appropriate observation period (see also, Annex A) (WHO TRS, WOAH Tech. Rev. Sci.).

[9] For the purposes of rabies surveillance, the WHO and WOAH defines a **suspected human rabies case** as compatible with the clinical case definition: a person presenting with an acute neurological syndrome (i.e. encephalitis) dominated by forms of hyperactivity (furious rabies) or a paralytic syndrome (paralytic rabies) that progresses towards coma and death, usually due to cardiac or respiratory failure, typically within 7–10 days of the first sign if no intensive care is instituted. The syndrome may include any of the following signs: aerophobia, hydrophobia, paraesthesia or localized pain, dysphagia, localized weakness, nausea or vomiting (see also, Annex B) (WHO TRS).

[10] For the purposes of rabies surveillance, the WHO and WOAH defines a **probable human rabies case** as suspected case plus a reliable history of contact with a suspected, probable or confirmed rabid animal (see also, Annex B) (WHO TRS).

[11] For the purposes of rabies surveillance, the WHO and WOAH defines a **confirmed human rabies case** as suspected or probable case that is confirmed in a laboratory using a standard diagnostic test as defined by WHO (see also, Annex B) (WHO TRS).

[12] In countries or areas enzootic for rabies, exposure to suspected, probable or confirmed rabid animals is categorized as follows: **Category I**: touching or feeding an animal or licks on intact skin: no exposure; PEP not indicated; **Category II**: nibbling of uncovered skin, minor scratches or abrasions without bleeding: exposure; PEP indicated with vaccine; to be treated as category III if exposure was to a bat; and **Category III**: single or multiple transdermal bites or scratches, contamination of mucous membranes with saliva from licks, licks on broken skin, exposure due to direct contact with bats: severe exposure; PEP indicated with vaccine and RIG (see also, Annex C) (WHO TRS).

[13] The International Companion Animal Coalition defines **owned-roaming dogs** as dogs that are without a clear owner, but may be wearing a collar or other evidence of ownership. They may behave confidently and remain located within, and potentially show defense of, a specific territory around their household (see also, Annex E, Annex F) (ICAM).

[14] The International Companion Animal Coalition defines **community dogs** as those that receive some form of regular care (food, water, shelter, etc) from one (or more) members of the community. Often community dogs have one or more names given by community members but no one states ‘that is my dog’. They may appear friendly towards people but may also be defensive of their territory with other dogs (see also, Annex E, Annex F) (ICAM).

10.0. Commonly Referenced Tables

Table 4.2 Animal rabies case definitions as recommended by the World Health Organization.

Suspect case	An animal that presents with any of the following signs • Hypersalivation • Paralysis • Lethargy • Unprovoked or abnormal aggression (biting two or more people or animals, and/or inanimate objects) • Abnormal vocalization • Diurnal activity of nocturnal species	• Notify appropriate local authorities of suspect rabid animal • Collect primary animal history if available (i.e., ownership status, vaccination status, prior exposures, date of onset for signs, etc.) • Collect CNS samples for laboratory diagnosis if available
Probable case	Any suspect animal with a history of a bite by another Suspect/Probable/Confirmed animal. AND/OR A suspect animal that is killed, died, or disappears within 4-5 days of observing illness.	• Systematically record secondary information and link to primary history • Notify appropriate authorities of probable animal rabies cases according to national protocols
Confirmed case	A suspect or probable animal confirmed using a standard diagnostic test as defined by WHO or WOAH (see rabies chapter) or WOAH manual (OIE,2016).[a]	• Notify appropriate authorities for follow-up of any human or animal exposures • Systematically record laboratory diagnostic results and link with case records
Not a case	A suspect or probable animal in which rabies is ruled out by laboratory diagnosis or epidemiological investigation	• Systematically record laboratory diagnostic results and link with primary history

[a] *If other diagnostic test are used, depending on the sensitivity and specificity of those test, a confirmation of results by a validated secondary test may be needed (particularly for negative results).*

Annex A: (CDC Africa: Framework for One Health Practice: https://africacdc.org/download/framework-for-one-health-practice-in-national-public-health-institutes/)

Table 13. Human case definitions and corresponding surveillance activity

Case	Definition	Surveillance activity
Suspected	A case that is compatible with the clinical case definition: a person presenting with an acute neurological syndrome (i.e. encephalitis) dominated by forms of hyperactivity (furious rabies) or a paralytic syndrome (paralytic rabies) that progresses towards coma and death, usually due to cardiac or respiratory failure, within 7-10 days of the first sign if no intensive care is instituted. The syndrome may include any of the following signs: aerophobia, hydrophobia, paranesthesia or localized pain, dysphagia, localized weakness, nausea or vomiting.	Notify the appropriate local authorities according to national protocols. Collect appropriate samples from the patient according to national protocols. Conduct a verbal autopsy to collect a case history for the patient for further characterization (Annex 11).
Probable	A suspected case plus a reliable history of contact with a suspected, probable, or confirmed rabid animal (see Table 12).	Identify contacts of the patient and/or animal involved for follow-up.
Confirmed	A suspected or probable case that is confirmed in a laboratory.[a]	Systematically record the laboratory diagnosis and link with verbal autopsy information. Notify the appropriate authorities of a confirmed human rabies case according to national protocols.

[a] Ante-mortem diagnosis of human rabies depends on the samples collected and the diagnostic tests available (see section 5).

Annex B: (WHO Expert Consultation on Rabies Third report, Table 13, Page 114)

Annex 8. Recommended post-exposure prophylaxis according to type of exposure

Category of exposure	Type of exposure to a domestic or wild animal suspected or confirmed to be rabid or animal unavailable for testing	Recommended post-exposure prophylaxis
I	Touching or feeding animals, licks on intact skin (no exposure)	None, if reliable case history is available[a]
II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding (exposure)	Administer vaccine immediately Stop treatment if animal remains healthy throughout an observation period of 10 days[b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques. Treat as category III if bat exposure involved.
III	Single or multiple transdermal[c] bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats (severe exposure).	Administer rabies vaccine immediately, and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulin can be injected up to 7 days after administration of first vaccine dose. Stop treatment if animal remains healthy throughout an observation period of 10 days[b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques.

