ORIGINAL RESEARCH

Defining Polio: Closing the Gap in Global Surveillance

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Abstract

BACKGROUND By late 2012 the Global Polio Eradication Initiative (GPEI) had nearly eradicated this ancient infectious disease. Successful surveillance programs for acute flaccid paralysis however rely on broad governmental support for implementation. With the onset of conflict, public health breakdown has contributed to the resurgence of polio in a number of regions. The current laboratory based case definition may be a contributory factor in these regions.

OBJECTIVE We sought to compare case definition rates using strict laboratory based criteria to rates obtained using the clinical criteria in modern day Syria. We also sought to examine this distribution of cases by sub-region.

METHODS We examined the World Health Organization (WHO) reported figures for Syria from 2013-2014 using laboratory based criteria. We compared these with cases obtained when clinical criteria were applied. In addition we sought data from the opposition controlled Assistance Coordination Unit which operates in non-Government controlled areas where WHO data maybe incomplete. Cases were carefully examined for potential overlap to avoid double reporting.

FINDINGS Whilst the WHO data clearly confirmed the polio outbreak in Syria, it did so with considerable delay and with under reporting of cases, particularly from non-government controlled areas. In addition, laboratory based case definition led to a substantial underestimate of polio (36 cases) compared with those found with the clinically compatible definition (an additional 46 cases). Rates of adequate diagnostic specimens from suspected cases are well below target, no doubt reflecting the effect of conflict in these areas.

CONCLUSIONS We have identified a gap in the surveillance of polio, a global threat. The current laboratory based definition, in the setting of conflict and insecurity, leads to under diagnosis of polio with potential delays and inadequacies in coordinating effective responses to contain outbreaks and eradicate polio. Breakdown in public health measures as a contributing factor is likely to result in a resurgence of previously controlled infectious diseases. The clinical definition should be reinstituted to supplement the lab-based definition.

KEY WORDS polio, vaccination, conflict, Syria, clinical diagnosis, acute flaccid paralysis

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est public health successes of our time. By the end of paign by the Global Polio Eradication Initiative

The near eradication of polio is one of the great- 2012, after 25 years and a multibillion-dollar cam-

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(GPEI), 99% of the poliovirus had been eliminated from the world and the number of countries with endemic polio had been reduced from 125 to 3. Eradication appeared imminent after the successful interruption of transmission in India in 2011, and only 223 cases were recorded in 5 countries in 2012. Of the 3 wild-type polioviruses, type 2 was eradicated in 1999 and type 3 has been undetected since November 11, 2012.

Yet over the course of 2013 the numbers almost doubled, with 416 new cases of type 1 wild polio in 8 countries. In 2014, the collective toll was 359 cases in 9 countries. The virus was detected in the sewers of several other countries that had previously eliminated polio: Palestine, Israel, Egypt, and Brazil, the latter in June 2014 after more than a 20-year absence. The type 1 virus not only is the most virulent-causing the most serious paralysis and the worst epidemics-but also has the highest ratio of paralytic to subclinical infection (1 in 200). Rather than being eradicated by the end of 2014, as per the target, polio now has a foothold on 3 continents. It has a persistent presence in Africa, it has re-emerged in the Middle East after more than a decade of absence with the outbreak in Syria and spread to Iraq, and it continues to flourish in Pakistan and Central Asia, threatening India's new polio-free status.

As the lead partner of the GPEI, the World Health Organization (WHO) is responsible for the polio eradication strategy. In late April 2014, WHO convened an emergency committee under the International Health Regulations (IHR) to address the international spread of polio. A week later, WHO declared that the conditions for a public health emergency of international concern had been met. Since then, this public health emergency has been renewed 4 times, most recently on February 27, 2015.

There are numerous reasons for this giant step backward, including attacks on polio vaccinators in Pakistan, myths about the debilitating effects of the polio vaccine in Somalia, and armed conflict interrupting public health efforts in Syria and Pakistan. Last October, the Independent Monitoring Board (IMB) report highlighted the dismal failure of the current strategy and made several critical recommendations to address some of these problems, singling out suboptimal surveillance.¹

An overlooked but key factor in the resurgence of polio is the current case definition. A precise case definition is of great importance because it is *the cornerstone of successful surveillance and thus directs* appropriate response measures. Notably, the eradication of smallpox, a much easier disease both to detect (every person infected had an obvious rash) and to prevent (1 vaccination was sufficient for 5 years) relied at every stage on accurate surveillance.

