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The OIE World Animal Health Information System: the role of OIE Reference Laboratories and Collaborating Centres in disease reporting

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Summary

One of the main objectives of the World Organisation for Animal Health (OIE) is to ensure transparency in and knowledge of the world animal health situation. To achieve this objective, the OIE relies on its network of Member Countries, which is complemented by the activities of 221 Reference Laboratories (RLs) and Collaborating Centres. The RL mandate states that, in the case of positive results for diseases notifiable to the OIE, the laboratory should inform the OIE Delegate of the Member Country from which the samples originated and send a copy of the information to OIE Headquarters. However, since 2006 the OIE has received a lower than expected number of notifications from RLs, which implies either that the majority of samples are sent to national laboratories or that some RLs are not fully complying with their mandate.

The OIE sent a questionnaire to RLs in preparation for the Second Global Conference of OIE Reference Laboratories and Collaborating Centres (Paris, France, 21-23 June 2010). Two main factors emerged: the need for RLs to clarify their role and responsibilities in disease reporting and the need for an awareness campaign to sensitise national Veterinary Services to the importance of conducting more surveillance (and consequently of submitting samples to RLs) for all OIE-listed diseases. Reference laboratories indicated two main reasons for not sharing more data on positive samples with the OIE: i) a perceived contradiction between their mandate as OIE RLs and the standards of the International Organization for Standardization (ISO) dealing with confidentiality; and ii) certain Member Countries or stakeholders asking RLs not to share positive results with the OIE, for political or economic reasons. The OIE has put forward proposals to help RLs resolve these problems in future. The use of ISO standards must be clarified and there must be improved communication between the OIE and its RLs. A lack of transparency about a significant disease event can jeopardise the biosecurity of several countries, an entire region or even the whole world. The reference status of a non-transparent RL could be questioned.

Keywords

Animal disease – Animal/human interface – Collaborating Centre – Early warning – ISO 17025 – Non-official information – One World, One Health – Reference Laboratory – Transparency – WAHID – WAHIS – Wildlife disease – Zoonotic disease.

Objectives of the OIE

One of the main objectives of the World Organisation for Animal Health (OIE) is to ensure transparency in and knowledge of the world animal health situation. To achieve this objective, the OIE relies on its successful network of OIE Member Countries, which constitutes the main source of OIE official information. This does, however, raise a number of basic questions. Do all countries know the health situation of their own domestic and wild animals? Are they aware of any major zoonotic diseases that may be present and do they have access to relevant information on the public health situation? Moreover, how can a country know the animal health situation unless it has at least the basic minimum laboratory infrastructure at the national level to diagnose diseases? How can a country know the disease situation if it lacks the resources to conduct active surveillance for important diseases, even if there is a good laboratory infrastructure? If insufficient resources are available for disease surveillance, what can be done, and by whom? Here, the discussion is limited to what can be done by the OIE and its network of expertise (Reference Laboratories [RLs] and Collaborating Centres) to achieve the objective of improving early detection and warning in the event of outbreaks of animal diseases, including zoonoses. The discussion takes place within the context of knowledge of the animal health situation with regard to OIE-listed diseases and to emerging and re-emerging diseases that are not yet listed.

The role of OIE Reference Laboratories and Collaborating Centres in disease reporting

Collaborating Centres play an important role as centres of expertise in a specified sphere of competence, such as epidemiology or wildlife. As well as organising training seminars and other capacity-building activities, they also participate in the OIE's capacity-building activities for the Delegate and focal points of each Member Country (focal points are nominated by the Delegate to be responsible, on his/her behalf, for collating and providing information and comments on particular topics and OIE activities, such as animal disease notification, wildlife or aquatic animals).

Reference laboratories work on the validation of laboratory tests, conduct tests on samples received from their own country and countries elsewhere, share reagents for laboratory test validation by certain national reference laboratories, organise inter-laboratory proficiency tests and, in some cases, participate in the OIE's laboratory twinning activities.