[a] If an apparently healthy dog or cat in or from a low-risk area is placed under observation, treatment may be delayed

[b] This observation period applies only to dogs and cats. Except for threatened or endangered species, other domestic and wild animals suspected of being rabid should be euthanized and their tissue examined for the presences of rabes antigen by appropriate laboratory techniques

[c] Bites especially to the head, neck, face, hands and genitals are category II exposures because of the rich innervation of these areas.

Annex C: (WHO Expert Consultation on Rabies Third report, Annex 8, Page 156)

Table 14.1. Standard reaction profiles of different RABV antigenic variants with MAbs

Monoclonal antibodies	C1	C4	C9	C10	C12	C15	C18	C19	AgV
CVS/ERA – SAD/PAST	+	+	+	+	+	+	+	+	LabL Lab
Dog/mongoose	+	+	+	+	+	+	-	+	1
Dog	+	+	-	+	+	+	-	+	2
Vampire bat	-	+	+	+	+	-	-	+	3
Tadarida brasiliensis	-	+	+	+	+	-	-	-	4
Vampire bat (Venezuela)	-	+	v	+	+	v	-	v	5
Lasiurus cinereus	v	+	+	+	+	-	-	-	6
Arizona fox	+	+	+	-	+	+	-	+	7
Skunk southcentral	-	-	+	+	+	+	+	+	8
***Tadarida brasiliensis* (Mexico)**	+	+	+	+	+	-	-	-	9
Skunk Baja SC	+	+	+	+	-	+	-	+	10
Vampire (other)	-	+	+	+	-	-	-	+	11

Annex D: (World Health Organization, Rupprecht, Charles E, Fooks, Anthony R & Abela-Ridder, Bernadette. (2018). Laboratory techniques in rabies, volume 1, 5th ed. World Health Organization. https://apps.who.int/iris/handle/10665/310836, Chapter 14, Page 146)

Table 2. Different sub-populations of dogs and factors relevant to dog population management.

Ownership status	Confinement status	Dependency on humans	Acceptance by community	Risk for rabies transmission (if unvaccinated)	Target for population reduction	Target for responsible dog ownership programs	Target for central-point vaccination	Target for capture-sterilize-release programs
Family owned	Confined	Fully dependent	High	Low	No	Yes	Yes	No
Family owned	Partially free roaming	Fully or Semi-dependent	High	Moderate	No	Yes	Maybe	Maybe[a]
Family owned	Free roaming	Semi-dependent	High	High	No	Yes	Maybe	Maybe[a]
Community owned	Free roaming	Semi-dependent	High	High	Maybe	Maybe	No	Yes[a]
No owner	Free roaming	Independent	Variable, but lower	High	Usually yes	No (unless abandonment rates are high)	No	Yes

[a]*The suitability of this program will depend on obtaining owner consent where needed.*

Annex E: (Taylor LH, Wallace RM, Balaram D, Lindenmayer JM, Eckery DC, Mutonono-Watkiss B, Parravani E and Nel LH (2017) The Role of Dog Population Management in Rabies Elimination—A Review of Current Approaches and Future Opportunities. Front. Vet. Sci. 4:109. doi: 10.3389/fvets.2017.00109)

Box 1. Key characteristics of dog guardianship for DPM purposes.
CONFINEMENT STATUS

- A *confined dog* remains under owner control at all times, often within a home or walled compound, and is walked on a leash or maintained under control when outside those confines.
- A *partially free-roaming dog* spends part of its time confined to a home or a walled property, but is also allowed to freely roam in the community.
- A *fully free-roaming dog* is never confined to a home or walled property.

OWNERSHIP STATUS

- A *family (or individual)-owned dog* is a dog that a family or individual states is their property or claims a right over.
- A *community-owned dog* is a dog that more than one individual or family state is their property or claim a right over.
- An *unowned dog* is not claimed by anyone in the community. It may be accepted, tolerated or despised by the community.

Annex F: (Taylor LH, Wallace RM, Balaram D, Lindenmayer JM, Eckery DC, Mutonono-Watkiss B, Parravani E and Nel LH (2017) The Role of Dog Population Management in Rabies Elimination—A Review of Current Approaches and Future Opportunities. Front. Vet. Sci. 4:109. doi: 10.3389/fvets.2017.00109)

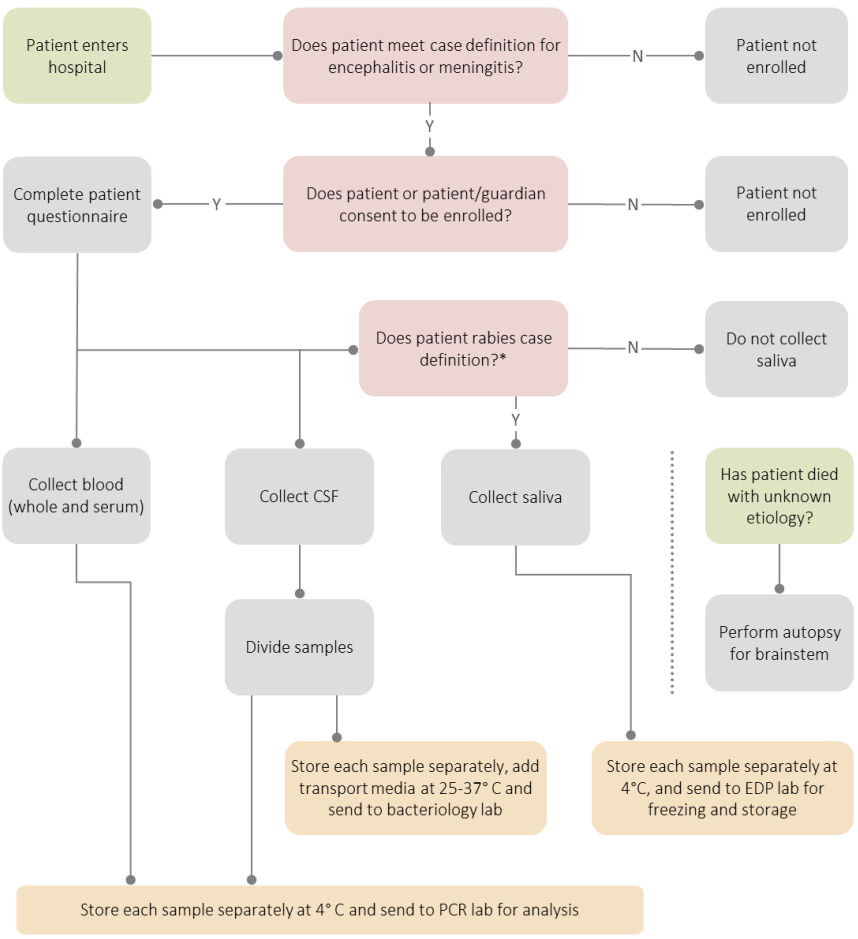
Table 1. Comparison of rabies assays and their use under different animal rabies surveillance programs. (35)

