

VIA FEDEX & EMAIL

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Re: *Death of Infants in Certain Developing Countries by Systematic Use of a Biologic*

Dear Ms. Bensouda,

The International Criminal Court (the “**ICC**” or the “**Court**”) is in many ways a forum of last resort for grievous harms that cannot find a forum for redress. Those it prosecutes have often acted in the cloak of benevolent leaders. The ICC looks past their titles and words, and carefully judges them by their knowledge and the consequences of their actions.

The diphtheria, tetanus, pertussis vaccine (“**DTP**”), first developed in the 1940s, began being widely used in the 1970s. However, between 1981 and 2008, every developed country in the world ceased using DTP due to its negative health effects. The clear scientific evidence reflects that the use of DTP significantly increases the risk of mortality in infants who receive this product. Nevertheless, we present herein a case against individuals who continue to affirmatively coordinate and participate in the systematic and widespread use of DTP in no fewer than 40 developing nations, despite knowing the product has caused, and continues to cause, the death of infants.

In fact, the seminal study regarding DTP and mortality found that children receiving this product during the first six months of life *died at 10 times the rate* when compared to children that did not receive this product. Despite this, and many similar studies, the United Nations Children’s Fund (“**UNICEF**”), continues to purchase, promote, and distribute DTP to developing and underdeveloped countries, and pushes its use on every newborn child long after knowing that the clear dangers it poses caused developed nations to stop using DTP decades ago.

In this case, looking past titles and words and judging UNICEF by its knowledge and actions is critical. It appears that, despite reasoned pleas to the individual decision makers at

UNICEF and their full knowledge of their ongoing crimes, they have no intent to stop causing the death of infants in some of the most disadvantaged countries in the world. The systematic and ongoing deaths of these infants is a crime against humanity that the ICC should investigate.

This introductory letter, therefore, respectfully requests that the Prosecutor exercise her authority pursuant to Article 15(1) of the Rome Statute of the International Criminal Court (the “**Rome Statute**”)¹ to investigate the serious allegations contained herein. The mere acknowledgment of an investigation will provide the first formal signal that these killings cannot go on with impunity and may alone bring an end to these unnecessary deaths.

I. UNICEF IS KNOWINGLY AND WILLFULLY CAUSING DEATH OF INFANTS IN UNDERDEVELOPED COUNTRIES

UNICEF has been instrumental in vaccination campaigns in many countries.²

A. DTP Causes Increase in Overall Mortality

As UNICEF is aware, it is well established that a vaccine may affect the overall mortality beyond what would be expected from use of the vaccine alone. Meaning, introducing a vaccine into a region can cause a decrease or an increase in the overall mortality in that region from causes beyond the infection against which the vaccine is intended. This is known as a “non-specific effect” of the vaccine.

For example, studies have found that the measles, mumps, and rubella vaccine (“**MMR**”) has the “non-specific effect” of reducing mortality for reasons beyond just reducing death from measles, mumps, and rubella. These studies found that upon introducing MMR to a developing country, the overall mortality among children declined more than what could have occurred from the reduction in mortality only from these three infections. Meaning, the reduction in mortality after introducing MMR was greater than the total number of deaths from measles, mumps, and rubella before introducing MMR. This pattern has been seen with the introduction of other live attenuated (*e.g.*, weakened) vaccines, such as the oral polio vaccine (“**OPV**”) and the Bacillus Calmette–Guérin vaccine (“**BCG**”). Studies of these vaccines in developing countries have found an overall decrease in mortality upon using these products beyond what could have occurred from reducing mortality from the target infections alone.

In contrast, studies of DTP, an inactivated-adjuvanted product, have found an *increase* in overall mortality among children who were administered this product. The culmination of this body of science was a capstone study conducted by respected experts and vaccine proponents from the World Health Organization (the “**WHO**”) published in February 2017. This capstone study, building on nearly a dozen other studies that found DTP increased overall mortality in infants,

¹ The Rome Statute of the International Criminal Court, adopted by the United Nations Diplomatic Conference of Plenipotentiaries on the Establishment of an International Criminal Court, Jul. 17, 1998, UN Doc. A/CONF.183/9 (available at <https://unispal.un.org/UNISPAL.NSF/0/26D5982060C2D2AD85256B3B0074F5F8>) (the “**Rome Statute**”).