When does a child have polio? Ordinarily, the answer is straightforward: when a child presents with acute onset of flaccid paralysis (AFP) and a WHO-accredited laboratory within the Global Polio Laboratory Network confirms that poliovirus is present in his or her stool. This is the current and sole definition used by WHO and its GPEI partners to inform the global eradication effort.

In the past, a clinical definition was used as a highly sensitive screen, but with limited specificity because a small number of other diseases can also cause flaccid paralysis. Under normal circumstances, when children are guaranteed access to healthcare and doctors can order investigations at will, this laboratory-based definition provides high diagnostic specificity. Sensitivity, however, is immediately constrained if laboratory access is compromised. In layman's terms, clinical diagnosis alone catches all cases of polio but is over-inclusive given that some are "false positives" as a result of other causes of AFP, whereas laboratory testing alone excludes false positives but misses many true cases in situations in which best-practice laboratory testing is difficult or impossible.

The limits of a laboratory test are evident in situations of armed conflict where insecurity hinders the collection and transport of a stool sample to a laboratory. War can also prevent an afflicted child from even seeing a doctor during the period when poliovirus is present in the stool. Currently, that is the grim reality in many areas of Syria, where polio reappeared 18 years after it was eliminated.² Yet the global health community has not yet adapted to a situation in which the Syrian military deliberately attacks hospitals, clinics, ambulances, and other parts of the healthcare system and has forced tens of thousands of doctors to flee the country.^{3,4} Rather than being a cooperative state concerned about the health of its citizens, the Syrian government uses disease and deprivation as an element of its internal war strategy against the civilian population in areas of the country considered politically unsympathetic. This includes the deliberate targeting of water treatment plants and the withholding of chlorine supplies needed to provide safe drinking water-an effective method of reducing transmission of polio and other waterborne diseases. After several years of indeterminate national

coverage,⁵ the regime ceased vaccinating children in opposition-held areas altogether. The only official laboratory for testing for the disease is situated in the government-controlled capital of Damascus, accessible only across treacherous frontlines. The data reported by the government from this laboratory have been delayed and unreliable. As a consequence, over 2013 and 2014 an epidemic of polio spread across northern and eastern Syria.

In this context of violent conflict and political insecurity, the insistence on laboratory testing as the sole method for officially recognizing the presence of polio impedes efforts to address the reemergence and spread of the disease. Children are being stricken by polio regardless of whether a laboratory test makes confirmation of their illness possible. Yet under the current case definition, these victims do not exist in official reports. That omission is compounded because for every child who develops paralytic polio, hundreds more are infected without ever becoming sick, spreading the disease for several weeks or months. The silent spread of such a destructive virus is a major reason why polio is so dangerous. That invisible transmission is not dissimilar to the asymptomatic spread of HIV by people unaware of being infected. The long lag between infection and signs of disease has contributed to the global spread of HIV. Polio is even more difficult to track because most infected people never develop symptoms at all.

WHO's sole reliance in recent years on the laboratory-based definition of polio is in accordance with rules drawn up in 2005 under the IHR and



ratified in 2007 to govern the surveillance and prevention of threats to global health. The requirement for laboratory confirmation of poliovirus was considered appropriate in the context of steady progress toward global eradication to permit conclusive determination of whether each remaining case of AFP was actually polio. Under the IHR, a suspected case is defined as a child under the age of 15 years presenting with AFP or a person of any age with paralytic illness if poliomyelitis is suspected. A notifiable case of poliomyelitis is defined as a suspected case with isolation of wild poliovirus from stool specimens collected from the suspected case or from a close contact with the suspected case.⁶ Some suspected cases will not have adequate samples, but if such cases have residual paralysis after 60 days of the onset, they are considered to be compatible cases.

