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Risk Assessment Group

PRIMARY RISK ASSESSMENT

cVDPV2 DETECTION IN MULTIPLE EUROPEAN COUNTRIES

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Date of the signal	Date of the RA	Signal provider	Experts consultation	Method
Various	**11/12/2024**	**Sciensano**	**Permanent experts:** Jean-claude Nyakiokibonga (AViQ), Bertrand Draguez (FOD/RMG), Anna Schmelz (DGOV), Heidi Theeten (Departement Zorg), Jorgen Stassijns (RAG coordinator, Sciensano), Adrae Taame (Vivalis). **Specific experts :** Kimberley Hansford (Sciensano – epi vaccine-preventable diseases), Laura Cornelissen (Sciensano – epi VPD), Veronik Hutse (Sciensano – wastewater epi), Marie Lesenfants (Sciensano, wastewater epi), Bavo Verhaegen (Sciensano – lab testing), Koenraad Vanhoorde (Sciensano – lab testing), Steven Callens (UZ Gent, HGR vaccinatie), Dimitri Vanderlinden (UCL), Elke Wollants (UZ Leuven, NRC poliovirus), Paloma Carrillo (ONE cellule vaccination), Pierre Van Damme (UAntwerpen), Ilse Decoster (UAntwerpen, NVC polio eradication), Lien Bruggeman (Fedasil), Bart Hoorelbeke (FOD/RMG)	Online meeting
Date of update	**Closing date**			

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SIGNAL	Several countries in the EU have reported detection of vaccine-derived poliovirus 2 through environmental surveillance of wastewater. Areas of detection include regions close to Belgium such as Köln (DE). So far, no human cases have been notified.

DESCRIPTION

Event

On 15 Nov 2024, Germany reported that VDPV2 had been isolated from a wastewater treatment plant (WWTP) in München, becoming the third European country to isolate VDPV2 from wastewater in 3 months following Poland (04 Nov 2024) and Spain (25 Sept 2024). Germany has had wastewater surveillance in place (as a research project) for over a year, but this was the first positive result.

22 Nov 2024, Germany published an update indicating that the virus had been isolated in Köln, Bonn & Hamburg. 04 Dec 2024, this had been expanded to include Düsseldorf, Dresden & Mainz. This means the virus has been detected in 7 cities in Germany, throughout the entire country. Genomic analysis indicated that the VDPV2 isolates have between 43 & 49 nucleotide exchanges in the VP1 region compared to the vaccine strain. This coupled with the spread of the isolates indicates sustained transmission of circulating VDPV2 (cVDPV2). **The strains detected in Europe bear strong similarities to a strain that appears to have originated in Nigeria and has been circulating mainly in North and West Africa since 2020, where it has also caused polio cases.**

05 Dec 2024, Finland reported VDPV2 in their wastewater, also with no known clinical cases. **This brings the total to 4 EU countries. As of 09 Dec 2024, no clinical cases have been reported in any of the EU countries.** *On 12 December, the UK equally reported the presence of cVDPV2 in 3/26 environmental samples (information not available at time of meeting)*

Twenty-three EU countries currently conduct environmental surveillance (see Annex 1) and no positive samples have been reported. The Netherlands have announced to increase their sampling in 4 major cities of the Bible belt. In Belgium, sampling is done monthly from WWTPs in Brussels, Antwerp, Wavre and Liège and has yielded only negative results. The most recent sampling was done on 09 Dec 2024 and results are expected in the coming weeks.

Vaccine-derived poliovirus is a well-documented strain of poliovirus, mutated from the strain originally contained in oral polio virus vaccine (OPV). OPV contains a live, weakened form of poliovirus that replicates in the intestine for a limited period, thereby developing immunity by building up antibodies. On rare occasions, when replicating in the gastrointestinal tract, OPV strains can genetically change and may spread in communities that are not fully vaccinated against polio, especially in areas where there is poor hygiene, poor sanitation, or overcrowding. The lower the population's immunity, the longer vaccine-derived poliovirus survives and the more genetic changes it undergoes.

In very rare instances, the vaccine-derived virus can genetically change into a form that can cause paralysis as does the wild poliovirus – this is what is known as a vaccine-derived poliovirus (VDPV). The detection of VDPV in at least two different sources and at least two months apart, that are genetically linked, showing evidence of transmission in the community, is classified as ‘circulating’ vaccine-derived poliovirus (cVDPV). Similar to wild poliovirus, cVDPVs can be of three types (1,2 or 3). To reduce the risk of cVDPV, the use of OPV is being phased out globally and replaced by IPV (inactivated poliovirus, to be administered intramuscular). Additionally, oral poliovirus vaccines that are currently used are bivalent vaccines (bOPV): they do no longer contain poliovirus 2.