A laboratory or centre applying to be an officially designated OIE RL or Collaborating Centre must fulfil a number of criteria. Self-evidently, it must have the necessary expertise and laboratory infrastructure. Moreover, the government of the country concerned (or another eligible source of support) must be willing to give it the necessary resources to fulfil its OIE mandate, which includes responding to relevant requests from OIE Member Countries for assistance.

The mandate of OIE RLs, adopted by all OIE Member Countries, is clear on the need for transparency. RLs are required to send two important communications: i) a report informing the OIE Delegate of the Member Country concerned of the results of sample testing, even if the samples have been sent by a private company, a veterinarian or an owner, and ii) a copy of this report to OIE Headquarters in the event of a positive finding relating to an OIE-listed disease.

The aim of this requirement is to improve the OIE's early warning system, thereby giving all 176 OIE Member Countries more time to take any necessary precautionary measures. All Member Countries expect that each OIE RL will respect its mandate.

Sharing information with the OIE

It was during its 72nd General Session in 2004 that the OIE General Assembly introduced changes to the RL mandate (Resolution No. XXVIII) by requiring that positive test results for notifiable diseases be reported to OIE Headquarters as well as to the Delegate of the Member Country from which the samples originated.

Once notified, the OIE Animal Health Information Department will decide on whether or not any further action is required. This will depend on the OIE's current knowledge of the animal health situation in the country concerned, based on a risk analysis to determine whether the new findings constitute an exceptional epidemiological event, which the country should notify immediately to the OIE, or if they should be notified in the country's six-monthly reports.

The results forwarded to the OIE will only be published by OIE Headquarters in agreement with the Delegate of the country concerned and after precise identification of the origin of the samples.

The requirement for OIE RLs to inform OIE Headquarters is designed to increase the effectiveness of the OIE's early warning system, giving all countries the necessary time and

information to conduct their own risk analysis and take any necessary precautionary measures. This information is important since any event posing a threat to the biosecurity of one country could jeopardise the biosecurity of other countries, regions or indeed the whole world. It cannot be emphasised too strongly that all OIE RLs are expected to comply fully with their mandate and should be aware of the importance of transparency in order to achieve the objective of the OIE World Animal Health Information System.

Although diagnostic testing assistance is not requested by Member Countries from all OIE RLs, the sharing of results by laboratories is less than expected, as shown in Table 1.

Table I
OIE Reference Laboratories that shared laboratory diagnostic results between December 2006 and 31 March 2010

Laboratory	Disease(s)
Veterinary Laboratories Agency, Weybridge, Surrey, United Kingdom	Highly pathogenic avian influenza
Institute for Animal Health, Pirbright, Surrey, United Kingdom	Foot and mouth disease Bluetongue African horse sickness
Istituto Zooprofilattico Sperimentale delle Venezie, Padua, Italy	Highly pathogenic avian influenza Newcastle disease
Onderstepoort Veterinary Institute, Pretoria, South Africa	African swine fever African horse sickness
Agence française de sécurité sanitaire des aliments (French Food Safety Agency), Unité Pathologie de l'abeille, Sophia Antipolis, Nice, France	Bee diseases

Since 2006, out of the 187 OIE RLs, only 6 have informed the OIE of the occurrence of listed diseases. There are two possible explanations for this situation: a lack of compliance with their mandate on the part of the Laboratories or a limited number of positive samples with regard to OIE-listed diseases and/or a lack of submitted positive samples for OIE-listed diseases to RLs, since the expertise is available in national laboratories.

Reporting positive test results for notifiable diseases: an analysis of Reference Laboratory responses to an OIE questionnaire

In preparation for the Second Global Conference of OIE Reference Laboratories and Collaborating Centres (Paris, France, 21-23 June 2010), a questionnaire was sent to all OIE RLs on the transport of infectious animal substances by air. Three of the questions were on actions taken by RLs to communicate information in the event of positive results.