Assay (References)		Stage 1: proof of burden	Stage 2: human rabies prevention	Stage 3: monitoring of control measures	Stage 4: verification of rabies elimination	Stage 5: post-elimination	Sample required
Molecular	Reverse-transcription polymerase chain reaction (RT-PCR) (32,33,36,37,38,39,40)	+++	+++	+++	+++	+++	Brain
	Nested RT-PCR (41,42,43)	++	-	+	-	-	Brain
	Quantitative RT-PCR (qRT-PCR) (33,36,39,44,45)	++	-	+	-	-	Brain
Antigen	Direct fluorescent antigen (DFA) test (29,46,47)	+++	+++	+++	+++	+++	Brain
	Direct rapid immunohistochemical test (DRIT) (30,31,48,49,50)	+++	+++	+++	+++	+++	Brain
	Indirect rapid immunohistochemical test (IRIT) (51)	++	-	+	-	-	Brain
	Immunochromatographic test (lateral flow device or LFD) (52,53)	++	-	+	-	-	Brain
Antibody	Rapid fluorescent focus inhibition test (RFFIT/fluorescent antibody virus neutralisation test (FAVN) (54,55,56)	++	-	+++	-	-	Serum
	Indirect fluorescence antibody (IFA) (57,58)	++	-	++	-	-	Serum
	Indirect enzyme-linked immunosorbent assay (iELISA) (59,60,61,62)	++	-	++	-	-	Serum
	Competitive ELISA (59,63)	++	-	++	-	-	Serum

-: not recommended
+: low recommendation, useful for confirmatory testing
++: moderate recommendation, useful for primary or confirmatory testing
+++: high recommendation, useful for primary testing

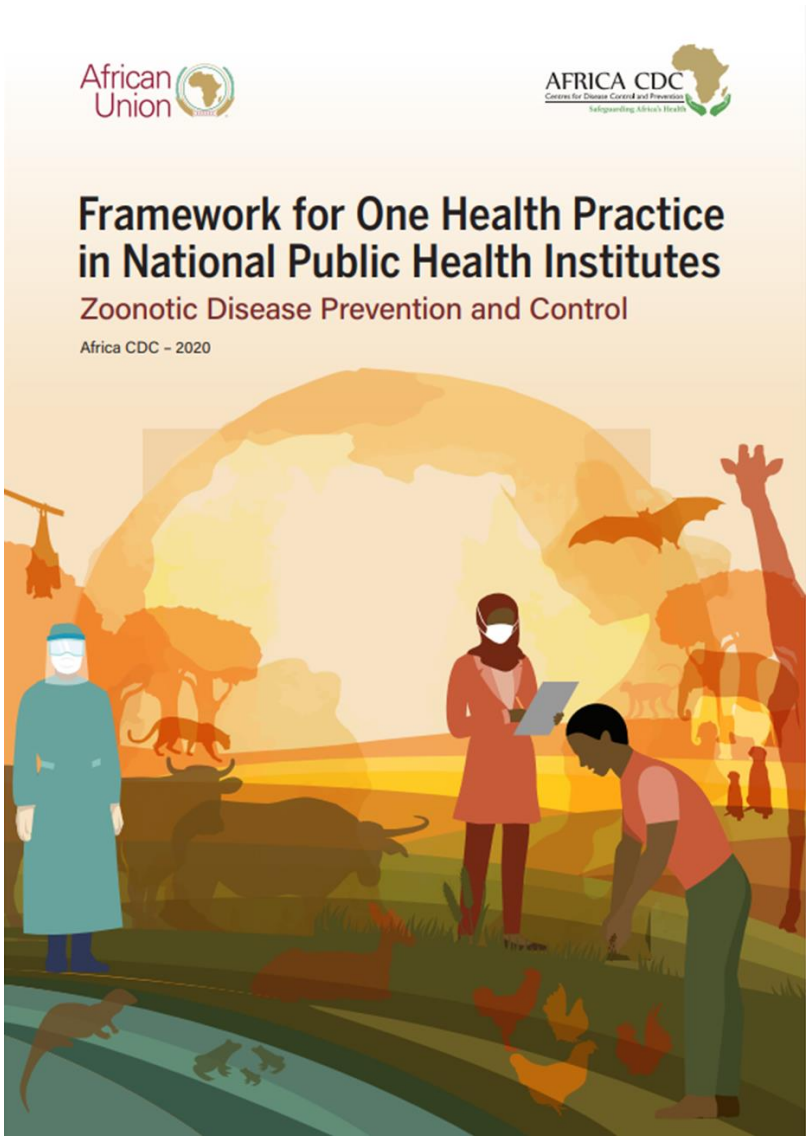
Annex G: (WOAH Rabies – Scientific and Technical Review, Vol 37 (2) - https://doc.oie.int/dyn/portal/index.xhtml?page=alo&aloId=37286)

Figure 2. Example of a sample collection algorithm that can be used to identify causative agents among persons with undiagnosed encephalitis and meningitis



* Rabies case definition. An acute neurological syndrome(encephalitis) dominated by forms of hyperactivity (furious rabies) or paralytic syndromes (dumb rabies) progressing towards coma and death, usually by respiratory failure within 7-10 days after the first symptom if no intensive case is instituted.