Type of risk	**Unexpected.** Europe was declared Polio free in 2002. There is no use of OPV in the EU, all countries use IPV only. However, polio was found in wastewater in London in 2022. Despite the absence of clinical cases, these detections prompted a vaccination campaign.
Severity of the risk	**Low risk of disease – medium risk of transmission.** The signal indicates that cVDPV2 is present in Europe and in particular in a neighbouring country. Therefore there is a high risk of importation. Vaccination coverage for infants in Belgium has been >90% for several decades. Adequately vaccinated persons are not at risk of paralysis caused by cVDPV. Poliovirus transmission occurs via fecal-oral and oral-oral routes, with viral replication primarily occurring in gastrointestinal mucosa and oropharyngeal epithelium, respectively. Viral transmission can be mitigated through targeted inhibition of viral replication at these anatomical sites. Belgium implemented an IPV-only vaccination schedule in 2001; however, evidence suggests that IPV vaccination does not significantly alter fecal viral shedding compared to unvaccinated individuals (1). While IPV may reduce nasopharyngeal viral shedding in both magnitude and duration, its impact varies by setting. In regions with advanced sanitation infrastructure, oral-oral transmission is presumed to be the predominant route, suggesting that IPV's effect on oropharyngeal viral shedding might be sufficient to interrupt transmission (2). Nevertheless, this hypothesis was challenged when Israel, despite maintaining 95% IPV coverage as of 2012, detected wild poliovirus type 1 in environmental surveillance during 2013, necessitating OPV reintroduction into their immunization program (2). Furthermore, longitudinal studies have demonstrated that OPV-induced mucosal immunity exhibits temporal decline (3). In Belgium, primary polio vaccination of infants is done using the combined hexavalent vaccine administered in a 3+1 schedule, followed by a booster at 5y of age. Other EU countries, such as Germany, use a 2+1 schedule, with a booster at 5-10y of age. Timing and number of doses of vaccination can influence effectiveness of vaccination. According to CDC, even 2 doses op vaccination would provide 90% of protection against paralytic polio, effect of dosage on mucosal immunity is not known.

Exposed population	**Incompletely vaccinated persons** are the population at-risk for paralytic polio.
	
	Although infant polio vaccination is mandatory in Belgium, there might be immunity gaps in the population.
	Particularly at risk are
	- children who have not (yet) received at least 2 doses of IPV
	- persons born outside of Belgium:
	  ○ who have come from countries where polio vaccination rates are low OR
	  ○ who have only been vaccinated with bOPV (bivalent oral poliovaccine, not containing poliovirus type 2); bOPV replaced tOPV since 2016. Vaccination schedules of all countries can be found here.
	- certain underserved or isolated groups, e.g.. London and New York 2022 outbreaks were linked to the Orthodox Jewish Community, of which there is a large community in Antwerp.

Risk of (inter)national dissemination	**High.** Transmission is already reported from several countries.

PREPAREDNESS & CONTROL MEASURES ALREADY IN PLACE

Preparedness

Surveillance

Poliovirus surveillance in Belgium is made up of 3 pillars: environmental surveillance, enterovirus surveillance and AFP surveillance.

- Monthly *environmental surveillance* for poliomyelitis has been in place in Belgium since January 2024. So far, none of the samples were positive. The most recent samples date from 6th of December and analysis is ongoing.. Although the methods were developed from the protocols of Regional Reference laboratories within the WHO polio lab network, the current sensitivity of the method is probably lower than what is being used in Germany.
- *Enterovirus surveillance* can be useful in identifying polio cases with less severe, non-paralytic symptoms (e.g. upper respiratory tract infections, gastrointestinal disorders, aseptic meningitis or meningoencephalitis). The network of sentinel laboratories reports positive samples for all enteroviruses isolated by culture or PCR. The National Reference Centre (NRC) for enteroviruses genotypes all enteroviruses on samples sent voluntarily by laboratories throughout Belgium.
- *AFP surveillance* is historically considered as the gold-standard. WHO guidance requires a minimum of 19 notifications per year for Belgium to consider the system sufficiently sensitive, but this standard is not met. There have been 4 cases of AFP in <15 year olds reported in 2024. All cases were diagnosed as Guillain-Barré syndrome, but only in 1 case poliovirus seems to have been explicitly ruled out with adequate virological testing.

