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## **Process evaluation of integrated West Nile virus surveillance in Northern Italy: an example of One Health approach in public health policy**

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## **Abstract**

West Nile virus (WNV) is endemic in the Po valley area in northern Italy. Regional health authorities have implemented integrated WNV surveillance following a One Health approach, based on collaboration between human, animal and environmental health institutions. We evaluated this integrated WNV surveillance system in Emilia-Romagna, Lombardy and Piedmont regions by means of a process evaluation. We examined the system's implementation fidelity, dose delivered and received, reach, and we identified strengths and weaknesses in the system. Qualitative and semi-quantitative data were obtained from three regional focus groups. Data were discussed in a follow up focus group, where participants suggested recommendations for improving the surveillance system.

Inter-institutional and interdisciplinary integration and the creation of a 'community of practice' were identified as key elements for effective surveillance. We identified differences in the degree of interdisciplinary integration in the three regions, likely due to different epidemiological situations and years of experience in surveillance implementation. Greater collaboration and sharing of information, public engagement and economic assessments of the integrated surveillance approach would facilitate its social recognition and guarantee its sustainability through dedicated funding. We demonstrate that a transdisciplinary research approach based on process evaluation has value for designing and fine-tuning integrated health surveillance systems.

**Keywords:** West Nile Virus, surveillance, One Health, process evaluation, surveillance system evaluation

## 1. Introduction

West Nile Virus (WNV) is an arthropod-borne *Flavivirus* which has worldwide distribution. It is maintained in a sylvatic cycle between mosquito vectors, mainly of the genus *Culex*, and birds as reservoir hosts. Birds are not usually clinically affected but develop high viral titres that are sufficient to infect mosquitoes during blood meals. Mammals, especially horses and humans, are susceptible to WNV infection but are dead-end hosts because they are unable to transmit WNV to insect vectors. After infection, most people do not develop symptoms, but about twenty percent may develop mild febrile illness (WNF) and less than one percent develop severe neurological disease (WNND). Blood transfusion and organ transplantation are additional transmission routes among people. The multiple routes of transmission and species involved result in a complex public health threat that requires a holistic approach for effective disease prevention and control.

Since it was first detected in Europe in the 1960s, the virus has spread and to date is endemic in several south and south-eastern European countries including Italy (ECDC, 2020). In Italy, WNV first appeared in horses in Tuscany in 1998 and re-emerged in 2008 with the first confirmed human cases of neurological disease in the Emilia-Romagna region (Rossini et al., 2008). West Nile Virus is endemic in the Po valley area of northern Italy where regional health authorities have implemented integrated WNV surveillance systems at regional levels within the regulatory framework of the national plan for the surveillance of human vector-borne diseases. The national plan is coordinated by the Ministry of Health which in Italy includes both public health and animal health services. West Nile Virus surveillance is based on a multi-disciplinary approach, involving experts from animal, human and environmental health (Rizzo et al., 2016). The main surveillance objective is the early detection of WNV circulation in birds (mainly corvids), mosquitoes, horses, and people, at the provincial level. Early detection triggers the rapid implementation of preventive measures at the provincial level that are aimed at reducing the risk of infection in people and horses.

A description of the WNV surveillance systems in the Emilia-Romagna, Lombardy and Piedmont regions of northern Italy has been previously reported (Angelini et al., 2010; Bellini et al., 2014; Chiari et al., 2015; Pautasso et al., 2016; Paternoster et al., 2017a). Surveillance consists of a number of activities that are adjusted yearly according to the epidemiological situation during the previous transmission season. Surveillance activities include continuous syndromic surveillance for WNND in horses and humans, and seasonal surveillance (from April to November) for the detection of antibodies in sentinel birds and to detect the virus in wild birds and mosquitoes. After the first positive result in any animal species in any province, human blood donations and organs from people residing in, or having visited that province are screened for WNV. Since 2016, the regions of northern Italy have established data sharing mechanisms to improve surveillance sensitivity. They systematically share entomological surveillance data obtained from mosquito traps placed within 5 km of their regional and provincial borders. Thus, the detection of WNV in one

of these entomological traps triggers control measures for blood and organ donations in the province(s) of that same region and also in adjacent province(s).

Since 2009 integrated surveillance for WNV has been implemented in the three regions covering the largest part of Italy's Po valley; including Emilia-Romagna beginning in 2009, Lombardy beginning in 2014 and Piedmont beginning in 2016. The main actors in WNV surveillance come from different sectors including: 1) animal health: Istituti Zooprofilattici Sperimentali della Lombardia e dell'Emilia-Romagna (IZSLER) e del Piemonte, Liguria e Valle d'Aosta (IZSPLVA), Veterinary Services (Local Health Authorities - LHU), veterinary practitioners, horse farm owners, and hunters; 2) human health: Public Health Services (Local Health Authorities – LHU), regional blood centers, reference laboratories for human diagnostic; physicians, and hospitals; and 3) environmental health: entomology centers (Centre for Agriculture and Environment - CAA for Emilia-Romagna, Institute for Plants and Environment - IPLA for Piedmont). In this manuscript, we define 'actors' as a subgroup of stakeholders acting in the context of the initiative, according to Ruegg et al. (2018).

A semi quantitative evaluation of WNV integrated surveillance in Emilia-Romagna, Lombardy and Piedmont in 2016 was conducted- previously (Paternoster et al., 2017a). The purpose of the current study was to evaluate the surveillance system and develop recommendations for improvements. We used a method called process evaluation (Saunders et al., 2005), which is an essential part of the design and testing of complex health interventions such as the WNV surveillance and response system in the Po valley. Compared to quantitative evaluations, process evaluation has the added value of clarifying how health interventions can be implemented and may provide different outcomes in different contexts. Process evaluation can provide valuable information for changing and improving health interventions. This qualitative evaluation was carried out through focus groups involving actors from all three health sectors (i.e. animal, human and environmental) and all three regions under study. The main objective of the evaluation was to identify strengths and weaknesses in system planning and implementation using the knowledge and experience of the actors involved.