[CSF = cerebrospinal fluid; EDP = Especially dangerous pathogens; PCR = polymerase chain reaction]



Annex H: Africa CDC Framework for One Health Practice in National Public Health Institutes, Page 38

11.0. Suggested Data Templates

Human Rabies Cases	Laboratory-Confirmed[11]	Probable (Clinically Confirmed)[10]	Suspected[9]	Test-Negative
Total, Human Rabies Cases				
Male				
Female				
Gender Unknown				
<5 years of age				
5 - 14 years of age				
>15 years of age				
Age Unknown				
Appropriately Vaccinated				
Delayed Vaccination (PEP)				
Incomplete Vaccination				
No Vaccination History				
Unknown Vaccination History				
Human rabies cases that survived infection				
Dog-transmitted human rabies				
Bat-transmitted human rabies				
Terrestrial wildlife-transmitted human rabies				
Other species-transmitted human rabies				
Unknown species-transmitted human rabies				
Canine Rabies Virus Variant				
Bat Rabies Virus Variants				
Terrestrial Wildlife Rabies Virus Variants				

Other Variants		
Unknown Variant		

Human Rabies Exposures*	Laboratory-Confirmed[5]	Probable (Clinically Confirmed)[6]	Suspected[7]	Not a Case**[8]
Total, Reported People with Category II or III Exposure				
Exposure from dogs				
Exposure from bats				
Exposure from terrestrial wildlife				
Exposure from other animal species				
Exposure (unknown animal)				
Male				
Female				
Gender Unknown				
Number of reported animal exposures in humans (Age <5)				
Number of reported animal exposures in humans (Age 5 - 14)				
Number of reported animal exposures in humans (Age >15)				
Number of reported animal exposures in humans (unknown age)				

* Report should be completed only for WHO Category II and III exposures
** Test-negative or clinical observation

Post-Exposure Prophylaxis	Case Classification of the Offending Animal			
	Laboratory-Confirmed[5]	Probable (Clinically Confirmed)[6]	Suspected*[7]	Not a Case **[8]
Total, Reported People Receiving PEP				
Number of people receiving PEP (Exposure Category I)				
Number of people receiving PEP (Exposure Category II)				
Number of people receiving PEP (Exposure Category III)				
Number of people receiving PEP (Exposure Category Unknown)				
Number of people receiving RIG				

* Animals with unknown case classification should be considered “Suspected”, per WHO case definition
** Test-negative or clinical observation

Animal Rabies	Laboratory-Confirmed[5]	Probable (Clinically Confirmed)[6]	Suspected*[7]	Non-rabid (clinical observation)[8]	Non-rabid (test-negative)[8]
Total, Animals Investigated for Suspicion of Rabies					
Dogs Investigated for Suspicion of Rabies					
Livestock Investigated for Suspicion of Rabies					
Bats Investigated for Suspicion of Rabies					
Other Animals Investigated for Suspicion of Rabies		x	x		
Unknown Species Investigate for Suspicion of Rabies		x	x		
Number of Cases with Canine Rabies Virus Variant					
Number of Cases with Bat-lineage Rabies Virus Variant					
Number of Cases with Wildlife-lineage Rabies Virus Variant					
Number of Cases with No Variant Information					

Dog Population Management	Owned-Confined	Owned-Stray	Unowned (Community)	Unknown Status	Total
Total Population					
Method of Estimation	*Select all: (Human-Dog-Ratio / Household Suveys / Field Surveys / Other / Unknown)*				
Number of Dogs Vaccinated					
Method of Vaccination Utilized	*Select all: (Private / Fixed Point / Door to Door / Capture Vaccinate Release / Oral Rabies Vaccination)*				
Method of Estimating Dog Vaccination Coverage	*Select all: (Census / Household Surveys / Field Surveys / Other / Unknown)*				
Number of Dogs Sterilized					

12.0. Resource Mapping Guide

Data Element	UAR Global Strategic Plan	WOAH Official Dog Program	WHO Validation	WHO Verification	Self-Declaration to WOAH of Freedom From Dog-Mediated Rabies
Profile: National Strategy	1.2.1 / 2.1.1 / 2.2.1	2 / 2.e / 3.b.i / 3.d.i	2.a / 2.b	3.1 / 3.2	8.15.4
Profile: Surveillance	1.3.1 / 2.2.1	3.b.ii	3.2a	3.2a / 3.2b	8.15.4.1c
Profile: Post-Exposure Prophylaxis	1.3.1 / 1.3.2 / 1.3.3		2.a	3.1	
Profile: Dog Population	1.2.3 / 2.2.1	1.b	2.a / 3.1	2.b / 3.1	8.15.4.1f
Profile: Facilities	1.3.1 / 2.2.1	3.b / 3.c.i	1.1	1.1, 3.1	
Human Rabies: Case Classification		3.a.i	3.2a	1.1b / 3.2a	8.15.4.1e
Human Rabies: Source of Infection		3.a.i		3.2b	8.15.4.1e
Human Rabies: Rabies Virus Variant		3.c.i		3.2b	8.15.4.1e
Human Rabies: Gender			3.2a	3.2a	
Human Rabies: Age			3.2a	3.2a	
Human Rabies: Disease Outcome			3.2a	3.2a	
Human Rabies: Vaccination Status			3.2a	3.2a	
Exposure: Case Classification		3.a.ii / 3.b.	3.2a	3.2a / 3.2b	
Exposure: Source of Exposure		3.c.i		3.2a / 3.2b	
Exposure: Gender				3.2a / 3.2b	
Exposure: Age				3.2a / 3.2b	
PEP: Exposure Case Classification	1.3.1	3.b	3.1	3.1 / 3.2	
PEP: Source of Exposure	1.3.1	3.b	3.1	3.1 / 3.2	
PEP: Rabies Immuneoglobulin	1.3.1		3.1	3.1 / 3.2	
Animal Rabies: Dogs	2.2.1	3.b	3.2a	3.2a / 3.2b	8.15.4.1a,1b,1c,1e
Animal Rabies: Livestock	2.2.1	3.b	3.2a	3.2a / 3.2b	8.15.4.1a,1b,1c,1e
Animal Rabies: Bats	2.2.1	3.b	3.2a	3.2a / 3.2b	
Animal Rabies: Other Species	2.2.1	3.b	3.2a	3.2a / 3.2b	8.15.4.1a,1b,1c,1e
Animal Rabies: Rabies Virus Variant	2.2.1	3.c.i	3.2a	3.2a / 3.2b	8.15.4.1e
Dogs: Vaccination	1.2.1	3.d.i	2.a	2.b	8.15.4.1f
Dogs: Vaccination Method	1.2.3	3.d.iii	2.a	2.b	8.15.4.1f
Dogs: Sterilization	1.2.3	3.d.iv	2.a	2.b	8.15.4.1f