In their latest assessment, the Regional Verification Committee of WHO Europe considered Belgium to be at intermediate risk of a polio outbreak, due to insufficient quality of surveillance. The assessment was based on 2022 data and environmental surveillance has meanwhile been introduced.

Vaccination coverage

The latest available data for infants are from 2019-2020 and showed a vaccination coverage of 94% for the fourth dose of polio-containing vaccine (Bxl 92.8%, FL 94.2% and WAL 94.3%) and 97.6% for the third dose. Coverage for the 3rd dose has been >95% since 2006. More granular vaccination coverage data is not available. Of note is that in London (2022) and currently in Germany granular vaccination coverage data indicated areas with low vaccination coverage (~40%) despite national coverage >90% (see also annex).

Vaccination of incoming applicants of international protection (IAP) is organized upon presentation to the central medical service. Children <12y are offered a first dose upon registration. For subsequent doses or vaccination of adolescents, individuals are referred to well-baby clinics and school health services. According to Belgian guidelines, catch-up vaccination of adults is only offered to those coming from countries where poliovirus is endemic or that are facing an outbreak. Due to capacity shortage in the system, first medical check-up for adult refugees often only takes place several months after arrival in Belgium. Moreover, e.g. displaced persons from Ukraine are not integrated in the system. Recent outbreaks of vaccine-preventable diseases such as measles and diphtheria have highlighted gaps in the system due to insufficient capacity and logistical challenges.

Outbreak response

A national outbreak plan exists and is currently being reviewed (expected for early 2025).

Specific Control Measures *(surveillance, control, communication)*

Sciensano is following up the situation and is in contact with other EU countries. Technical aspects of wastewater surveillance have been discussed. Initial wastewater testing protocols were set up in accordance with WHO guidance. In the current context, to increase sensitivity, for the samples which were received 09 Dec 2024, for Brussels North, Brussels South and Liege an additional cell culture will be conducted to improve sensitivity.

The October flash, sent by Sciensano, included the increase in positive WW samples, specifically the VDPV2 in Barcelona.

PUBLIC HEALTH IMPACT IN BELGIUM

Low.

WHO's IHR emergency committee confirmed on the 6th of November that the risk of international spread of poliovirus remains a Public Health Emergency of International Concern. Whilst a one-off detection of cVDPV2 in wastewater (as was recently the case in Spain and Poland) might not require important additional actions, additional actions might be required in case of sustained transmission. To prevent further spread of virus, WHO issued temporary polio vaccine recommendations for travelers staying >4 weeks and residents departing from countries with risk for poliovirus spread.

High routine vaccination coverage in Belgium importantly reduces the risk of paralytic polio cases occurring.

RECOMMENDATIONS

Raise awareness:

- Inform all vaccinators about the current situation and the importance of timely polio vaccination
- Ask neurologists and neuropediatricians to be on high alert for any case of acute flaccid paralysis. All AFP cases should be notified to the regional health authorities and appropriately investigated to rule out poliovirus (2 negative stool samples collected within 14 days of paralysis onset, at least 24 hours apart).

Increase surveillance:

- AFP surveillance : cf. supra

- Enterovirus surveillance : Sentinel laboratories should be reminded to send enterovirus positive CSF and stool samples to NRC for typing.

- For environmental surveillance, the current sampling plan will be initially maintained, as this was set up to cover populations with lower vaccination coverage. The primary objective would be to *increase sensitivity* by:
    - Doubling the sample volume for Brussels owing to the higher population density for that WWTP. Discuss options for increasing replicates.
    - Continue to exchange best-practices with counterparts in other European countries. Based on information already gathered, it is believed the sensitivity can be improved 4-5 fold.
    - Ask for confirmation of negative samples by additional testing at NRC or RIVM

- Resources permitting, as a secondary objective, the area with highest risk of importation in the current context (= German-speaking community with lots of cross-border movement to Germany) can be added to the sampling plan. This would be the WWTP in Eupen.

Close immunity gaps:

- Urgently implement recommendations from previous risk assessments and working groups on vaccination of refugees and asylum seekers.
- Investigate options (incl. assessment of completeness of the data) to obtain more recent and granular vaccination coverage through registration of the mandatory vaccination at municipalities and use of Vaccinet.
- Make sure all persons at increased risk of exposure to poliovirus are adequately vaccinated (through occupational health services). This includes all staff handling wastewater, healthcare workers and lab personnel as well as staff working in crèches.