The questions on laboratory-confirmed positive results were as follows:

– Question 30 (Q30): In the case of confirmed positive results for diseases that are notifiable to the OIE, do you inform the OIE Delegate of the Member Country from which the samples originated?

– Question 31 (Q31): In the case of confirmed positive results for diseases that are notifiable to the OIE, do you also inform OIE Headquarters?

– Question 32 (Q32): If your reply is 'never' or 'sometimes' either for Q30 or Q31, please state reasons (e.g. perceived problems) for not reporting these confirmed positive results to the OIE Delegate and/or OIE Headquarters.

Responses of Reference Laboratories for terrestrial animal diseases

The responses of RLs for terrestrial animal diseases are summarised in Table II. Twelve out of the 90 RLs that returned the questionnaire left Q30 and Q31 unanswered. Eighteen RLs indicated that they never inform the OIE Delegate or the OIE and one stated that it always informs the OIE but only sometimes passes the information to the Delegate. Fifteen RLs answered that they sometimes inform the OIE, four of which did not give any explanation. Thirty-six RLs answered that they always inform both the OIE Delegate and the OIE; this is far higher than the number of laboratories actually sharing information with the OIE, as shown in Table I.

Table II
Information sharing by OIE Reference Laboratories for terrestrial animal diseases
As part of an OIE questionnaire, Reference Laboratories were asked how often they informed OIE Headquarters and/or the relevant OIE Delegate when samples tested positive for notifiable diseases

Inform OIE Delegate (Question 30)	Inform OIE Headquarters (Question 31)	No. of Reference Laboratories
Not answered	Not answered	12
Always	Always	36
Never	Never	18
Always	Never	7
Never	Always	1
Always	Sometimes	8
Sometimes	Always	1
Sometimes	Sometimes	6
Not answered	Sometimes	1
	Total	**90**

Among the 54 RLs that did not answer 'always' to both Q30 and Q31, 40 of them explained why in their answer

to Q32. The reasons given for answering Q30 and Q31 with 'never' or 'sometimes', or for not answering, were as follows:

– sixteen out of 40 RLs believed that someone else has to report positive results (e.g. the submitting laboratory/institute/country or the OIE Delegate) and two laboratories explained that they follow the principle that their clients' results are confidential

– twenty-two out of 40 RLs considered either that the duty to report no longer applies (i.e. that the disease is no longer OIE-listed), or stated that they never received samples, or that the samples received never gave positive results

– some laboratories gave more than one of the reasons listed above.

The RL that answered 'never' to Q30 and 'always' to Q31, indicated that it reports the results to the national laboratory in the country concerned and sends a copy to OIE Headquarters.

Responses of Reference Laboratories for aquatic animal diseases

The responses of the 19 aquatic RLs who returned their questionnaire are summarised in Table III. One aquatic RL did not respond to Q30 or Q31.

Table III
Information sharing by OIE Reference Laboratories for aquatic animal diseases
As part of an OIE questionnaire, Reference Laboratories were asked how often they informed OIE Headquarters and/or the relevant OIE Delegate when samples tested positive for notifiable diseases

Inform OIE Delegate (Question 30)	Inform OIE Headquarters (Question 31)	No. of Reference Laboratories
Not answered	Not answered	1
Always	Always	9
Never	Never	2
Always	Sometimes	4
Sometimes	Always	1
Sometimes	Sometimes	1
Not answered	Sometimes	1
	Total	**19**

In Q32, 10 aquatic RLs gave explanations for their responses to Q30 and Q31. The main reasons given for answering 'never', or 'sometimes', or for not answering, were as follows:

– seven believed that someone else has to report positive results (e.g. the submitting laboratory/institute/country or the OIE Delegate)

– one applied the principle that their clients' results are confidential

– one answered that the question was not applicable, both because the disease in question was not on the OIE list and because the Laboratory had never received any samples

– some laboratories indicated more than one of the reasons listed above. One of the two aquatic RLs that answered 'never' to both Q30 and Q31 stated in reply to Q32 that it would send reports to both in future.