13.0. Annex 13: Application for endorsement by WOAH of an official control programme* for dog-mediated rabies

The overall objective of an *official control programme* for dog-mediated rabies endorsed by the World Organisation for Animal Health (WOAH founded as OIE) is for Member Countries to progressively improve their dog-mediated rabies situation and eventually make a self-declaration in accordance with Chapter 1.6. as a country free from dog-mediated rabies. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined subpopulations only.

The following information should be provided by WOAH Member Countries to support an application for endorsement by WOAH of an *official control programme* for dog-mediated rabies in accordance with Chapter 8.15. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the topics under the headings provided in Sections 1. to 4. below to describe the actual situation in the country and the procedures currently applied, demonstrating the commitment of the Member Country to comply with the requirements of Chapter 8.15. of the *Terrestrial Code*.

In Section 4, the dossier should describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for endorsement of an *official control programme* should submit documented evidence that the provisions of Article 8.15.11. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the national *official control programme* for dog-mediated rabies as detailed below.

The dossier should provide maps, figures and tables wherever possible.

1. Introduction

    a. Human demographics. Provide a general description of the population distribution, census, socio-economic and cultural features and rural and urban development of the country that are relevant to the spread of rabies virus in dogs. Provide maps identifying the features above. Specify whether the application includes any non-contiguous territories.

    b. Dog demographics. Describe the composition of dog population in the country and a breakdown in *zones*, if relevant. In particular, provide an estimation of the dog population size including the *free-*

roaming dog[*] population in accordance with Chapter 7.7. and human:dog ratio, dog distribution (rural/urban) and ecology. Describe the methodology used for the estimation (e.g., dog registration databases, household questionnaires, and surveys of dogs, owners, dog shelters, direct observation, mark-resight, etc.);

c. If the endorsed plan is implemented in stages to specific *zones* of the country, the boundaries of those *zones* should be clearly defined. Provide a map with the description of the geographical boundaries of the *zones*.

2. Governance of the national control programme for dog-mediated rabies
   a. Competent Authorities.
   Identify all *Competent Authorities* involved in the supervision, control, enforcement and monitoring of rabies-related activities. Provide a description of the role and responsibilities for the management of the dog-mediated rabies control programme, indicating the role of *Veterinary Services*, human health authorities and other *Competent Authorities* such as municipalities and those responsible for *wild* and *feral* animals, other organisations such as non-governmental organisations, kennel clubs and breeders, dog-owners, and other relevant groups in rabies control.

   b. Veterinary Authority.
      i. Describe how the *Veterinary Authority* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor rabies-related activities.

      ii. Provide information on any WOAH PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to the control of dog-mediated rabies.

   c. Human health system.
      i. Describe the health care system and services related to human rabies prevention and its links to the *Veterinary Services*.

      ii. Describe how the human health authorities supervise, control, enforce and monitor rabies-related activities.

   d. Other Competent Authorities.
      i. Describe how other *Competent Authorities* supervise, control, enforce and monitor rabies-related activities.

   e. Legal framework
   Legislation. Provide a table listing all relevant legislation, regulations and directives in relation to rabies control and a brief description of the relevance of each. What are the mechanisms in place to monitor and ensure compliance with the legislation?

3. Current status and control of dog-mediated rabies
   Submit a concise description of the measures for the current control and eventual elimination of dog-mediated rabies in the country, including:

   a. Epidemiology
      i. Describe the spatial and temporal rabies situation of at least the past five years. Provide tables and maps showing the date of detection, the number and location of *cases* in susceptible animals (by species) and in humans.

[*] According to the *Terrestrial Code* Glossary adopted at the General Session of May 2022, **Free-roaming dog**: means any *owned dog* or unowned dog that is without direct human supervision or control, including *feral* dogs.

ii. Describe the general epidemiology in the country highlighting current knowledge (e.g. high-risk areas, socio-cultural factors affecting rabies epidemiology) and gaps in knowledge and the progress over the last five years that has been made in controlling dog-mediated rabies.

iii. Provide information on the epidemiological situation of rabies in the surrounding countries.

b. Rabies surveillance

Provide documented evidence that *surveillance* for rabies in the country complies with provisions in Chapter 1.4. and Article 8.15.13. of the *Terrestrial Code*, and Chapter 3.1.18. of the *Terrestrial Manual*. The following information should be included:

i. the notification and reporting procedures (by whom and to whom) within the country, to other *Competent Authorities* and to WOAH.

ii. how is clinical *surveillance* conducted? Provide details of the process in place. Which susceptible species are part of the *surveillance* programme?

iii. the sampling, submission and testing procedures that are used to identify and confirm presence of the rabies virus.

iv. the role of human health and other *Competent Authorities* in dog-mediated rabies *surveillance*.

v. the *surveillance* data management systems, including how data are collected, aggregated, shared with other *Competent Authorities* (e.g. public health) and transmitted from community to national level.

vi. the system for recording, managing and analysing the diagnostic data and how it is integrated in the animal health *surveillance* database and how the data are exchanged between human health, other *Competent Authorities* and *Veterinary Services*;

Provide a summary table and a map indicating, for at least the past 24 months, the number of suspected *cases*, the number of samples tested for animal rabies, species, type of sample, testing methods and results.