This new predominantly laboratory-based definition supplanted the earlier clinical case definition used by WHO from the beginning of its polio campaign in 1988—a campaign that led to the elimination of polio from the Americas, Europe, Middle East, and Pacific. That definition included the following, as verified in written communication with WHO on August 8, 2014: "A case of acute flaccid paralysis without adequate sample collection or laboratory testing with residual paralysis 60 days after onset of paralysis that is compatible with clinical poliomyelitis confirmed by an expert committee."

Virologic confirmation was performed wherever possible to supplement that test but was not the sole route to identifying a notifiable polio case.⁷ Over time, as countries developed their AFP surveillance systems and access to WHO-accredited laboratories for testing samples, the virologic AFP case classification scheme was applied. By the mid-2000s, all countries with AFP surveillance had shifted to virologic case classification (Figure 1).

The IHR's stated reason for requiring a laboratory test for a notifiable case of polio is that "Poliomyelitis cannot be diagnosed reliably on clinical grounds because other conditions presenting with acute paralysis can mimic poliomyelitis. Surveillance for polio eradication therefore requires the reporting of all children <15 years with acute onset of flaccid paralysis, with subsequent laboratory testing of stool specimens."⁶

To be effective, this laboratory definition of polio requires robust surveillance. This entails reporting all children with acute paralysis within 48 hours of onset and testing 2 stool samples collected within 14 days in at least 80% of the cases. Unlike HIV, malaria, or even strep throat, there is not yet a rapid diagnostic test for polio (a very useful area, it should be noted, for research investment). Surveillance personnel must collect fresh stools from children too young to defecate on demand, and then send these samples to the designated national or nearest Global Polio Laboratory Network laboratory. Specimens must arrive within 72 hours of collection. If that is not possible, stool must be packed and frozen to -20° C or the poliovirus will not survive the journey. Even when all these conditions are met, the turnaround time for testing once a specimen reaches a lab is typically 4 weeks, with several more weeks until a case is officially reported.^{8,9} During that time, polio can infect many children. This extended testing time also delays public-health remedial measures such as social mobilization, intensified vaccination, and environmental surveillance of sewers.

In Syria, surveillance for polio is compromised at best and broken down at worst. Collecting stool in a timely manner is often unfeasible, and transport across frontlines and through checkpoints is dangerous and prohibitively expensive. When health workers do manage to get stool samples to the National Polio Laboratory in Damascus, testing and reporting by the Syrian government has proven unreliable.^{10,11} For months the Syrian Ministry of Health hid the presence of poliomyelitis in the country, maintaining that its Early Warning Alert and Response System, set up with the help of WHO in September 2012, was reliable.¹² Only at the end of October 2013 did it concede that an outbreak of polio was underway after separate undeniable laboratory proofs were provided through the coordinated efforts of doctors working inside conflict areas, the opposition-supported Assistance Coordination Unit (ACU), the Turkish government, and the US Centers for Disease Control and Prevention (CDC). Officially, the Syrian government still maintains that the polio outbreak began in late October, although it admits that the first laboratory-confirmed case dates back to July 14, 2013.^{8,13} However, the first clinically determined polio case dates back to May 23, 2013.¹⁴

According to the IHR and GPEI, robust surveillance requires laboratory testing for poliovirus in at least 80% of cases of AFP.^{6,15} Yet because of the war, neither the GPEI nor the ACU was able to meet this requirement in 2013 in Syria.^{9,14} Even when there is adequate stool sampling, laboratory testing and reporting, as noted, can take months. A review of the surveillance in Syria revealed a lag of almost 4 months⁸ (Figure 2).

In such absence of a functioning laboratory network and health system, polio should also be identified using clinical criteria. The CDC website provides a clinical definition-published in 2010 by the US Council of State and Territorial Epidemiologists (CSTE)-which could supplement the laboratory definition.¹⁶ It defines a *probable* case of paralytic poliomyelitis as "acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss...from a cluster area of known polio." A confirmed case is defined as the "acute onset of [such] a flaccid paralysis from a cluster area... in which the patient still has a neurologic deficit 60 days after onset of initial symptoms."

This definition of a confirmed case does not require laboratory isolation of poliovirus for diagnosis of a probable or confirmed case of paralytic poliomyelitis. If the case is from a cluster area of known polio, clinical criteria suffice.