For some OIE-listed diseases, the relevant RLs mentioned that they were not receiving any samples. A possible explanation is that for some of these diseases, even though they are OIE-listed and therefore notifiable to the OIE, countries do not consider it sufficiently important to identify them or confirm their absence. A strategy to raise awareness of these diseases among Member Countries and to encourage them to send samples to OIE RLs, if their national laboratories lack the appropriate diagnostic capabilities, should be developed to correct these weaknesses.

Problems that need to be resolved to achieve better information sharing

After consultations with some of the Laboratories and taking into account some of the answers provided in the questionnaires, the explanations for not sharing or experiencing difficulty in sharing positive diagnostic results can be summarised as follows.

The primary problem mentioned by some OIE RLs appears to be that there is a possible contradiction between their mandate as an OIE RL and their status as an ISO 17025 accredited laboratory. Some RLs do not immediately inform OIE Headquarters and the Delegate concerned in the event of positive test results because the ISO 17025 standard requires them to protect the confidentiality of their customers. However, the OIE interpretation of the standard is that it addresses concerns about the confidentiality of data management in the laboratory's relations with other customers (e.g. protection against data theft and violation of confidentiality with dishonest intent). The parts of the standard that address the subject of confidentiality are as follows:

> '4.7 Service to the customer
> The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work

performed, provided that the laboratory ensures confidentiality to other customers.

4.13 Control of records
All records shall be held secure and in confidence.

5.4 Test and calibration methods and method validation

5.4.7 Control of data

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that […]

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing'

The OIE takes the view that an RL's obligations to the OIE do not conflict with ISO requirements. Firstly, the ISO confidentiality requirements are there to protect customer data from being shared with other customers, and as the body which confers reference status to the laboratory, rather than a country that submits samples for testing, the OIE is not a customer; and most importantly, the standard itself makes provision for a broad interpretation of its content which could even be understood to encourage laboratory compliance with the OIE mandate:

'1.6. NOTE 1. It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner.'

'4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.'

The obligations between the laboratory and the customer are essentially contractual. The contract between an ISO 17025 accredited OIE RL and the customer could therefore specifically mention the obligation on the part of the Laboratory to report relevant results to OIE Headquarters and the Delegate of the country concerned, without being incompatible with the ISO standard. Indeed, this is what the OIE recommends that their RLs do. The problem appears to be 'commercial' rather than 'legal'. Some laboratories may not wish to frighten away potential customers by informing them that they may be obliged to transmit the results directly to OIE Headquarters and to the Delegate of the country concerned.

The other problems mentioned by RLs on the difficulties they encounter in sharing data with the OIE are as follows:

– some Member Countries do not want the laboratory to report the results of a referral diagnosis to the OIE, since information disseminated by the OIE is trade sensitive

– some Member Countries prefer to avoid a situation in which the OIE contacts the OIE Delegate for an explanation of the laboratory findings

– some OIE RLs receive samples because it is known that they will not inform the OIE

– some laboratories inform the country concerned and other regional or international partners without informing the OIE, and others inform the country concerned and other partners and ask the country to notify the OIE.

The OIE is looking forward to improving communication channels with its RLs so as to overcome these situations.

A strategy needs to be developed to encourage countries to submit samples on OIE-listed diseases.

Reference Laboratories should continue to work on improving rapid diagnostic tests and making them more affordable for all countries and laboratories and enhancing their diagnostic capabilities.

The OIE is currently improving its worldwide information system on wildlife diseases by collecting more detailed data on the wildlife species affected. It is important, therefore, to undertake a review of the suitability of current diagnostic tests for OIE-listed diseases for wildlife disease surveillance and diagnosis. In consultation with OIE RLs, the OIE needs to determine what diagnostic tests are available for a given disease and which of them would be suitable for use in some or all of the relevant wildlife species. It is also important to identify any known or anticipated problems of sensitivity and specificity when each test is applied to species for which it has not been validated, so as to develop a strategy for further test validations.