² See UNICEF Supply Division Update Sept. 17, 2019 (available at <https://www.unicef.org/supply/media/3176/file/VIC-2019-Session-1-UNICEF-Update.pdf>) (the “**Supply Division Update 2019**”).

found that children vaccinated with DTP were *10 times more likely to die* in the first six months of life than those children that were unvaccinated (the “2017 Study”).³

This 2017 Study was published in an Elsevier peer-reviewed journal which collaborates with *The Lancet* and was funded by the Ministry of Foreign Affairs of Denmark and the European Union.⁴ The authors of this study include Dr. Peter Aaby, Dr. Søren Wengel Mogensen, Dr. Andreas Andersen, Dr. Amabelia Rodrigues, and Dr. Christine S. Benn. Its lead author, Dr. Aaby, is renowned for studying and promoting vaccines in Africa and has over 300 published studies.⁵ Dr. Aaby, among other things, in 1978, established and continues to direct the Bandim Health Project, a Health and Demographic Surveillance System site in Guinea-Bissau.⁶ Among his accolades, in 2000, Dr. Aaby was awarded the Novo Nordisk Prize, the most important Danish award within health research,⁷ and in 2009, the Danish Ministry of Foreign Affairs selected Dr. Aaby as a leader in the fight against global poverty.⁸

UNICEF has and continues to be instrumental and the central worldwide actor in the purchase, promotion and distribution of DTP in under-developed countries.⁹ UNICEF has continued this conduct despite the clear evidence that it increases mortality and despite the fact that DTP has not been subjected to a single randomized placebo-controlled trial to prove its safety.¹⁰ UNICEF even continues to purchase, promote and distribute DTP to under-developed countries **decades after every single developed country in the world had ceased using DTP due to its adverse effects.** Developed countries instead use a different product believed to have fewer adverse reactions.¹¹

³ P. Aaby et. al., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, 17 EBIO MEDICINE 192–198 (2017) (available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>) (the “2017 Study”). A copy of the 2017 Study is attached as **Exhibit A**.

⁴ *Ibid.*

⁵ See Dr. Aaby’s published articles at <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>.

⁶ <https://www.bandim.org/>.

⁷ See Novo Nordisk Prize Recipients (available at <https://novonordiskfonden.dk/en/prizes/the-novo-nordisk-prize/>).

⁸ <https://www.bandim.org/press>.

⁹ See Supply Division Update 2019 *supra* note 2.

¹⁰ See the 2017 Study *supra* note 3 at § 5 Conclusions; see also P. Götzsche, *Expert Report on the Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*, VACCINE SCIENCE FOUNDATION, Jun. 19, 2019 at 19 (available at <https://vaccinescience.org/wp-content/uploads/2019/07/Expert-Report-Effect-of-DTP-Vaccines-on-Mortality-in-Children-in-Low-Income-Countries.pdf>) (the “White Paper”).

¹¹ See *infra* notes 33, 34.

B. UNICEF Letter Exchange with ICAN Regarding the Clear Scientific Evidence that DTP Increases Mortality

The Informed Consent Action Network (“**ICAN**”) is a not-for-profit organization that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. ICAN sent a letter to UNICEF on December 5, 2017,¹² enclosing a copy of the 2017 Study, and stated that: “We write to bring to your attention an alarming study, published this year, which found that children vaccinated with DTP were 10 times more likely to die in the first six months of life than those children that were unvaccinated.”¹³

ICAN demanded that UNICEF cease the distribution of this product or at least, pursuant to the Nuremberg Code,¹⁴ advise the parents or the guardians of the children receiving DTP prior to administering this product that, according to the best available scientific evidence, DTP will render their child more likely, not less likely, to die.¹⁵ ICAN even explained to UNICEF that:

The Nuremberg Code ... draws a sharp line when stating that no human being should receive a medical procedure and/or product without informed consent. Failing to advise the findings of Dr. Aaby’s study to parents prior to administering the DTP vaccine would violate this basic human right.¹⁶

ICAN’s letter of December 5, 2017, further called on UNICEF to identify the infants killed by this product in order to provide their families with reparations.¹⁷

UNICEF responded to ICAN in a letter dated February 6, 2018.¹⁸ UNICEF’s extensive response, however, did not address or even discuss the 2017 Study. Instead, UNICEF pointed to a 2014 review of DTP and mortality by the Strategic Advisory Group of Experts (“**SAGE**”), an advisory group to the WHO, which found that “the available data neither excludes nor confirm[s] the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality” (the “**2014 SAGE Review**”).¹⁹

¹² A copy of ICAN’s letter of Dec. 5, 2017 is attached as **Exhibit B**.