## **2. Methods**

### **2.1 Study design**

We conducted a process evaluation of the integrated WNV surveillance system in three regions of northern Italy—Emilia-Romagna, Lombardy, and Piedmont—using focus groups. In total, we organised four focus groups including:

- three initial focus groups, one in each of three regions under study, in order to collect information from the WNV surveillance actors in each region.

- one follow up focus group was organised in Piedmont with participants from all three regions. The fourth focus group was used to provide feedback to stakeholders about the information collected in the previous three regional focus groups, to critically appraise the outputs from the first three focus groups and to produce shared recommendations for improving the surveillance system regional and inter-regional levels (communication, solution sharing, etc.).

We followed the community-based research (CBR) approach in public health (Israel et al., 1998) by collaborating with the communities of practitioners involved in planning and operating the WNV surveillance system in the study area. According to CBR concept, communities and people are not objects of research, but agents, or co-researchers.

The process evaluation was designed to examine key elements of the WNV surveillance system, according to Saunders et al. (2005): (i) implementation fidelity, defined as the extent to which the surveillance activities were implemented as planned in the WNV regulatory framework; (ii) dose delivered, i.e. the completeness of the interventions; (iii) dose received, i.e. extent to which participants actively were engaged and satisfied with the plan; (iv) reach, i.e. participation rate of actors and stakeholders.

Results were produced through qualitative (transcript of recordings) and semi-quantitative (questionnaire) data obtained in the three regional focus groups. These findings were discussed in the follow-up focus group involving all three regions, where researchers and participants identified strengths and weaknesses and suggested recommendations to improve the WNV surveillance system.

## **2.2 Study area and period**

Emilia-Romagna, Lombardy, and Piedmont (the study area) have a combined resident population of about 18.9 million inhabitants, corresponding to 31.4% of Italy's population (ISTAT, 2019). The four focus group discussions were conducted between December 2016 and May 2018. We carried out the first three regional level focus group discussions, at the headquarters of the Regional Health Authority in Bologna (Emilia-Romagna) and in Milan (Lombardy), and at the University of Turin (Piedmont) between December 2016 and January 2017. The fourth "follow up" focus group which included participants from all three regional focus groups was held in Piedmont in May 2018.

## **2.3 Process evaluation**

**Study participants.** Focus group participants were selected using purposive sampling, which included participants who share particular characteristics and have the potential to provide rich, relevant and diverse data about the research question (Tong et al., 2007). In total 24 participants were selected. They included representatives and experts from different disciplines (entomology, veterinary and human health) and from the public health institutions involved in WNV surveillance

within the study area. The variety of disciplines and sectors, along with participant experience in WNV were the main criteria for the inclusion of participants.

To identify potential study participants, we sent emails explaining the objectives of the study to regional representatives, asking them to nominate up to 9 potential participants from their region to attend one of the three first regional focus group meetings. For Emilia-Romagna and Lombardy, the email was sent to a representative of the existing trans-disciplinary groups working on WNV surveillance. These “working groups” are voluntary (i.e. not required by law) and have established information flows and regular meetings of stakeholders involved in WNV surveillance (Paternoster et al., 2017a). In Piedmont, where an established working group was not present, we contacted representatives of the different institutions participating in WNV surveillance as required by regional legislation. For convenience, these participants were also called a “working group” in this study.

Three participants per region (representing human, animal, and environmental health) were invited to the follow up focus group. The follow up focus group was held in Piedmont as this was a convenient location for research team. Due to the long distance of Piedmont from Lombardy and Emilia-Romagna, only one participant from these two regions was present in the last focus group discussion. Characteristics of focus group participants are detailed in Table 1.

**Research team.** Focus groups were moderated by two interviewers (one professor of sociology, and one research assistant) with extensive experience in qualitative research and focus group discussion moderation. The interviewers did not have any previous relationships with participants prior to the study.

Two facilitators (one researcher and one PhD assistant professor, both doctors in veterinary medicine) introduced the study objectives, the interviewers, and informed participants that the session would be recorded (audio only). These two facilitators had previous established research collaborations with some of the focus group participants. A third facilitator (veterinary medicine student), who had no previous contact with focus group participants, audio recorded the focus group discussion, and then transcribed, cleaned, and analysed transcriptions under the supervision of the interviewers and facilitators.

**Study of the regulatory framework of WNV surveillance.** We gathered information about the regulatory framework of WNV surveillance as a reference for assessing the implementation fidelity of the surveillance system in each of the three regions. We considered both soft law and hard law as legal sources. Soft law, such as protocols and technical/scientific instructions for sector operators (e.g. veterinarians, medical doctors, entomologists, biologists), introduced valuable legal effects into the public health institutions and systems. Since the WNV surveillance regulatory framework includes different levels of government, we collected legal references at the European, national, and regional levels. The description of the regulatory framework used in this study is detailed elsewhere (Paternoster et al., 2017a).

**Regional focus groups.** The research team used audio recording during the three regional focus group discussions. The duration of each meeting was 90 minutes. We structured the outline (main discussion topics presented in Table 2) following the key elements of a process evaluation plan: fidelity, dose delivered, dose received and reach (Saunders et al., 2005). During focus group discussions, one interviewer asked participants neutral and open questions on the surveillance system and its regulatory framework. The interviewer used prompts to obtain more detailed answers whenever respondents' answers were unclear or unspecific and took notes on a large flip chart that was visible to all focus group participants. The second interviewer took notes about his impressions of the group dynamics and non-verbal communication.