Conclusion

In recent years, there has been a steady, overall improvement in transparency and in knowledge of the world animal health situation. This has been achieved thanks to a global policy applied by the OIE. Some of the key developments include the pro-active searching for non-official information and investigation into rumours on animal health and public health (from 2002),

implementation of the World Animal Health Information System (WAHIS) and the new requirements for notification of exceptional epidemiological events (from 2005), and regular training for WAHIS and WAHID (World Animal Health Information Database) focal points who are responsible for disease notification to the OIE. While the results of these activities are extremely encouraging they are not yet sufficient, and further work is required in building capacity and infrastructure to ensure that all countries have at least the minimum capabilities needed for early detection and warning, including a satisfactory level of laboratory infrastructure and expertise. OIE RLs that have not been fully complying with their obligations, under the terms of their mandate, to share their laboratory diagnostic results with the Delegates of the countries concerned *and* with OIE Headquarters are urged to start doing so. A lack of transparency on the part of a small number of countries is unacceptable and a strategy for better communication between the OIE and its RLs must now be developed to overcome the current problems.

The non-compliance of RLs with OIE transparency requirements must be discussed and the possibility of withdrawing official recognition of non-compliant laboratories could be considered. With globalisation, increasingly mobile human populations and the development of international trade in animals and animal products, early warning and transparency are, more than ever, key factors in protecting the biosecurity of each country. When a country fails to share information on an exceptional disease event it can endanger the biosecurity of other countries, whole regions and even the world. There is also growing public concern with health issues and the increase in emerging and re-emerging diseases. Given the potential consequences, OIE Headquarters and RLs must all think very carefully about how to handle situations, especially when dealing with a disease crisis, since they may subsequently be held accountable for their decisions and actions.

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Le Système mondial d'information sanitaire de l'OIE : le rôle des Laboratoires de référence et des Centres collaborateurs de l'OIE dans la notification des maladies animales

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Résumé

L'un des objectifs principaux de l'Organisation mondiale de la santé animale (OIE) est de s'assurer que la situation de la santé animale dans le monde soit connue et communiquée en toute transparence. Pour réaliser cet objectif, l'OIE s'appuie sur son réseau de Pays Membres, ainsi que sur les activités de ses 221 Laboratoires de référence et Centres collaborateurs. Le mandat des Laboratoires de référence stipule qu'en cas de résultats confirmés positifs pour une maladie à déclaration obligatoire auprès de l'OIE, le Laboratoire de référence doit en informer immédiatement le Délégué du pays Membre dont proviennent les prélèvements ainsi que le siège de l'OIE. Or, depuis 2006, les notifications adressées à l'OIE par les Laboratoires de référence sont moins nombreuses que prévu, ce qui peut signifier, soit que la majorité des prélèvements sont adressés aux laboratoires nationaux, soit que certains Laboratoires de référence ne s'acquittent pas correctement de leur mandat.

L'OIE a adressé un questionnaire aux Laboratoires de référence préalablement à la Deuxième Conférence mondiale des Laboratoires de référence et des Centres collaborateurs de l'OIE, tenue du 21 au 23 juin 2010 à Paris, France. Les réponses fournies ont fait apparaître deux impératifs majeurs : la nécessité de clarifier le rôle et les responsabilités des Laboratoires de référence dans le domaine de la notification des maladies animales, et la nécessité de conduire une campagne de sensibilisation afin que les Services vétérinaires prennent davantage conscience de l'importance de renforcer la surveillance (et donc de faire