¹³ Exhibit B at 1.

¹⁴ The Nuremberg Code (1947), 313 *BMJ* 1448 (1996) at ¶1 (also available at <http://www.cirp.org/library/ethics/nuremberg>) (“The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.”).

¹⁵ Exhibit B at 3.

¹⁶ *Ibid* at 2, 3.

¹⁷ *Ibid* at 2.

¹⁸ A copy of UNICEF’s letter of Feb. 6, 2018 is attached as **Exhibit C**.

¹⁹ SAGE Non-Specific Effects of Vaccines Working Group, Background Paper for SAGE Discussions, Jun. 6, 2014 (available at https://www.who.int/immunization/sage/meetings/2014/april/1_NSE_Backgroundpaper_final.pdf); J. Higgins *et al.*, *Systematic review of the non-specific effects of BCG, DTP and measles containing vaccines*, Report to

The 2014 SAGE Review identified 16 studies that compared death rates between children receiving DTP and children not receiving DTP.²⁰ Shockingly, SAGE found that a “majority of studies indicated a negative effect of DTP,” meaning a majority of the studies SAGE reviewed found that DTP killed more children than it saved.²¹ For example, one study found that children receiving DTP were between 154% and 1,219% more likely to die than those who did not receive DTP.²² Nevertheless, SAGE chose to give little weight to these studies despite their being conducted by WHO’s respected vaccine experts, because SAGE stated: (i) these studies were not “randomized” (*i.e.*, children were not randomly assigned to either receive or not receive DTP, hence potentially introducing bias²³), (ii) “OPV [Oral Polio Vaccine] was administered concomitantly with DTP in most included studies” and hence it “was not possible to separate any possible effects of DTP from OPV in the available studies,”²⁴ and (iii) these studies were often conducted in communities with existing “herd immunity” that could have introduced further bias.²⁵

ICAN responded to UNICEF in a letter dated March 15, 2018,²⁶ in which it explained that the 2017 Study was expressly designed to address the three issues identified in the 2014 SAGE Review. The 2017 Study addressed the “randomized” issue by comparing children vaccinated solely based on birthdates, thereby creating a random grouping.²⁷ It addressed the “OPV with DTP” issue by comparing children receiving no vaccines with those only receiving DTP.²⁸ It also addressed the “herd immunity” issue by looking at death rates at the time of the introduction of DTP in that region.²⁹ As explained in the introduction to the 2017 Study:

WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs [Non-Specific Effects] of ... diphtheria-tetanus-pertussis (DTP) ... and recommended further research (Higgins et al., 2014; Strategic Advisory Group of Experts on Immunization, 2014).

WHO, Mar. 13, 2014 (available at https://www.who.int/immunization/sage/meetings/2014/april/1_NSE_Background_paper_final.pdf) (the “SAGE Review”).

²⁰ *Ibid.*

²¹ *Ibid.*

²² *Ibid.*

²³ For example, unvaccinated children often do not receive vaccines because they are very frail, malnourished or sick, and hence more likely to die irrespective of vaccination. Thus, the unvaccinated group is often sicker than the vaccinated group, making the vaccine appear safer. By randomly picking which children receive or do not receive the DTP vaccine, a researcher can avoid this type of bias.

²⁴ See the SAGE Review *supra* note 19.

²⁵ *Ibid.*

²⁶ A copy of ICAN’s letter of Mar. 15, 2018, is attached as **Exhibit D**.

²⁷ The 2017 Study *supra* note 3.

²⁸ *Ibid.*

²⁹ *Ibid.*

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP (Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the “unvaccinated” children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the “unvaccinated” were therefore not frail children.³⁰

The 2017 Study also explains why it is the best study and the best evidence that modern science will almost certainly ever have to determine whether DTP kills more children than it saves:

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee [Immunization and Vaccines Related Implementation Research Advisory Committee] to which SAGE delegated the follow-up studies of the NSEs [Non-Specific Effects] of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study [the 2017 Study] may remain the closest we will ever come to a RCT [Randomized Controlled Trial] of the NSEs of DTP.³¹

The 2017 Study, therefore, represents the closest and best data UNICEF will likely ever have regarding whether DTP kills more children than it saves; and as noted, it concluded that children receiving DTP in the first six months of life *died at ten times the rate* of those children who received no vaccines in the first six months of life.³²

³⁰ *Ibid* at § 1 Introduction.