Clinical case definitions of polio

IHR Notifiable: "A suspected case with isolation of wild poliovirus from stool specimens collected from the suspected case or from a close contact of the suspected case."

IHR Suspected: "A child under 15 years of age presenting with AFP, or a person of any age with paralytic illness if poliomyelitis is suspected."

CSTE Probable: "Acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss ... from a cluster area of known polio."

CSTE Confirmed: "Acute onset of [such] a flaccid paralysis [from a cluster area of known polio] in which the patient still has a neurologic deficit 60 days after onset of initial symptoms."

The 2 definitions present significantly different pictures of the scope of the polio outbreak in Syria. According to data from GPEI, there were 35 confirmed cases of polio of 180 cases of AFP in Syria in 2013.¹⁷ GPEI acknowledges that 12 additional clinical cases compatible with polio occurred in 2013, but they have not been publicly reported in accordance with the WHO standards for surveillance and reporting.^{15,17}

By contrast, the Syrian opposition's ACU, which was assisted by the CDC in developing field



surveillance to detect polio, reported 73 cases of AFP in 2013 using clinical as well as laboratory criteria.¹⁴ Polio was verified in 13 of the cases by laboratories outside of Syria; Stool samples were collected in 24 cases, 22 of which were adequately collected and transported for testing in national and regional laboratories. An additional 34 clinically suspected cases from the ACU have been classified as compatible cases by the National Expert Committee (NEC) in Turkey on the basis of their clinical criteria¹⁴ but have never been published as such on the GPEI website.

Table 1 summarizes the different pictures of polio in Syria by comparing the numbers provided by a laboratory-only approach with those provided by a clinical definition.

The absolute numbers are important, but perhaps the distribution is even more so: All cases are in opposition-held areas, targeted by the government's armed forces and inaccessible to WHO without the permission of the government. Of note, the GPEI still maintains that the outbreak began in Aleppo on June 14, 2013, and the duration of the outbreak was a total of 38 weeks, lasting until April 7, 2014.²¹ This seems epidemiologically unlikely, given the clustering of cases in Deir Ezzor, as shown, and that the cholera outbreak of 2009 originated in the same village, Spighan, in Deir Ezzor²² (Figure 3).

In the ACU's limited experience, of the 73 clinically identified cases of probable polio in this outbreak, 64% were later confirmed to have been properly identified as polio either through laboratory testing or expert clinical review: 13 cases of laboratory-confirmed wild polio type 1, and an additional 34 declared polio compatible

Table 1. Laboratory and clinical cases of polio in Syria			
	2013	2014	Total
IHR laboratory-only definition*	35*	1	36
NEC confirmed clinically compatible ^{\dagger}	46	6	52
Minimum total polio cases, 2013-2014	81	7	88
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IHR, International Health Regulations; NEC, National Expert Committee * Twenty-five of these cases were reported by the Syrian Ministry of Health and the World Health Organization (WHO). The Global Polio Eradication Initiative (GPEI) has indicated that its figures reconcile all laboratoryconfirmed cases and thus infers that 10 of the 13 laboratory-confirmed Assistance Coordination Unit (ACU) cases are included in this figure of 35. Cases without stool verified as polio compatible by the National Expert Committee (NEC) in Damascus and Turkey: 12 and 34, respectively, in 2013: and 2 and 4, respectively, in 2014. In its final meeting of the year in December 2014, the Turkey NEC found 4 cases of suspected polio to be compatible with the clinical criteria. WHO's Eastern Mediterranean Regional Office (EMRO) reported 2 compatible case for 2014.18 Sixteen cases from the Early Warning and Response Network (EWARS) await classification: 2 from 2014 and 14 from 2015.^{18,19} For EWARN, there are 10 pending cases from 2014 (clinical classification) and 16 from 2015 (4 clinical and 12 laboratory).14

by the National Expert Committee in June 2014.^{14,20} This is similar to the published percentage of confirmed polio in outbreaks of AFP cases elsewhere, including recent outbreaks in Tajikistan and the Republic of Congo in 2010.^{23,24}

By contrast, the confirmation rate for suspected clinical cases is dramatically lower when assessed by the Syrian NEC in Damascus, suggesting a continuing interest on the part of the government to downplay the extent of the outbreak. For 2014, although only 153 cases of AFP were anticipated according to the indicators for polio surveillance, 306 cases of AFP were officially reported. Only 1 was officially declared polio through laboratory confirmation, and 2 have been classified as compatible.¹⁸ No plausible diagnoses have been provided



for any of the remaining 133 cases of AFP in 2013 or the 303 cases in 2014.