At the end of each regional focus group, a questionnaire was distributed to collect written responses about the participants' degree of satisfaction with the planning and implementation of the WNV surveillance system and their role within it (Table 3). Respondents could select a score from "1" ("totally unsatisfied") to 10 ("fully satisfied") and add additional written comments. These data were collected to examine the dose received and to gain insights on strengths and weaknesses of the WNV surveillance system as reported by participants. Regional focus group questions were developed in Italian and were not provided to participants before the meetings.

**Follow up focus group.** Participants from the three regions were invited to the follow up focus group, which also lasted 90 minutes and was audio recorded. The focus group outline included discussion points that emerged from the analysis of the transcripts and questionnaires obtained during the regional focus groups. Participants in the follow up focus group discussed and validated findings, and developed a shared analysis of the results. During the discussion, the interviewer focused the discussion on the results in order to more clearly describe suggestions to improve the surveillance system.

**Data analysis.** The regulatory framework for WNV surveillance was examined by identifying actions, procedures, actors, information, and sample flows in a schematic way. This summary was used as a reference to structure questions and prompts during the regional focus groups.

After transcribing the audio recordings of the regional focus groups, we evaluated implementation fidelity using the description of the surveillance system provided by participants in relation to the regulatory framework. We analysed dose delivered, dose received, and reach of the initiative. All transcripts were divided into three topics: i) opinions on the surveillance regulatory framework and implementation, ii) communication flows within and outside the "working group", and iii) weaknesses of planning and implementation. We analysed the transcripts using a thematic content analysis (Braun et al., 2019) with a coding framework to identify patterns and themes. We also collected indicative quotes from the participants.

We analysed the questionnaires from the regional focus groups by computing the range and median of the scores for the four questions. We evaluated significant ( $p < 0.05$ ) differences by region, years of professional experience, gender, and professional background, using non-



parametric tests (Wilcoxon test and Kruskal-Wallis rank sum test). We then grouped the main concepts reported as positive or negative to be used to identify the main strengths and weaknesses in the WNV surveillance system. Transcriptions of the audio recordings were not returned to focus group participants for comments. Instead, results of the analysis were presented and used to prompt discussion with participants during the follow up focus group.

### 3. Results

#### 3.1 Regional focus groups: main discussion points

##### 3.1.1 Strengths of surveillance planning and implementation

Participants from all three regions fully agreed on the importance of the high level of integration among actors and public health institutions present within the WNV surveillance regulatory framework. This integration reflects transdisciplinarity, a core aspect of the One Health (OH) approach. Transdisciplinarity is defined as the integration of knowledge and perspectives of different sectors and disciplines (Ruegg et al., 2018). Our qualitative data revealed an overall high level of fidelity to the regulatory framework, especially in Emilia-Romagna:

*In Emilia Romagna regulations are usually respected. [...] We make an effort to write what we can do* [Focus group Emilia-Romagna]

Integration emerged from our study at institutional, disciplinary and personal levels. Institutional integration was reported to be crucial and much needed by participants from all three regions because WNV surveillance involves several public and private institutions. Interdisciplinary integration was also reported to be crucial because WNV surveillance requires joint intervention by professionals from different disciplines, with different expertise, knowledge and cultural approaches. This interdisciplinary exchange was reported to be beneficial for an effective response.

*Thanks to interprofessional collaboration we manage to anticipate, as (a colleague) said before, the viral circulation (WNV presence in animal hosts) in the territory, so the blood plan (testing blood donations for WNV) is not triggered, which is much more expensive [...] Our goal is health, achieved in the best way and at lowest costs* [Focus group Emilia-Romagna]

Actors participating in WNV surveillance reported the importance of their voluntary organisation into working groups in Emilia-Romagna and Lombardy:

*Deciding whether to enhance the (mosquito) trapping and the collection of the samples in one place rather than another is not obvious, for this reason we discuss [...] you can understand that it is a very complex process, because there are so many animal species, so many professionals* [Focus group Emilia-Romagna]

Differently, representatives of institutions involved in WNV surveillance in Piedmont interact as proscribed by the regional law, and no voluntary working group has yet been established:

*In our region, I have to say that there is not a real working group, just relationships. We collaborate well with IPLA (i.e. the entomological centre) [...] however we really should create it (a real working group) because the working group means meeting before an activity, and thinking together on how to organize an activity [Focus group Piedmont]*

### **3.1.2 Communication flows within and outside the “working group”**

Although information flows to create a chain of coordinated communication are required by law, our analysis highlighted that integration at the personal level through informal and non-codified relationships among actors were positive aspects of the surveillance system. This type of integration was reported by participants as an increase in the degree of sharing of objectives, resources, languages and operating practices.

There were differences among regional working groups in the frequency in which meetings were held (Paternoster et al., 2017a). In Emilia-Romagna, informal relationships and communication flows were reported to be a consolidated practice. When a human sample tests positive for WNV, this is communicated to the whole working group, not just to the institutions that are required to be informed by law. Participants did not report this to be a redundancy in information communication, rather they reported it as an information alignment within the working group:

*Information on positive samples travel by email [...]. We have this mailing list, which has been built and modified over time [...], if I send the information to the mailing list it means that I send it to the group [...] which is composed of all [working group's] components and professionals [Focus group Emilia-Romagna]*

In Piedmont, participants reported that the official communication flow followed the requirements of the regulatory framework:

*(Regarding) the timeliness of the information [...] we should receive, according to the protocol, communications via certified mail<sup>1</sup>, but our center does not have its own certified mail; we rely on the certified mail of our General manager, who does not always notify us before 12 hours [...] so, if we don't get an unofficial phone call or even a non-certified email, we risk not retrieving it [Focus group Piedmont]*

### **3.1.3 Weaknesses of surveillance planning and implementation**

Focus group participants reported weaknesses in the dose received and the reach of WNV surveillance. In particular, they reported difficulties involving the actors and stakeholders responsible for active surveillance of birds. They reported that this was due to economic limitations for refunding the hunters Emilia-Romagna and due to scarce involvement and training of provincial police officers in Lombardy. The problem was reported to be the result of recent organizational and institutional changes at the provincial level:

*Another critical point, for the veterinary area, is bird sampling and testing: the hunters that previously received from the province authorities a refund for gasoline and bullets used for birds captures, now work on a voluntary basis, due to the suppression of provinces [Focus group Emilia Romagna]*

*In my opinion, a big deficiency of the plan is active surveillance on birds [...] it is carried out by provincial police officers that 95% of the time are obliged to carry out this activity, sometimes they don't even reach the minimum numbers of samples requested. In my opinion (this happens) also because they don't understand why they must do it. This will be an increasingly complicated aspect of surveillance in future years due to the recent organizational changes in the provinces' asset [Focus group Lombardy]*

Also, general practitioners, municipalities and equine veterinarians were reported to be scarcely involved in the surveillance system:

*In my opinion [...] professionals who were a little "excluded" in these years are general practitioners [Focus group Lombardy]*

*[...] motivating municipalities that are in charge of disinfection (against mosquitoes) to do their job well could be an improvement [Focus group Lombardy]*

*Veterinarians who deal with equine pathology in Lombardy are much less attentive and perceptive about this problem than [...] in Emilia-Romagna, where disease history is more established and there is probably more attention to horse vaccination [Focus group Lombardy]*

Information feedback on confirmed human cases was perceived as a weakness, especially for veterinarians:

*However circular feedback is missing. We, from the veterinary side, report our cases to everyone but then return of information is missing, there is no feedback [Focus group Piedmont]*

Social recognition of the surveillance system was reported to be weak by regional focus group participants:

*There is little appreciation, there is little perception of what is the intrinsic value of this activity, and also the public health benefits that derive from it [Focus group Lombardy]*

Focus group participants reported difficulties due to short term limited financial resources:

*The first critical point I would like to highlight is linked to resources. This [the WNV surveillance system] is an activity that has a variable trend during the year and therefore consumes resources in a limited period of the year. This is never a good thing for a public institution, because it [public health institutions] do not have the flexibility to hire seasonal staff [Focus group Emilia-Romagna]*

*The critical aspect that we face as entomologists is the fact that entomological surveillance activity ends up in the large “mosquito monitoring and control project” in Piedmont, which is financed every year. [...] So, every year until April, or sometimes May it is not known if this project will be financed or not. [...] This is a critical point because it does not allow [us] to plan the activity and to train the staff properly [Focus group Piedmont]*

Finally, focus group participants highlighted the lack of flexibility in the national surveillance plan with respect to the duration of entomological surveillance. Nation regulations require entomological surveillance to continue until the end of November. Participants suggested that because of the climatic characteristics of northern Italy entomological surveillance could be interrupted before the end of November based on the results of the yearly regional surveillance up to that time. This would be a cost saving but it would maintain the current high level of safety of the system:

*‘The Health Ministry said that the activity [entomological surveillance] should be continued until November and we had to do it until November, although our data suggest that we could suspend it in September, so in this way the national plan is rigid’ [Focus group Lombardy]*

### **3.2 Regional focus groups: questionnaires**

Of the 24 regional focus groups participants, 21 (88%) completed and returned questionnaires aimed at describing their degree of satisfaction with the planning and implementation of the WNV surveillance system and their role within it. We aggregated the participants' written answers by topic and scored (median and range) for each of the four questions (Table 3).

Over all respondents reported a high degree (median score = 8.0) of satisfaction with the planning of the surveillance system (question 1). We found a significant difference between the median score among participants from Piedmont (score = 7.5) compared to participants from the other two regions (score = 8.0) (Kruskal-Wallis rank sum test,  $p = 0.02$ ). Participant satisfaction with the implementation of surveillance (question 2) also scored high (median score = 8.0), with no significant difference between regions. Respondents were very positive about their own role in the surveillance system (question 3 median score = 9.0, and question 4 median score = 8.5) with no significant difference between regions. There were no significant differences in the scores reported by respondents to all four questions for gender, years of professional experience or professional field. The main positive aspects reported by respondents were the high level of collaboration and cooperation between actors with a clear definition of roles and tasks that guaranteed an efficient and cost-effective surveillance system. The main negative aspects reported were the scarce feedback of information (among different health sectors and actors, especially from the human health domain) and the insufficient funding for surveillance activities.

### 3.3 Follow-up focus group: main findings

Within regional focus groups, researchers observed strong alignment of the surveillance plan implementation to the regulatory framework (fidelity), complete implementation of planned interventions (dose delivered) and a high degree of satisfaction of the actors with the plan and their involvement in it (dose received). Some critical issues that emerged were the low degree of active engagement of some actors (dose received) and the low participation of general population and some actors (e.g. hunters in Emilia-Romagna, provincial police officers in Lombardy, general practitioners, municipalities and equine veterinarians) (reach). In the final focus group, we discussed possible corrective actions for these issues with participants. Three main themes were addressed: 1. communication among actors and stakeholders and collaboration among regions; 2. social recognition of the surveillance system; 3. funding.