³¹ *Ibid* at § 5 Conclusions.

³² *Ibid* at § 4.1 Main Observations (emphasis supplied). The 2017 Study also found that infants receiving DTP *died at five times the rate* as compared to infants that received OPV.

ICAN, therefore, called for UNICEF to join every single developed country in the world in ceasing the use of DTP.³³ It pointed out that Japan, for example, ceased using this product in 1981, South Korea in 1989, New Zealand in 1994, the United States in 1997, and China in 2008.³⁴ ICAN also again implored UNICEF to cease distribution of this product or at least obtain informed consent from parents before administrating this product. As ICAN made unmistakably clear: “Continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study’s unmistakable findings would violate various laws designed to protect children from harm.”³⁵ Despite these strong arguments and the clear science against the continued distribution of DTP, UNICEF did not respond to ICAN’s letter of March 15, 2018.

ICAN, therefore, sent another letter on July 26, 2018,³⁶ which attached all prior letters and again attached a copy of the 2017 Study. That letter stated:

Despite the passage of over four months, UNICEF has failed to respond to our March 15, 2018 letter and it has now been over eight months since we brought to your attention the fact that UNICEF is purchasing, distributing and widely promoting a vaccine for which, as is plain from our letter exchange, the best available evidence clearly demonstrates it is killing far more children than it is saving.

As you are likely also already acutely aware, on the heels of our last letter, Dr. Aaby and his renown vaccine advocate colleagues published an article on March 19, 2018, in the journal *Frontiers in Public Health*, entitled *Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?* (the “**2018 Study**”). ...

As you will recall, the 2017 Study found that babies younger than six months of age receiving DTP vaccine died at ten times the rate as babies in the same age range that did not receive any vaccines. The 2018 Study looked at children between six and thirty-five months of age and compared DTP-vaccinated children that were generally healthier and had better nutritional status with non-DTP-vaccinated children who generally were unhealthier and had worse nutritional status. The incredible result: “Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher

³³ Exhibit D at 5.

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ A copy of ICAN’s Jul. 26, 2018 letter is attached as **Exhibit E**.

mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.³⁷

ICAN's letter of July 26, 2018, then concluded, in relevant part, by imploring the decision makers at UNICEF to stop purchasing and distributing a product that they could no longer plausibly deny knowing was killing infants:

In our letter from March 2018, we ... asserted that continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study's unmistakable findings would violate various laws designed to protect children from harm.

It has now been over eight months since we provided you, on two occasions, a copy of the 2017 Study. Yet, despite your verbose response in February 2018, you have failed to provide even a single argument to contest the 2017 Study's methodology or conclusions. In fact, you have failed to address this study altogether. And you have also failed to indicate that UNICEF will, at the least, as required by the Nuremberg Code, assure that parents are being advised of the increased risk of death from DTP vaccine prior to administering this vaccine to their child.

Copies of this letter with all exhibits will be distributed directly to all members of UNICEF that we can identify that are involved in the purchase, distribution and promotion of DTP vaccine. For all UNICEF individuals receiving this letter, please take notice that your continued distribution of this for-profit product violates various laws, including various international human rights law. Furthermore, absent forthwith confirmation from UNICEF that it has either ceased distribution of DTP vaccine or has evidentiary support for why the 2017 Study and 2018 Study are incorrect, we intend to take appropriate remedial action, including referral to the International Criminal Court, against all individuals at UNICEF involved in continued purchase, distribution and promotion of a product that the best available evidence makes clear is killing far more children than it is saving.³⁸

ICAN's letter of July 26, 2018, was sent to the following individuals:

³⁷ Exhibit E (citations omitted).

³⁸ *Ibid.*

Henrietta H. Fore
Executive Director,
UNICEF
3 United Nations Plaza
New York, New York 10017

Dr. Stefan Peterson
Associate Director, Health
UNICEF
3 United Nations Plaza
New York, New York 10017

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF
3 United Nations Plaza
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Krista Hund
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Heather Deehan
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Benjamin Hickler
Medical Anthropologist
Communication for Development
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Immunization Supply Chain Financing
Consultant
UNICEF
18 Tremont St #820
Boston, MA 02108

Helena Ballester Bon
Communication for Immunization
UNICEF
3 United Nations Plaza
New York, New York 10017

ICAN's letter of July 26, 2018 was also sent to various United Nations representatives of over one-hundred countries.³⁹ Further, ICAN's first letter of December 5, 2017 was sent to Dr. Anthony Lake, then Executive Director of UNICEF who has since resigned from his post.