Of the 106 cases of AFP presenting to field surveillance officers of the ACU (EWARN) through 2014, less than two thirds (62.9%) had adequate stool samples available for laboratory testing.²⁰ Because the ACU does not have access to the National Polio Laboratory in Damascus, it was forced to send stools cross-border to a laboratory in Turkey. The political sensitivity of these cross-border operations means that obtaining the results has been and remains extraordinarily difficult, with many cases still listed as "pending."^{14,20}

Laboratory confirmation of poliovirus is the gold standard in an ideal world. However, in conditions like those in Syria (and indeed other countries today), the perfect can be the enemy of the good. There are strong reasons why an inclusive definition is preferable to an exclusive one that depends on frequently unattainable timely laboratory testing. Polio is highly contagious, and the cramped and unhygienic quarters in which the millions of people displaced by the Syrian conflict are forced to live facilitate transmission, particularly in light of the neglect of safe drinking water and the deliberate withdrawal of chlorine, one of the few agents that kills polio, from water treatment plants.²¹ All of these factors facilitate the virus's spread, as does frequent displacement itself.

The case of an afflicted 3-year-old Syrian boy illustrates the danger of relying solely on a laboratory definition of polio. Using a clinical test, EWARN identified him as a probable case of polio in early February 2014 in the district of Menbij in Aleppo governorate, very close to the Turkish border. However, using only a laboratory test, he was not considered as a case of polio until the GPEI reported laboratory confirmation of his case in late April 2014.²⁵ In the meantime, war conditions displaced his family several times among 4 governorates in Syria-from Aleppo to Raqqa to Deir Ezzor to Hama-potentially spreading poliovirus widely. Use of the clinical definition to supplement the laboratory one could have, and should have, prompted earlier remedial steps to contain the virus and protect children.

One might defend the exclusive use of a laboratory definition by arguing that the precise number of polio cases does not matter given the GPEI's decision to vaccinate all children in Syria and surrounding countries, but events on the ground tell another story. Despite the regional vaccination campaign aimed at 21 million children, polio crossed international borders. On February 10, 2014, a 6month-old baby in Baghdad developed paralytic polio-a diagnosis that was officially confirmed 2 months later. The most recent known case in Iraq with onset of paralysis in a 3-year-old girl on April 7, 2014 was publicly confirmed only in late May 2014.²⁶ Both children in Iraq were infected by the same strain of polio identified in Syria; neither had left Iraq nor had been immunized. Probable cases of polio have been identified in both Syria and Iraq that have never been officially reported; it is relevant that the sole compatible case reported for 2014 was officially acknowledged only in April 2015.²⁷ GPEI data reveal that Lebanon and Turkey fall short of the mandatory 80% stool sampling rate for 2014, and it is hard to have any level of confidence in the reported figure of 89% in Iraq.²⁷ A threat to the people of Syria has become a threat to the people of the region.

The absence of laboratory confirmation of polio in Syria 1 year after the most recent laboratoryconfirmed case²⁸ is not necessarily reassuring, given the lack of timely and reliable data, the ongoing armed conflict, and the escalating health crisis involving other diseases transmitted by the oralfecal route such as typhoid and hepatitis A. WHO raised concerns over a cholera epidemic in February,²⁹ yet months later rapid diagnostic tests are still unavailable, let alone an accredited WHO laboratory, as required by the current standards, to confirm the presence of *Vibrio cholerae*.