Finalize national polio outbreak plan and request validation at RMG

ACTIONS

Sciensano Unit Vaccine Preventable Diseases - epidemiology:
- Provide template for communication to vaccinators
- Provide template for communication to neurologists/neuropediatricians
- Send out communication to sentinel labs to send samples to NRC in order to reinforce enterovirus surveillance
- Finalize revisions of national polio outbreak plan and submit for validation

Sciensano Service Waste Water laboratory:
- Implement actions to increase sensitivity
- In collaboration with Sciensano wastewater-epi team: add testing of WWTP in Eupen, resources permitting

FPS Public Health:
- Follow up and facilitate the implementation of previous recommendations regarding vaccination of refugees
- Investigate options to provide granular and recent polio vaccination coverage data based on the polio vaccine mandate

AVIQ/DepZorg/Vivalis/German Speaking Community
- Send out communications to neurologists and neuropediatricians
- Send out communications to occupational health services

ONE/DepZorg:
- Send out communication to vaccinators
- DepZorg: investigate options to provide granular and recent polio vaccination coverage data based on Vaccinet

Fedasil:
- Optimize vaccination coverage for refugees, including children, in collaboration with other stakeholders and as previously discussed in working group on vaccination of refugees chaired by FPS Public Health.

REFERENCES

1. Hird TR, Grassly NC. Systematic Review of Mucosal Immunity Induced by Oral and Inactivated Poliovirus Vaccines against Virus Shedding following Oral Poliovirus Challenge. PLOS Pathogens. 2012 Apr 19;8(4):e1002599.

2. Parker EP, Molodecky NA, Pons-Salort M, O'Reilly KM, Grassly NC. Impact of inactivated poliovirus vaccine on mucosal immunity: implications for the polio eradication endgame. Expert Rev Vaccines. 2015 Aug 3;14(8):1113–23.

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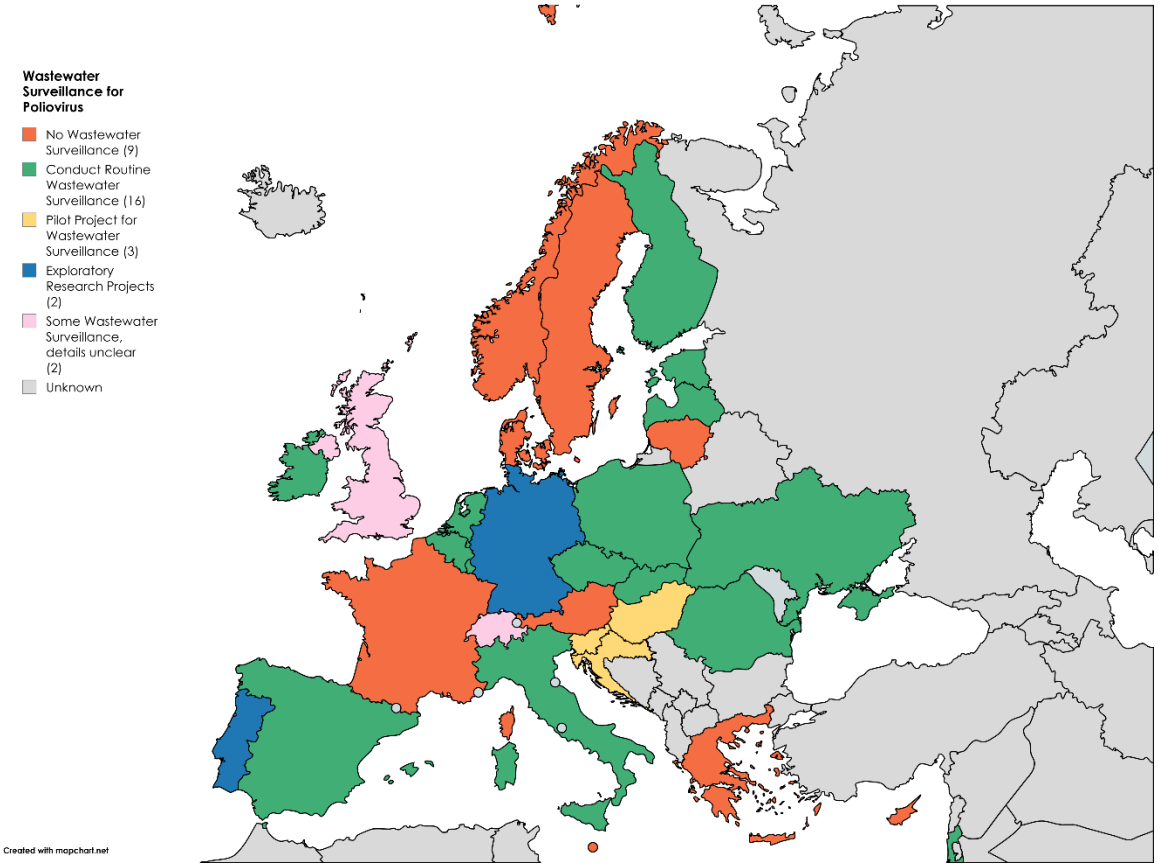
ANNEXES