The foregoing list of individuals, as well as all other individuals and entities that have participated in the purchase, promotion, and distribution of DTP with knowledge of the scientific findings regarding this product and mortality are collectively referred to herein as the **"Defendants."**

³⁹ See Exhibit E, Appendix.

C. UNICEF Receives Letter & Report from the Vaccine Science Foundation Regarding the Clear Scientific Evidence that DTP Increases Mortality

UNICEF also received a letter from the Vaccine Science Foundation⁴⁰ which attached a white paper, published June 19, 2019, by world-renowned scientist Peter C. Gøtzsche, Professor, DrMedSci, MSc, entitled *Effect of DTP Vaccines on Mortality in Children in Low-Income Countries* (the “**White Paper**”).⁴¹ The White Paper reviewed all existing evidence regarding DTP and its effect on mortality and reached the same conclusion as that in the 2017 Study. The Vaccine Science Foundation’s letter to UNICEF, therefore, provided, in relevant, part as follows:

The Vaccine Science Foundation proudly supports UNICEF’s goal of reducing child mortality worldwide. For this reason, the Vaccine Science Foundation urges you to read the expert report *Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*, to ensure that UNICEF can productively engage in its goal of reducing child mortality.

The Vaccine Science Foundation respectfully requests that UNICEF explain whether it accepts the conclusion of the attached expert report. If it does, explain the actions it intends to take. If it does not accept the conclusion of this report, please explain the basis for rejecting its conclusion.⁴²

UNICEF never responded to the letter from the Vaccine Science Foundation. UNICEF has also never responded to the letters from ICAN dated March 15, 2018 and July 26, 2018.

D. UNICEF Fails to Offer Any Evidence to Rebut the Clear Scientific Evidence that DTP Increases Mortality

UNICEF has never, in over 3 years, provided any evidence to rebut the findings of the 2017 Study, the 2018 Study, or the White Paper. UNICEF nonetheless continues to purchase, promote, and distribute DTP to the following countries which are also parties to the Rome Statute:

Afghanistan, Albania, Antigua and Barbuda, Bangladesh, Benin, Bolivia, Bosnia and Herzegovina, Bulgaria, Burkina Faso, Cambodia, Central African Republic, Chad, Congo, Cote d'Ivoire, Democratic Republic of Congo, Djibouti, Gabon, Georgia, Ghana, Guyana, Honduras, Jordan, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Moldova, Mongolia, Namibia, Niger,

⁴⁰ A copy of the Vaccine Science Foundation’s Letter is attached as **Exhibit F**.

⁴¹ The White Paper *supra* note 10.

⁴² Exhibit F.

Nigeria, Palestine, Senegal, Seychelles, Sierra Leone, Tajikistan, Tanzania, Uganda, Zambia.⁴³

The countries above shall be referred to herein collectively as the “**Countries.**”

UNICEF is charged with protecting the children of the world, yet it continues – knowingly and with full knowledge and aforethought – to promote, distribute, and direct the injection of a product it knows is causing far more deaths of infants in developing countries across the globe than it is saving. UNICEF’s conduct may be, in part, explained by its conflicting interest in promoting a “healthy” pharmaceutical industry.

UNICEF has declared that a “healthy industry is vital to ensure uninterrupted and sustainable supply of vaccines” and has extensive financial arrangements and a “long-standing relationship with” pharmaceutical companies producing vaccines.⁴⁴ Indeed, in 2019 alone, UNICEF purchased over \$1.656 billion of vaccine products from these companies and spent an equally significant sum paying companies for their distribution, in total amounting to over a third of UNICEF’s budget.⁴⁵ ICAN sincerely hoped that political and economic considerations, as well as UNICEF’s understandable instinct of self-preservation and its desire to safeguard its reputation, would not cloud UNICEF’s judgment when evaluating its clear moral, ethical and legal duty to protect children from death from DTP.