Provide data and a map on human cases, dog-bite incidents and post exposure prophylaxis in humans for the past 24 months.

Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

c. Rabies diagnosis

Provide documented evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.18. of the *Terrestrial Manual* are applied. The following points should be addressed:

i. Provide an overview of the *laboratories* performing rabies tests in the country, including the following:

- the logistics for shipment of samples, the biosecurity and biosafety measures applied, the follow-up procedures and the time frame for reporting results;
- details of the tests undertaken for rabies diagnosis and the proficiency testing programme. Provide details of the number of rabies tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
- if characterisation of virus isolates from human and animal *cases* is in place, describe it.

- procedures for quality assurance e.g. official accreditation of *laboratories*, Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

- details of participation in inter-*laboratory* comparison tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

- details of the handling of live rabies virus, including a description of the biosecurity and biosafety measures applied;

ii. If rabies *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

d. Dog-mediated rabies control strategy
Describe the control strategies in the country, including the following:

i. Description of the *vaccination* programme. Provide information on the *vaccination* strategies applied, the results of the *vaccination* campaigns during the last 24 months: frequency of *vaccination* campaigns, geospatial and temporal description of the campaigns, number of dogs vaccinated per population per campaign, *vaccination* coverage per year and by regions, etc. Data provided should differentiate emergency *vaccination* from systematic *vaccinations*. Provide maps if available. Describe the methods used for estimating *vaccination* coverage should be clearly stated. Provide data on dog *vaccination* activities as part of a response to human rabies cases.

ii. Provide a brief summary of the technical specifications of the dog rabies vaccines used and available in the country. Provide a description of the regulatory procedures in place, source of vaccines, cold-chain management, and management of the vaccine stock(s). Provide evidence that the vaccines used comply with Chapter 3.1.18. of the *Terrestrial Manual*. Provide information on the registration and licensing process for the vaccines used.

iii. Describe the supervision during the *vaccination* campaigns, post-*vaccination* monitoring strategy and the results of the *vaccination* coverage estimation, including in *free-roaming dog*[*] populations.

iv. Describe how dog populations are managed. Provide documented evidence that the relevant provisions of Chapter 7.7. of the *Terrestrial Code* are applied and the *Competent Authority* coordinating and involved in the implementation of *free-roaming dog** population control.

v. Describe the measures implemented to prevent reintroduction of rabies, the criteria applied to approve importation of susceptible animals, the controls applied to entry of such animals and to their internal movements.

e. Case investigation protocol
Describe the *case* investigation procedures used by the *Veterinary Services* for dealing with suspected or confirmed *case* of rabies in humans and animals. The *case* investigation protocol should be attached as an annex, if available.

f. National and international collaboration
Describe the existing coordination mechanisms nationally and internationally in support of the decision-making process for the implementation and management of the control programme. In particular, describe:

i. Intersectoral, One Health coordination mechanism (e.g. task forces, IHR-PVS National Bridging Workshops) between the relevant *Competent Authorities* and other stakeholders.

ii. Cross-border collaboration. Describe the cooperation, if any, with *Veterinary Authorities* and human health authorities of neighbouring countries in the control of dog-mediated rabies.

[*] According to the *Terrestrial Code* Glossary adopted at the General Session of May 2022, **Free-roaming dog**: means any *owned dog* or unowned dog that is without direct human supervision or control, including *feral* dogs.

iii. Regional collaboration. Describe coordination, collaboration and information-sharing activities with other countries in the region for the control of dog-mediated rabies.

g. Rabies awareness and education programmes

Provide a description of the awareness campaigns, training and education programmes on rabies, responsible dog ownership and dog bite prevention. Describe the targeted audience and collaboration with other *Competent Authorities*.

Provide details of training programmes for personnel involved in *surveillance*, dog *vaccination* campaigns and rabies prevention.

4. Work plan, timelines and budget of the official control programme for dog-mediated rabies for the next five years

Describe the progressive objectives including monitoring and evaluation framework and expected outcome to be achieved for each year for the next five years, for *zones* (if applicable) and for the whole country including:

a. Performance indicators and timeline[1]. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed to decrease incidence of *cases* in dogs and humans. These may include, but are not restricted to, strengthening all relevant *Competent Authorities*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, movement control, disease awareness, etc. Describe how the performance indicators of the *official control programme* will be monitored, evaluated and reviewed. This should include documented evidence demonstrating that the control programme is implemented and that the first results are favourable.

b. The outcome of the monitoring should be reflected when submitting the annual reconfirmation of your country's endorsement to WOAH. The primary measurable indicators for success of the programme will be decreased incidence of *cases* in dogs and in humans in the whole country and selected *zones* as described in the programme. Additional performance indicators showing evidence of success should include, but not be limited to, *vaccination* data, number of trace back activities or 10-days observation under veterinary supervision following human or animal exposures, successfully implemented import measures, control of dog movements. This should include documented evidence of the effective implementation of Section 4.a. above.

Describe the funding required for the implementation of the control programme and annual budgets for the next five years. Provide details of budget for any planned *vaccination* campaign(s), *laboratory* support, logistical support and awareness campaigns, etc. Indicate for which years funding has been secured and any anticipated gaps in funding the proposed activities.

[1] Member Countries can consider tools and resources available for example at: www.caninerabiesblueprint.org.

14.0. Annex 14. Template dossier for validation and verification

This template dossier was designed to help managers of national rabies programs prepare a dossier with supporting evidence for presentation to WHO, requesting validation that rabies has been eliminated as a public health problem and/or requesting verification that dog-mediated rabies has been eliminated. The information presented in the dossier will help reviewers to understand the achievements of the program by providing both epidemiological evidence and the broader context.