#### 3.3.1 Communication among actors and stakeholders and collaboration among regions

During regional focus group discussions, informal communication emerged as the strategy most commonly used for rapid and effective circulation of information. But it was also useful for creating more integration at the personal level, for example:

*Email is used to say “I communicated this to you”, the phone call is used to verify if whoever receives the email is on vacation or not, if he or she is at work or not, because we should keep in mind that this activity takes place in July or August. Therefore, people may be on vacation, in a place where they cannot see the email [participant from Emilia-Romagna]*

*In my opinion a phone call is also important because it is a way to make less formal, aseptic, the relationship with the interlocutor. Therefore, there is also that interaction, collaboration, exchange [...] [participant from Lombardy]*

The interviewees suggested enhanced use of technology could facilitate better communication exchanges within the group. For example using institutional smartphones to read email messages even when outside the workplace, and increasing the importance of formal communication (using certified e-mails):

*If all of us had means to read institutional emails everywhere, then it would be fine. But my work phone does not have these functions [...] so, it is the phone call that triggers an alert on an important thing [participant from Piedmont]*

Where absent, the creation of communication mailing lists would be useful to ensure all surveillance actors were notified and to ensure wider circulation of information. One participant emphasized that:

*The first positivity in a province gives the start to “everything”, but who makes this diagnosis, even before preparing the test report, sends an email to the whole group, in which there are all the regional levels and also the regional blood center, which, in turn,*

*acts as an intermediary for the national blood center, that decides if starting the controls on blood donations [...] [participant from Emilia-Romagna]*

In Emilia-Romagna, communication and collaboration within the working group were reported to be consolidated and efficient. This has resulted in the creation of other interdisciplinary working groups that tackle several other diseases under the leadership of the regional health authority:

*We are now trying to create other groups: the group on foodborne diseases, there is already another group that works on antibiotic resistance [...] but in my opinion this is the way: by creating working groups, also involving [...] colleagues working in the territory, because there are remarkable professionals in the area [...]. The problem is that the more institutions are involved, the more difficult it becomes to collaborate. Having a single head anyway at a regional level, which gives funding, gives directives... it is definitely an advantage [participant from Emilia-Romagna]*

Communication between regions was described as very efficient in the context of the inter-regional data sharing system for entomological surveillance data:

*So, we have these "talking traps"...you know why they are called talking traps? [...] The progress of the surveillance plan was examined from year to year and we identified some gaps, and among these gaps there was the fact that it could happen that a (entomological) trap was administratively in a province and the human case occurred five kilometres from the trap, but in another province - where the surveillance on the blood had not been activated, or in another region. Therefore, we decided that the traps close to the administrative boundaries could 'talk' to more than one region or province [participant from Emilia-Romagna].*

However, one participant reported the need for greater collaboration between professionals who carry out the same activity in the three regions as a way to exchange best practices and experiences:

*I deal with mosquito sample identification and I have direct knowledge about the positioning of mosquito traps. I would like to talk with the people doing this job in Lombardy, In Emilia Romagna, etc. [...] to see if there are innovations, for example on how to keep the refrigerated counter where we put mosquitoes [...] then the best practices from all the Regions can be used [...] [participant from Piedmont]*

This collaboration could facilitate the formulation of specific change requests that could be sent to the national health authority (i.e. Ministry of Health) for their consideration. This could result in beneficial changes to the current regulatory framework, that would be based on the collective experience within the three regions:

*We used to meet all together and our inter-regional meetings were aimed at formulating collective requests to the Ministry, to give more weight to our requests. Everything is then*

*translated into a national intervention plan, which is then distributed into regional plans [...]*  
[participant from Emilia-Romagna]

### **3.3.2 Social recognition of the surveillance system**

Focus group participants reported that greater integration within the working groups made them more 'attractive' to participants, more capable of transmitting the 'sense of the norm' within the working groups, and more able to inform and involve more actors, stakeholders and citizens:

*My opinion is that this should not be limited to this specific topic only, but there should be a sort of ritual frequent habitual visiting of cross cutting issues, as it happens in other countries, for example in The Netherlands, where public and veterinary health professionals meet every month to exchange ideas and make decisions [...]. With such greater knowledge, greater frequency, and a stronger habit of sharing, it would be easier to overcome uncertainties [...]. I believe that real thinking in terms of One Health should be promoted and facilitated by regional institutions, by creating consultative bodies or working groups that can periodically discuss all the health issues, of course not only West Nile [...]. I believe that this would absolutely help in the development and application of surveillance plans in an area [participant from Lombardy]*

Strong central coordination of regional activities, as well as the creation of specific working groups for health issues were reported by participants to be strategic elements for creating ideal conditions for integration.

According to some focus group participants better integration resulted in the legitimization and social recognition of the value of the surveillance system. This resulted in better citizens' awareness of West Nile disease and the importance of personal prevention (e.g. protection from mosquito bites, reduction of domestic sources for mosquito breeding, etc.).

Several participants reported the importance of better communication to the public for improving prevention of WNV infection using citizen science. This would also provide an opportunity for gathering additional surveillance data:

*The fact of giving correct and timely information (to citizens) may be considered a form of "prevention" [...] Do not wait for it to become the subject of a general psychosis, or sensational tabloid [...] Correct information, given in advance, is always the best thing [...] maybe we should transmit the scientific message...with a more youthful spirit, to try to convey information with more modern methods. [...] We are also talking about citizen science, about citizens as users but perhaps we should understand how helpful they can be in acquiring information [participant from Lombardy]*

*First, in the case of reporting problems, (citizens) could actually be encouraged to report cases that occurred in relatives, friends, acquaintances, and this could be for all infectious diseases [...] On the other hand, as for preventive measures, citizens can play an active*