1. Map of EU countries known to be conducting environmental surveillance for Poliovirus



2. Detailed geographical vaccination coverage Germany

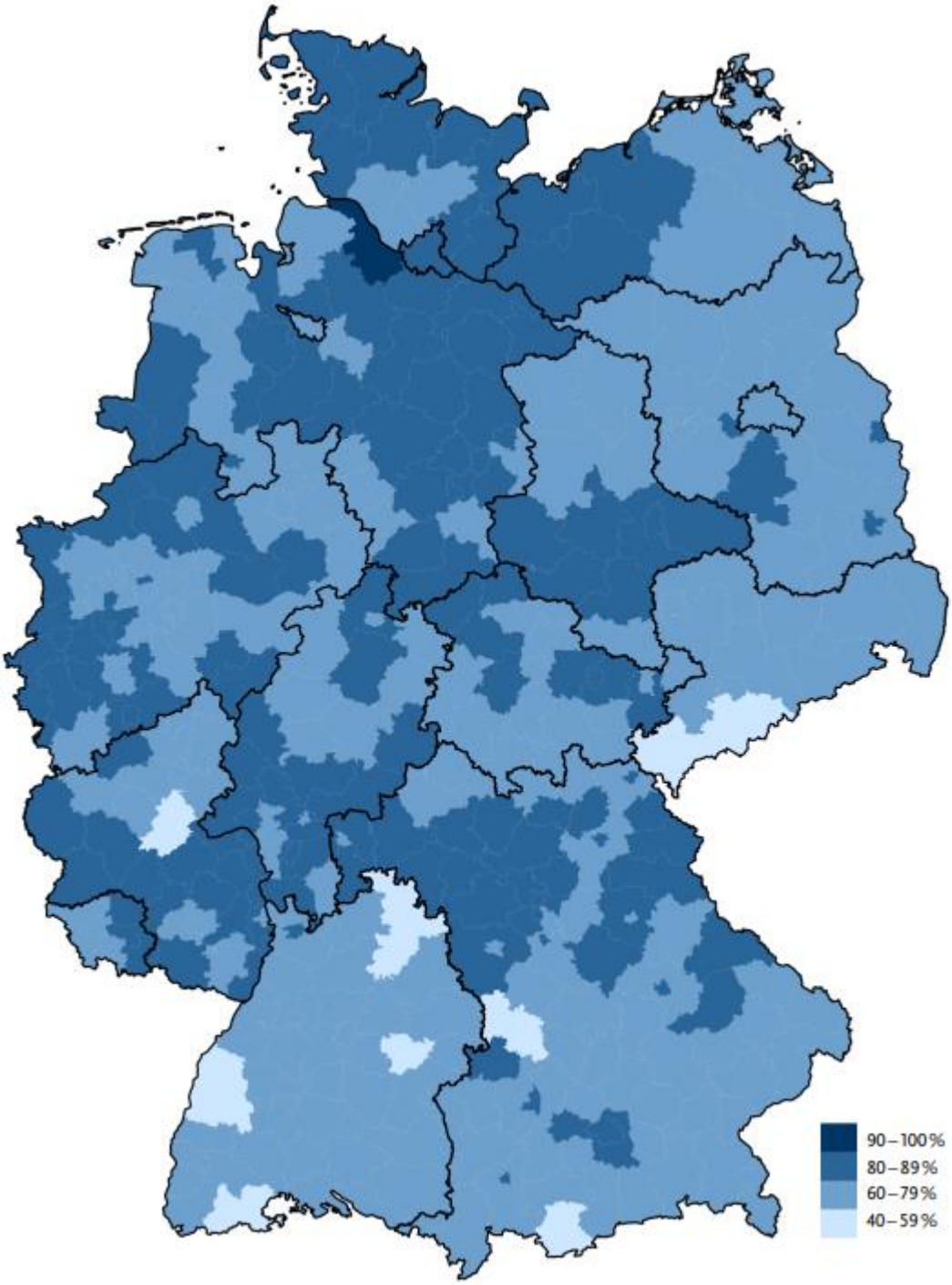


Abb. 2 | Polioimpfquote für den vollständigen Impfschutz auf Kreisebene, Geburtsjahrgang 2021 mit 24 Monaten