[Country]
Date of submission:
Date of review:

1. Background

A country previously endemic for rabies may apply for accreditation as having eliminated rabies as a public health problem (validation) if it has not had a human death from dog mediated rabies for at least 2 years (24 months), is operating and continues to maintain an adequate surveillance and reporting system for rabies and demonstrates effective implementation of a rabies control program in human and animal populations. A country may apply for accreditation as having eliminated dog-mediated rabies (verification) if it, in addition to meeting the criteria for validation described above, is operating and continues to maintain an enhanced surveillance and reporting system for rabies and demonstrates an effective strategy for maintaining freedom from dog mediated rabies.

1.1 General documentation (optional)

Adequate documentation is necessary to provide the essential data for validation and verification. It is preferable that these data and subsequent documentation be standardized among countries within a region.

a. For both *validation* and verification, provide an overview of:
- i. Demographic and economic features of the country
- ii. Overview of the health care system in the country
- iii. Overview of the animal health system in the country
- iv. Information about past rabies epidemiology in the country, including interventions before enforcement of the current national rabies program

b. For *verification*, also provide an overview of:
- i. Procedures for provision of post-exposure prophylaxis
- ii. Procedures for clinical and laboratory diagnosis of human and animal cases
- iii. If completed, evidence of zero human rabies deaths (e.g. documentation submitted for validation)

2. Rabies program overview (required)

a. For *validation*, describe in narrative form:
- i. Evidence of a national rabies control program, including:
  - Regulatory framework relevant to rabies, including rabies notification
  - National rabies control strategy, including implementation, responsibilities by sector, structure and year established
  - Data collection and management system
- ii. Evidence that control activities are in place, including:
  - Availability and provision of PEP in the country

- Campaigns on rabies awareness and dog-bite prevention
- Overview of dog vaccination campaigns
- Information on dog population management measures in place, including movement regulations
- WOAH endorsement of an official control program for dog-mediated rabies, if successfully sought

b. For *verification*, describe in narrative form:

i. For formerly endemic countries, evidence that mass dog vaccination programs controlled rabies i.e.:

- Overview of dog vaccination campaigns over at least 5 years, including ongoing mass dog vaccination programs in at-risk areas or other evidence of successful control of canine rabies
- Estimated dog population size, methods for coverage and population estimates

ii. Information on dog population management measures in place / Evidence that the national control program has controlled rabies

- A decrease in the occurrence of rabies over at least 5 years for countries with a recent history of endemic rabies
- WOAH self-declaration of freedom from rabies if successfully sought (https://www.woah.org/fr/ce-que-nous-faisons/normes/codes-et-manuels/acces-en-ligne-au-code-terrestre/index.php?id=169&L=1&htmfile=chapitre_selfdeclaration.htm) (optional)

3. Implementation of national rabies control and prevention strategy

3.1 Evidence of control activities (required)

For both *validation* and *verification*, describe in narrative form:

- Availability and provision of PEP in the country, including:
  - type of vaccine and RIG available and their distribution mechanisms sub-nationally
  - number and proportion of animal bite treatment or primary health care centres with capacity for PEP (provision of vaccine only versus vaccine and RIG)
  - standard operating procedures for PEP administration
  - number of vaccine and RIG doses administered per year
  - proportion of PEP courses administered by intramuscular or intradermal regimens
  - PEP payment systems
- Number and geographical coverage of campaigns on rabies awareness and dog bite prevention
- Dog vaccination campaigns during the past 5 years, including:
  - number of dogs vaccinated per year and by appropriate administrative subdivision
  - vaccination coverage by year and by appropriate administrative subdivision
  - estimated dog population in the country
  - target animal populations for vaccination
  - type of vaccine used
  - source of vaccine
  - current vaccine stocks
- Dog population management, including regulations on dog movement.

For *verification*, also describe:

- The method by which dog vaccination coverage and population sizes were estimated over a minimum of 5 years.
- Emergency preparedness and response plan to be implemented in case of introduction or re-emergence of dog-mediated rabies.

3.2 Rabies surveillance (required)

For both *validation* and *verification*, describe:

a. Evidence that adequate rabies surveillance is in place to detect rabies deaths if they were to occur, including:

i. National notification of both human and animal rabies cases

ii. Capability to diagnose rabies cases with WHO-/WOAH-recommended standard diagnostic tests

iii. Evidence of sample submissions from all parts of endemic and adjacent (rabies-free) areas of the country, including maps showing positive and negative test results to assess coverage and possible gaps in surveillance

iv. The number of suspected or probable human rabies cases or probable rabies exposures that have been investigated each year and the nature of the investigation (including clinical and laboratory diagnosis, verbal autopsy, community surveys, trace-back investigations)

v. Incidence of cases of acute encephalitis syndrome (AES)[2] per 100 000 people per year and description of the surveillance system for detection, reporting and investigation of cases of human AES from all areas of the country;

OR

vi. If AES data are not available, or are not exhaustive, demonstration of a surveillance system able to detect, report and investigate suspect cases of human rabies from all areas of the country

vii. Rabies surveillance for animals in line with the WOAH Terrestrial animal health code (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_surveillance_general.htm), including:

– Number of rabies cases in dogs and other animals (clinical and laboratory confirmed)
– Number of dog and other suspected rabid animal bite incidents in humans and animals per year
– Number of routine epidemiological investigations on suspected or probable rabies cases in dogs, including procedures for rapid collection and transport of samples from suspected cases to a laboratory for diagnosis
– Sampling strategy used
– Methods for monitoring dog vaccination coverage

[2] AES is clinically defined as a syndrome in a person of any age, at any time of year involving acute onset of fever and at least one of: (a) change in mental status (including symptoms such as confusion, disorientation, coma or inability to talk); (b) new onset of seizures (excluding simple febrile seizures). Other early clinical findings may include increased irritability, somnolence or abnormal behaviour greater than that seen with usual febrile illness. The incidence of AES will be evaluated with reference to expected levels.