*role in (mosquito) bite prevention. Prevention of vector-borne diseases mainly consists of individual prevention. We have not yet decided which is the best way to communicate this message to people, but it is essentially individual prevention [participant from Emilia-Romagna]*

Another suggestion for reaching the general population was to encourage more active involvement of general practitioners. They are considered to be 'neglected' actors in the current system who are often unaware of WNV surveillance activities. Participants reported that, although general practitioners rarely diagnose West Nile disease as it is usually diagnosed at hospital level, they often represent the first, trusted communicator to citizens about health issues making them key figures for informing the public about individual protection and prevention:

*The activity [of informing and involving] general practitioners has a cost, however informing them could lead to data return, to something more...also because now that this surveillance is in place, adding "something more" would be useful, wouldn't it? [...] it is not possible that general practitioners are not aware of this activity [...] in my opinion, general practitioners are especially important for activities like this one [participant from Piedmont]*

### **3.3.3 Funding of the surveillance system**

Participants explained that the seasonal activity of mosquitoes and occurrence of the disease makes WNV surveillance a routine but seasonal activity which is currently funded by short-term research projects. They reported that it is essential for WNV surveillance funding to be included in regional prevention plans. This would provide stable, possibly multi-year funding and would facilitate better planning:

*Three-year funding would be ideal to deal with this type of problem. Those of us who deal with regional public administrations know well how budgets are often approved annually and three year budgets may change, so funds given in 2018 [...] may decrease or disappear in 2019 [participant from Piedmont]*

Participants also reported the importance of conducting economic evaluations of the WNV surveillance system in the study area using surveillance data from all three regions to quantify the costs and benefits of the high level of integration existing between them. This analysis was previously done in Emilia-Romagna (Paternoster et al., 2017b) and demonstrated that integrated One Health approaches can be cost saving. This was and was recalled by two participants:

*In my opinion, another thing [...] that is fundamental is an economic analysis, proving that this activity is cost-saving from an analytical point of view...it is a matter of fact [...]; it is an element on which even the politicians are particularly sensitive... Available data suggest that savings are considerable, in the order of millions of euros [participant from Lombardy]*



*We are trying to show that this type of surveillance is cost-saving, because what is spared in (undone) blood transfusion testing covers the surveillance costs. Moreover, with this surveillance activity, we collect other data that may be useful even in other situations*  
[participant from Emilia-Romagna]

#### **4. Discussion**

In our process evaluation we analysed operational WNV surveillance systems in three regions of northern Italy. During three initial regional focus groups, we assessed the completeness of the interventions, the engagement of stakeholders, and identified barriers to implementation. In a follow-up focus group, we worked collaboratively with surveillance actors (study participants) to produce suggestions for improvement of the legislation, taking into account practical issues that could potentially negatively affect surveillance implementation. Our evaluation was a participatory approach which included some actors who were both producers and implementers of their regional surveillance legislation. For this reason, both policy level decision-makers and actors involved in the day-to-day activities of the surveillance system will find the results of our study useful. Future process evaluations could monitor improvements in surveillance activities and the effectiveness of steps taken towards a more integrated approach to health.

Our transdisciplinary research approach is novel in the domain of infectious diseases surveillance. It is our opinion that this type of approach will be valuable for evaluating and improving other disease surveillance systems in different geographical and socio-economic contexts.

Transdisciplinary approaches that include people from the social sciences are essential for exploring socioeconomic drivers of infectious diseases spread and for increasing the effectiveness of surveillance. We recommend more extensive use of these approaches in public health research. Future research could use similar tools to explore the organisational and social context conducive to more effective One Health surveillance. The focus groups were essential as they provided an in-depth description of surveillance operations and they highlighted the importance of interpersonal dynamics between actors involved in the process. Despite the complexity of data analysis for comparing regional differences in the internal cohesion of each “working group”, the focus groups were an effective tool for clarifying the importance of the quality and intensity of relationships between groups and individuals.

Currently there is a growing body of literature about methods for the evaluation of integrated approaches to health (Jerolmack, 2013; Binot et al., 2015; Ruegg et al., 2018). These studies have identified both key aspects of One Health (OH) and difficulties in implementing integrated health initiatives. Several studies have demonstrated the benefits of OH approaches for specific disease surveillance and control programs. For example, in Emilia-Romagna, WNV integrated surveillance has been reported to be efficient in preventing WNV transmission via blood transfusion and efficient in cost saving (Paternoster et al., 2017b). This contrasts with the 2000 WNV epidemic in

the USA where the delay in controlling the epidemic was attributed to scarce communication between public and animal health institutions which resulted in failure to link the animal and human outbreaks (GAO, 2000). Several other examples have demonstrated the benefits of OH approaches to disease surveillance and control (e.g. for anthrax, tuberculosis, brucellosis, etc.) (World Bank Group, 2012). Globally, transdisciplinary actions to address complex health issues have been promoted (FAO-OIE-WHO, 2010 and 2017). However, there are barriers to transdisciplinary research and policy development (OECD, 2020), including limited institutional capabilities, scarce information sharing, financial constraints, and under-reporting of disease cases (World Bank Group, 2010).

Some of these barriers emerged during our process evaluation even though actors participating in WNV surveillance in northern Italy reported a high level of satisfaction with surveillance planning and implementation and with their role in the surveillance system. Barriers emerged during focus group discussions and from the questionnaire analyses. Comments were predominantly positive and could be grouped in broad macro-categories (good collaboration among actors, efficient/cost-effective surveillance, etc.). Negative aspects were more varied and were linked to individual perspectives. There are two potential explanations for this observed contradiction. The first explanation refers to the so-called 'social desirability bias' (Marlow and Crowne, 1961; van de Mortel, 2008). It is reasonable to assume that some of respondents over-reported their satisfaction. Over-reporting may have been lower when respondents provided answers for single specific aspects (e.g. weaknesses in individual tasks or phases of the process) and higher for elements such as good cooperation among actors or cost-effectiveness of the system which could be perceived as indicators of success/failure of the surveillance system as a whole. The second explanation is based on organizational learning theory. According to this theory people working in organisations learn from their mistakes (Nicolini et al., 2003). Therefore, respondents can easily recognize when learning occurred when reporting about specific activities although they do not associate individual tangible practices into the broad macro-categories mentioned above. Both explanations are possible. They are not mutually exclusive, but we consider the second one more convincing.