Sadly, despite repeated demands over three years, UNICEF has failed to provide a single explanation for why the 2017 Study, which confirmed earlier findings and whose findings were reaffirmed in the 2018 Study, is incorrect. Up until UNICEF’s response letter on February 6, 2018, and even until ICAN’s follow-up letter of March 15, 2018, UNICEF could potentially have claimed ignorance or mistake in distributing DTP. But after it had been provided the 2017 Study twice and could not provide any proof to contradict its findings, the decisionmakers within UNICEF were acting with full knowledge they were killing infants.

It is understandable that those making serious mistakes are reluctant to change course. UNICEF’s desire for self-preservation is, however, no excuse for continuing to cause the death of children in developing and underdeveloped countries. These acts constitute crimes under international law and must stop, and those harmed must receive recompense.

⁴³ This list was compiled from the following reports from the United Nations Children’s Fund (“UNICEF”): https://www.dcvmn.org/IMG/pdf/27th_suvi_stockpiling_strategies_and_priorities.pdf; <https://www.fondation-merieux.org/wp-content/uploads/2017/03/vaccination-ecosystem-health-check-2015-heather-deehan.pdf>; [https://www.unicef.org/supply/media/556/file/Diphtheria,%20tetanus%20and%20pertussis%20\(DTP\)%20vaccines%20supply%20update.pdf](https://www.unicef.org/supply/media/556/file/Diphtheria,%20tetanus%20and%20pertussis%20(DTP)%20vaccines%20supply%20update.pdf); <https://www.gavi.org/progress-report>; <https://www.unicef.org/supply/resources/annual-reports>; https://www.unicef.org/mena/sites/unicef.org.mena/files/2018-04/immunization%20financing%20Web_0.pdf). Additionally, an attempt was made to reach Heather Deehan, Chief of Vaccines at the UNICEF Supply Headquarters in Copenhagen, Denmark via e-mail. UNICEF Supply Division refused to divulge information as to the countries for which it procures DTP.

⁴⁴ See Supply Division Update 2019 *supra* note 2; see also, UNICEF Supply Division Website (available at <https://www.unicef.org/supply/pricing-data>).

⁴⁵ See UNICEF Supply Division Annual Report 2019 (available at <https://www.unicef.org/supply/sites/unicef.org/supply/files/2020-06/Supply-Annual-Report-2019.pdf>).

II. THE COURT HAS JURISDICTION OVER THE ALLEGED CRIMES

A. The ICC Has Jurisdiction *Ratione Temporis* Over the Alleged Crimes Because the Crimes Have Taken Place Since the Establishment of the Court

As explained above, since at least February 6, 2018, the Defendants have been engaged in the procurement, distribution and supply of DTP while being conscious that DTP may result in an increased mortality in infants. Thus, the Court has jurisdiction *ratione temporis* over the allegations contained in this letter pursuant to Article 11(1) of the Rome Statute.⁴⁶ Further, when the crimes were committed in the Countries, the Countries were and remain members of the Rome Statute to satisfy the jurisdictional requirements of Article 11(2) of the Rome Statute.⁴⁷

B. The ICC Has Territorial Jurisdiction over the Alleged Crimes Because the Crimes have Taken Place Within the Territories of ICC State Parties

The alleged crimes have been committed in the territories of the Countries, all of which are members of the Rome Statute.⁴⁸ By procuring, distributing, and supplying DTP to the Countries with the knowledge that administering this product to children increases the mortality rate, the Defendants have committed the alleged crimes in the territories of the Countries. Accordingly, the Court has jurisdiction over all the alleged crimes pursuant to Article 12(2)(a),⁴⁹ irrespective of the nationality of the accused individuals.

C. The ICC Has Jurisdiction *Ratione Materiae* Over the Alleged Crimes Because the Allegations Herein Constitute Violations of Article 7 of the Rome Statute

The Defendants have committed crimes against humanity in all of the Countries as stipulated in Article 7(1) of the Rome Statute. They are guilty of Persecution (Article 7(1)(h)), Murder (Article 7(1)(a)), and Other Inhumane Acts (Article 7(1)(k)).

At the outset, the Defendants' conduct satisfies the five contextual elements of the *chapeau* to Article 7(1) of the Rome Statute.⁵⁰ The Defendants have engaged and are continuing to engage in (i) an attack directed towards a civilian population (ii) in furtherance of an organizational policy (iii) wherein the attack is widespread and systematic in nature (iv) and bears a nexus with the Defendants' acts (v) while having knowledge of the attack.⁵¹

⁴⁶ Rome Statute *supra* note 1.