For *verification*, also describe:

b. Evidence that enhanced dog rabies surveillance has been in place for at least 24 months after the last detected rabies case, including:

i. Risk assessment of probable exposures presenting to health facilities
– Numbers of probable exposures reported (and PEP courses initiated)
– Number of alerts on and early detections of any imported cases

ii. Epidemiological investigations of probable exposures undertaken rapidly (< 14 days from clinical presentation) and the outcome of the investigation, including:
– Numbers of probably rabid animals reported
– Sample collection and testing of all dead or killed suspected rabid animals. It is expected that samples can be recovered from ~50% of suspected animals. All animals that did not survive the 10-day observation period should be tested.
– In the event of a confirmed human or animal rabies case, molecular characterization of the virus isolate to identify whether the case was due to infection with a wildlife variant, a bat lyssavirus or a non-indigenous infection (if available).

3.3 Procedures to maintain *validation* and/or *verification* (required)

For both *validation* and *verification*, describe in narrative form:

a. Plans for post-validation and/or post-verification rabies surveillance, including:

i. Procedures and evidence of continued surveillance to ensure early detection of any imported case and the appropriate treatment of people exposed to non-canine rabies variants or lyssaviruses or bitten while travelling

b. Plans for continued provision of human post-exposure prophylaxis
c. Cross-border plan to prevent reintroduction of rabies from neighbouring countries

For *verification*, also describe:

a. WOAH self-declaration of country free from infection with dog-mediated RABV (see Chapter 1.6 of the WOAH Terrestrial animal health code: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_selfdeclaration.htm).

b. Evidence that a contingency plan is in place to effectively respond to an introduction

i. Animal movement regulations

ii. Regular risk assessments

– Of incursions from other countries/regions

– Of other circulating wildlife rabies variants/ lyssaviruses

iii. Outbreak response strategy, including evidence of continued access to dog vaccines and PEP in the event of an outbreak

4. Resources and partnerships (optional)

For both *validation* and *verification*, provide:

a. Briefly describe the human resources employed to implement the program
b. Estimate internal and external financial resources used for the program over time
c. Sustainable resource mobilization strategy for the post-validation/verification phase

5. Special issues (optional)

For both *validation* and *verification*, provide the following:

a. Descriptions of any special circumstances that have affected the program. These could include, but are not limited to:

i. Stability or security issues in the country; and/or

ii. Re-introduction from other rabies-endemic countries.

b. Descriptions of any specific efforts to investigate rabies cases and/or intervention coverage in difficult-to-reach populations (e.g., nomadic peoples, internally displaced persons, or refugees).

6. Bibliography (required)

Insert a bibliography of all data sources used to develop this dossier, including:

- Ministry of health records
- Records from veterinary services
- Published papers (scientific, policy, etc.)
- Academic theses and dissertations

Copies of unpublished documents may be requested by WHO.

7. Abbreviations (required)

Insert a list of all abbreviations used in the dossier, with their definitions.

15.0. Annex 15: Data Security Statement

Data Security is the practice of protecting data against unauthorized access and corruption to ensure privacy and fidelity of analysis and interpretation. Data security systems should be designed to ensure:

- Confidential information and systems are protected
- Ensure the availability and integrity of data assets
- Protect the reputation of the responsible authority
- Enable continuity of operations

Data security should not inhibit critical functionalities of a rabies program, but must protect the confidentiality, integrity, and availability of data that is collected, whether it is electronic, physical, or procedural. Singular, multi-disease data platforms that serve all needs of the responsible Ministry(s) are ideal but may not be achievable in many settings. Implementing modern, electronic data systems for rabies should not be delayed for an idealized system. Rabies-specific data platforms should be capable of establishing data-sharing connections to Ministry(s) systems with minimal resource-needs. Alternatively, platforms that enable access by relevant users, across Ministries, may provide a more secure means of data sharing while supporting a One Health Approach. Any data sharing mechanisms should adhere to the data security standards described herein.

The World Health Organization has established a Data Policy that provides guidance for ensuring data security and privacy of sensitive information. This guidance follows the principles of the hierarchy of controls. Before data is collected, there are actions that can be conducted to prevent misuse of data.

- All data collection systems should clearly describe the **terms applicable to the provision of the data** to eligible partners. At a minimum, data should be collected in accordance with applicable national laws, including data protection laws to protect confidentiality of sensitive information.

- Data systems should have defined **terms applicable to the use of the data** by eligible partners. Typically, such terms will require that public release or publication of data can only occur if it is stripped of personal identifiers. These terms should also define which agencies are eligible to view, analyze, or release data collected by the system and describe the process for obtaining approval to release data.

- Any system that is established to share data should have an explicit **ethical framework governing data collection and use**. Such measures are required to protect privacy and confidentiality and avoid stigmatization or exclusion of people or communities as a result of data collection. Criteria typically found in an ethical framework include obtaining informed consent agreements when collecting sensitive or personally identifying information and adopting security measures to foster public trust.

Devices that collect electronic data should have encryption technology, such as passwords to access the device. Two-way encryption, such as also requiring a password to access an electronic application is preferred if sensitive data is collected. For highly sensitive data collection, electronic applications should have the ability to block screenshots and screen sharing. If the data security features of an electronic application are in question, tools have been developed to help evaluate data systems (e.g. OWASP).

Organizations that are responsible for data collection, as well as organizations developing or storing electronic data, should have a dedicated data security manager. Data security managers should be up to date with security announcements and have oversight of organizational, configuration, and technical aspects of the electronic application and data storage system. Security plans should be in place that clearly describe backup and recovery plans, software version management, user and role management, and training and messaging. Users of electronic tools must maintain current versions of the software and developers much release patch fixes and communicate to users when application upgrades are necessary to maintain data security standards. Developers need to have a mechanism for user-reported data security concerns. Updates to electronic systems should not negatively impact active users, and developers should provide ample time to allow system-users to transition to version updates.

Microsoft Word - WHO_data-sharing-policy-collected-by-member-states-outside-PHE_PDF_EN.docx

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