analyser des prélèvements par les Laboratoires de référence) pour toutes les maladies de la liste de l'OIE. Les Laboratoires de référence ont évoqué deux raisons principales pour expliquer le nombre limité de rapports adressés à l'OIE concernant les prélèvements trouvés positifs : i) les laboratoires perçoivent une contradiction entre leur mandat en tant que Laboratoires de référence de l'OIE et les normes de l'Organisation internationale de normalisation (ISO) relatives à la confidentialité, et ii) certains Membres de l'OIE ou parties prenantes demandent parfois aux laboratoires de ne pas communiquer les résultats positifs à l'OIE, pour des raisons politiques ou économiques. L'OIE a avancé quelques propositions destinées à aider les Laboratoires de référence à résoudre ces problèmes. Il conviendra notamment de clarifier l'utilisation des normes ISO et d'améliorer la communication entre l'OIE et ses Laboratoires de référence. Le manque de transparence sur un épisode sanitaire important peut compromettre la biosécurité à l'échelle de plusieurs pays, d'une région, voire du monde entier. Un Laboratoire de référence qui ne respecte pas ses obligations de transparence pourra voir son statut remis en cause.

Mots-clés
Alerte précoce – Centre collaborateur – Information non officielle – Interface entre les animaux et l'homme – Laboratoire de référence – Maladie affectant les animaux sauvages – Maladie animale – Norme ISO 17025 – Transparence – Un monde, une seule santé – WAHID – WAHIS – Zoonose.

El Sistema Mundial de Información Zoosanitaria de la OIE: función de los Laboratorios de Referencia y los Centros Colaboradores de la OIE en la notificación de enfermedades

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Resumen
Uno de los principales objetivos de la Organización Mundial de Sanidad Animal (OIE) estriba en velar por el conocimiento y la transparencia de los datos sobre la situación zoosanitaria en el mundo. Para ello, la OIE cuenta con su red de Países Miembros, a la que se suma la labor de 221 Laboratorios de Referencia (LR) y Centros Colaboradores. En el mandato de los LR se establece que, en caso de resultado positivo a una de las enfermedades de declaración obligatoria a la OIE, el laboratorio debe informar al Delegado ante la OIE del País Miembro del que procedan las muestras, con copia a la Sede de la Organización. No obstante, desde 2006, la OIE ha recibido un número de notificaciones de los Laboratorios de Referencia inferior al previsto, lo que puede significar dos cosas: bien la mayoría de las muestras se envían a los laboratorios nacionales; o bien algunos Laboratorios de Referencia no están cumpliendo estrictamente su mandato.
En preparación de la Segunda Conferencia Mundial de Laboratorios de Referencia y Centros Colaboradores de la OIE (París, Francia, 21-23 de junio de 2010), la Organización envió a los LR un cuestionario cuyos resultados pusieron de manifiesto dos grandes tareas necesarias y pendientes: aclarar el papel y las responsabilidades de los LR respecto de la notificación de enfermedades; y llevar a cabo una campaña de información y sensibilización

de los Servicios Veterinarios nacionales acerca de la importancia de intensificar la vigilancia (y, por consiguiente, el envío de muestras a los LR) de todas las enfermedades incluidas en la lista de la OIE. Los Laboratorios de Referencia señalaron dos razones principales para explicar el insuficiente número de resultados positivos que comunicaban a la OIE: i) una aparente contradicción entre el mandato de los LR de la OIE y las normas de confidencialidad de la Organización Internacional de Normalización (ISO); y ii) el hecho de que ciertos Países Miembros u otras partes interesadas pidieran a los Laboratorios de Referencia que no comunicasen los resultados positivos a la OIE por razones políticas o económicas. La OIE ha formulado propuestas para ayudar a los LR a solventar estos problemas en el futuro. Es preciso aclarar la utilización de las normas ISO y mejorar la comunicación entre la OIE y sus Laboratorios de Referencia. La falta de transparencia en torno a un episodio sanitario importante puede poner en peligro la seguridad biológica de varios países, toda una región o incluso el mundo entero. Cabría reconsiderar el estatuto de establecimiento de referencia de todo LR que actúe sin la debida transparencia.

Palabras clave
Alerta precoz – Centro Colaborador – Enfermedad animal – Enfermedad de la fauna salvaje – Información no oficial – Interfaz animal/ser humano – ISO 17025 – Laboratorio de Referencia – 'Un mundo, una salud' – Transparencia – WAHID – WAHIS – Zoonosis.