We observed a strong allegiance between plan implementation and the regulatory framework. Although surveillance implementation differed across regions, integration and sharing of objectives and knowledge across health sectors was considered to be of key importance by all participants. Participants acknowledged that collaboration and integration of different skills and expertise was particularly important. In addition to activities and information flows required by law, common objectives, resources and language, emerged and were essential for the implementing the plan. The indicators for the integration observed in the regional working groups were the frequency and methods of meetings and the presence of informal practices and communication flows. Integration was based on trust and interactions between people, which led to the creation of stable working

groups with clear and recognized leadership. We observed the highest degree of integration in the working group from Emilia-Romagna. It was expressed as a community of practice, i.e. a "group of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis" (Wenger et al., 2002). The codified and uncodified habits of the actors involved in the plan evolved over time and were strengthened within these communities. A community of practice is "attractive" to the outside, in the sense of involving, training and informing stakeholders and obtaining greater social recognition. The differences in the degree of integration within the working groups of the three regions under study can be linked to different forms of financing and regulations. Variable financing and integration also affect plan implementation and the organization of activities, thus affecting relationships between actors and institutions. Second, the degree of integration of WNV working groups mirrored their duration of existence. Emilia-Romagna was the first region affected by WNV and had already established an interdisciplinary group in 2007 in response to the Chikungunya epidemic in the region. Over the years, this group has consolidated and as the working group gained experience.

Lack of communication (especially poor feedback and information sharing) and poor information provision to stakeholders and citizens were identified as weaknesses in the plan. In the follow-up focus group, participants suggested that the creation of "mailing lists" that included all surveillance actors and more extensive use of technology (e.g. smartphones) could help to overcome information feedback issues and facilitate more rapid information exchange. Participants also suggested strengthening communication and collaboration among different regional working groups and institutions, which could lead to a "sharing of practice" among professionals who are in charge of the same activity (e.g. vector trapping) in different regions. Another suggestion was more active involvement of general practitioners who are fundamental for risk communication to citizens and may play an important role in explaining how to prevent the disease, especially in endemic areas. Finally, enhancing the use of social media and websites was seen as potentially useful for involving stakeholders and citizens and communicating information to them. There are good examples of WNV websites that target the public in the USA (e.g. <https://westnile.ca.gov/>; <https://vectorsurv.org>). Communicating via social media may also result in better social recognition of the surveillance system. Some actions in this direction have already been undertaken. In 2020, Emilia-Romagna launched an app to inform the public about mosquitos and mosquito transmitted diseases, provide advice to citizens about dealing with mosquitos, and to collect data on citizens' approaches for dealing with mosquitos (<https://zanzaratigreonline.it/it/comunicazione/app-zanzar-rer>).

Under funding and short-term funding of surveillance activities emerged as a weakness in the plan. Uncertainty and lack of continuity in the allocation of resources was reported to make the programming of surveillance activities difficult. The absence of *ad-hoc* allocation of funds for WNV

surveillance suggests a lack of social recognition of this activity primarily by the political decision-makers. Shared finances is beneficial for OH initiatives but is constrained by low and unequal budget allocations. In particular, environmental and animal health institutions generally have significantly lower financial resources for disease control than public health institutions (World Bank Group, 2010). To overcome this weakness, participants in the follow-up focus group proposed including surveillance activities in regional prevention plans which are multi-year. To achieve this goal, participants stressed the importance of carrying out economic evaluations of the OH approach in WNV surveillance, similar to what was done in Emilia Romagna (Paternoster et al., 2017b), and in addition to evaluate the efficiency of the system (Calzolari et al., 2020).

Infectious diseases, such as West Nile disease pose increasing challenges to public health worldwide. The current Covid-19 pandemic demonstrates the urgent need to adopt OH approaches in health policy making. The challenge is putting OH into practice through health governance and promotion that embraces animals and the environment in addition to humans. Disease impact can be mitigated by the adoption of integrated interventions (Semenza and Zeller, 2014; Zinsstag et al., 2018) and our study demonstrates the importance of undertaking evaluations to assess how these interventions are being implemented, in order to fine tune their activities. In particular we stress the importance of a 'participatory evaluation', which considers the local context and includes the input from actors that implement surveillance in the field. This will help to identify weaknesses and find solutions to overcome barriers to integrated approaches. Recent experience with Covid-19 supports this approach as interventions have been shown to be more successful in territories where integration of different professionals was achieved (e.g. territorial public health and specialist medical institutions). This 'place-based' surveillance, rooted and specific to a territory may be successful for dealing with health threats using a public health approach that is supported by interdisciplinary research, intersectoral policies, and effective health governance.

#### Footnotes

*Page 9:* <sup>1</sup> Certified e-mail is an electronic system that provides the legal equivalent of a traditional registered letter. This system is used in Italy as well as in Switzerland, Germany and Hong Kong.