In this far-from-perfect context, emphasis should be shifted away from the unrealizable ideal of laboratory diagnosis and back toward a more practical reliance on clinical assessment. If this is not done, there is a greater chance that response measures will be targeted away from areas where outbreaks are occurring. The sequence analysis reviewed in 2014 indicated that wild polio virus cases were in all likelihood missed during 2012-2013 surveillance in Afghanistan, Cameroon, Chad, Niger, Nigeria, and Pakistan. This likelihood was subsequently borne out in the outbreaks in Cameroon and Syria in 2013.³⁰

The excuse proffered by the Syria government, WHO, and the IMB—that polio's re-emergence in Syria is a result of the conflict—is undermined by the lack of re-emergence of polio in Iraq during the 8 years of war in 2003-2011. A better understanding of the extent of polio's re-emergence and spread in Syria should have prompted a more vigorous response overall and in specific regions not under government control. For example, because

WHO, as a United Nations agency, can work in a country only with a government's permission, it was constrained by Damascus's limited permission from working in opposition-held parts of Syria where the polio outbreak occurred. Similarly, the government's vaccination campaign was inappropriate for an active outbreak. It was conducted from health facilities, without any documentation of coverage or independent monitoring as WHO standards require. Earlier acknowledgment of the outbreak would have permitted earlier implementation of non-WHO-dependent strategies such as the highly effective vaccination effort conducted by the ACU, involving multiple door-to-door campaigns along with intensified surveillance and independent monitoring to establish coverage gaps. The ACU effort ultimately proved a great success, with a coverage rate of 92%,³¹ but it had a difficult time attracting the international funding and support needed for a sustainable response.

A more vigorous response should also include programs to vaccinate newborns, decontaminate drinking water, rehabilitate water-treatment and chlorination plants, and survey sewers for early detection of the virus. Moreover, identifying each case of polio makes an enormous difference for the prognosis of those stricken. Polio is not curable, but contrary to popular belief, it is treatable. With timely supportive care, more than 50% of acutely disabled children either recover completely or are left with only mild residual paralysis. But a polio diagnosis that excludes children whose stools cannot be tested in a laboratory denies them effective therapy. That can mean the difference between substantial recovery or a lifetime of paralysis and stigmatization.

The re-emergence of polio in the Middle East has revealed an important gap in global public health. In settings of conflict and insecurity where laboratory confirmation is not possible, there is no clear internationally accepted standard for diagnosis of polio, yet it is in precisely these settings that polio is most likely to spread. Adherence to an impractical definition that relies on laboratory testing when it is so often unattainable has fostered polio's spread in Syria and beyond its borders. The many countries experiencing war or civil strife, such as Ukraine, the Central African Republic, and South Sudan, illustrate the urgent need to address this issue. Comprehensive surveillance is needed in both government and opposition-controlled areas. Where the central government precludes WHO and

GPEI from reaching conflict areas, other agencies must be encouraged to step in with novel ways of surveillance and response to address the problem.

The most recent reports by IMB and the World Health Assembly remind us that the Middle East remains at particularly high risk of re-infection and transmission.^{1,32} With summer—the season of highest polio transmission—upon us, in combination with the growing regional insecurity in Iraq, Ukraine, and Yemen, this gap is a cause for considerable concern.

Public health requires pragmatism-doing what works to protect people from preventable diseases. The clinical definition previously used by WHO or the CSTE criteria published by the CDC could readily be reinstated to supplement the laboratory definition. The absence of evidence of polio according to a test that cannot be reliably implemented must not be mistaken for the absence of polio. For example, the inadequacy of surveillance in Afghanistan that allowed GPEI to report that endemic transmission had ceased was made clear when the Afghan strain was detected in May 2014 after "an absence" of 2 years. In Somalia, even as the conflict has become less severe, the authors of the most recent IMB report¹ state that "no polio has been detected since August 2014, but few of sound mind would declare that polio has certainly gone. The surveillance system has too many holes that need to be closed."

Polio is a barometer of global health, and surveillance an issue of global governance. The rise and re-emergence of polio and other global threats such as Ebola reveal the critical need for a new approach to crises in the Middle East, Africa, and other fragile states. Polio is only part of the public health catastrophe in Syria; the rise of all manner of infectious diseases, including tuberculosis and HIV, illustrates the gravity of this crisis. Redefining the diagnosis of polio is not just an academic exercise. Our willingness to revisit the standards by which we understand polio to be present reflects our ability to meet the minimum standards of surveillance and public health.

AUTHORS' NOTE

Since submission of this manuscript, the first reported case of confirmed polio in Syria for 2015 has been made by the first Expert Committee meeting for the year on May 18, 2015.

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