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Region	Emilia Romagna (n=8)	Lombardy (n=7)	Piedmont (n=9)
Gender:			
Female	3	2	5
Male	5	5	4
Profession:			
Physician	1	3	2
Veterinarian	3	4	3
Biologist	2	-	1
Entomologist	2	-	1
Agronomist	-	-	1
Other	-	-	1
Years of experience in professional field:			
Less than 5	-	-	-
5 to 10	-	4	1
More than 10	8	3	8

Table 1. Characteristics of participants of the focus groups in the three regions (sex, profession, years of experience in their professional field)



	Main discussion topics
Fidelity	The interviewer asked neutral and open questions related to activities that had been planned and implemented, how, by whom, and why precisely those activities.
Dose delivered	The interviewer asked neutral and open questions about important activities that had not been planned and why. She asked whether there were any critical aspects in the plan implementation and possibly why they were critical.
Dose received	The interviewer asked neutral and open questions related to the “meaning” of the surveillance. Specifically, she asked whether participants believed the surveillance was “useful”. If it was reported to be useful, for what, and if not, why not.  In addition, she investigated whether the “sense of the norm” had been achieved and shared by all the surveillance actors, whether training had been provided to all actors in order to get their active involvement and understanding.
Reach	The interviewer asked neutral and open questions related to critical points in communication in the surveillance system.  She asked questions to understand the degree of social recognition of the value of the surveillance system; whether there was a shared public opinion about the usefulness of the integrated surveillance and appreciation of its intrinsic value, and, if not, why. In addition, they asked questions about the degree of public (public opinion, blood donors, funding institutions, etc.) engagement and awareness of the West Nile virus issue.

Table 2: Main discussion subjects of the three regional focus group

Question	Score: median (range)	Positive aspects reported (n of answers)	Negative aspects reported (n of answers)
1. "How satisfied are you with the surveillance system's planning?"	8.1 (6 - 9)	<ul style="list-style-type: none"> <li>- High level of collaboration between actors (n=16)</li> <li>- Clear definition of actors' roles and tasks (n=3)</li> <li>- Efficiency (n=3)</li> <li>- Cost-effectiveness (n=3)</li> </ul>	<ul style="list-style-type: none"> <li>- Scarce funding (n=4)</li> <li>- Scarce epidemiological in-depth analysis (n=3)</li> <li>- Lack of/scarce feedback from the human health sector (n=3)</li> <li>- Programming defects of some activities, e.g. birds captures, identification of 'talking traps' (n=2)</li> <li>- Scarce exchange of information among Regions (n=1)</li> </ul>
2. "How satisfied are you with the surveillance system's implementation?"	8.3 (7 - 9)	<ul style="list-style-type: none"> <li>- High level of collaboration between actors (n=7)</li> <li>- Rapidness and effectiveness of surveillance activities (n=6)</li> <li>- Cost-effectiveness of the surveillance system resulting in savings for the health system (n=3)</li> <li>- Clear definition of actors' roles and tasks (n=3)</li> </ul>	<ul style="list-style-type: none"> <li>- Lack of/scarce feedback from the human health sector (n=2)</li> <li>- Presence of specific 'languages' (jargon) of each discipline involved (n=1)</li> <li>- Scarce information to veterinarians and general practitioners (n=1)</li> <li>- Scarce information to the citizens (n=1)</li> <li>- Lack of involvement of some stakeholders (e.g. general practitioners, hunters) (n=1)</li> <li>- Absence of <i>ad-hoc</i> funding for veterinary surveillance activities (n=1)</li> <li>- Scarce flexibility in surveillance implementation (n=1)</li> <li>- Scarce general awareness on the importance of surveillance (n=1)</li> </ul>
3. "How satisfied are you with your planned role in the	8.4 (6 - 9)	<ul style="list-style-type: none"> <li>- Coordination and cooperation between actors with a clear definition of actors' roles in the</li> </ul>	<ul style="list-style-type: none"> <li>- Scarce appreciation or definition of own role in surveillance (n=3)</li> <li>- Lack of/scarce feedback of information (n=2)</li> </ul>

surveillance system?"		<p>surveillance system results in appreciation of their work (n=10)</p> <ul style="list-style-type: none"> <li>- Own role in the surveillance system defined as "key" (n=4)</li> <li>- Decision-making autonomy (n=2)</li> </ul>	<ul style="list-style-type: none"> <li>- Shortage of funding (n=2)</li> <li>- Difficult relationship with local authorities (n=1)</li> <li>- Waste of time due to programming defects of some activities (n=1)</li> </ul>
4. "How satisfied are you with your implemented (i.e. actual) role in the surveillance system?"	8.4 (6 – 9)	<ul style="list-style-type: none"> <li>- Contact and cooperation among experts of the three sectors to decide measures to be taken on a case by case basis (n=5)</li> <li>- Own role defined, and own competences and expertise appreciated (n=4)</li> <li>- Good functioning of the surveillance system, especially entomological surveillance and rapid communication of positive samples (n=2)</li> <li>- Involvement in education/training activities (n=1)</li> </ul>	<ul style="list-style-type: none"> <li>- Lack of/scarce feedback of information (n=2)</li> <li>- Need for better training/education (n=1)</li> <li>- High workload (n=1)</li> </ul>

Table 3. Summary of the written answers provided by regional focus group participants about their satisfaction with the planning and implementation of the WNV surveillance system and their role within it. Scores were on a 10-point numeric scale from 1 (totally unsatisfied) to 10 (fully satisfied).

**Author contributions**

MM: Data curation, Formal analysis, Investigation, Writing- Original draft preparation; GP and LT: Conceptualization, Methodology, Investigation, Formal analysis, Project administration, Resources, Writing- Original draft preparation; GB, ARF: Conceptualization, Methodology, Investigation, Formal analysis, Writing- review and editing; Regional Working groups: Investigation, Writing - review & editing; JB: Writing - review & editing.

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