⁴⁷ *Ibid.*

⁴⁸ *See supra* § I (D).

⁴⁹ Rome Statute *supra* note 1.

⁵⁰ *See Situation in the Republic of Côte d'Ivoire*, Corrigendum to 'Decision Pursuant to Article 15 of the Rome Statute on the Authorization of an Investigation into the Situation in the Republic of Côte d'Ivoire', ICC-02/11-14-Corr, Nov. 15, 2011, ¶ 29 (available at <https://www.icc-cpi.int/Pages/record.aspx?docNo=ICC-02/11-14-Corr>).

⁵¹ *Ibid.*

As an attack need not be a military attack for it to constitute a crime against humanity,⁵² the Defendants' course of conduct in supplying potentially a fatal injection to infants and children in the Countries amounts to an attack within the meaning of Article 7(1) of the Rome Statute. This attack is specially directed towards the civilian populations of the Countries. Moreover, the attack is in furtherance of the Defendants' organizational policy to inject DTP into millions of children.⁵³ The Defendants actively promote and encourage⁵⁴ governments of the Countries to use DTP.⁵⁵ The Defendants' actions are widespread as they impact millions of children in the Countries. Their actions are also systematic, as the Defendants have been aware of the increased mortality effect of DTP since at least 2018, if not since 2014, and yet they continue to purchase, supply, promote and distribute DTP. They also continue to mandate that many of the Countries procure this product through them in order to receive continual aid and support.⁵⁶ The Defendants' conduct is an organized plan⁵⁷ in furtherance of their common policy to achieve high injection uptake of this product, even if it caused an increase in mortality to innocent children. There is a sufficient nexus between the alleged crimes of humanity and the Defendants' actions because the Defendants are directly responsible for procuring, supplying, distributing, and promoting DTP in the Countries. The Defendants continue to do so with the knowledge that purchasing, promoting, and distributing DTP to the Countries would cause increased mortality among infants in the Countries.

1. *Crime Against Humanity of Persecution (Article 7(1)(h))*

The foregoing conduct violates Article 7(1)(h), the crime against humanity of persecution. This crime against humanity has roots in conduct that is inherently discriminatory against a group of persons by reason of their membership to the group and by denying the group basic fundamental human rights.⁵⁸ The Defendants targeted infants in developing or under-developed countries, namely the Countries, to the exclusion of all developed countries. The targeting was based on nationality and political identities of the children in the Countries. The Defendants have discriminated against the children in the Countries because they are aware that developed countries have abolished the use of DTP; as such, their only means of furthering their economic and political interests is to purchase, promote and distribute DTP to the Countries with full knowledge that this

⁵² Elements of Crimes, Introduction to Article 7 of the Rome Statute, ¶ 3.

⁵³ See UNICEF Immunization Data (available at <https://data.unicef.org/topic/child-health/immunization/>) (emphasis supplied).

⁵⁴ See Elements of Crimes, Introduction to Article 7 of the Rome Statute, ¶ 3.

⁵⁵ See UNICEF Immunization Data *supra* note 53 (“The percentage of children receiving the diphtheria, tetanus and pertussis vaccine (DTP) is often used as an indicator of how well countries are providing routine immunization services.”).

⁵⁶ For example, see UNICEF's Immunization Financing in MENA Report, May 2018, *supra* note 43 (stating that the Sudan currently uses UNICEF SD to procure all its vaccines. “As a Gavi-transitioning country, it will benefit from manufacturer pledges for continued prices for a period of time following the transition, as long as it continues to procure through UNICEF SD”).

⁵⁷ See *Situation in the Republic of Kenya*, Corrigendum of the ‘Decision Pursuant to Article 15 of the Rome Statute on the Authorization of an Investigation into the Situation in the Republic of Kenya’, ICC-01/09-19-Corr, Mar. 31, 2010, ¶ 96 (available at <https://www.icc-cpi.int/pages/record.aspx?uri=854562>) (stating that the word “systematic” refers to “organized nature of the acts of violence and the improbability of their random occurrence”).

⁵⁸ See W. Schabas, *THE INTERNATIONAL CRIMINAL COURT: A COMMENTARY ON THE ROME STATUTE* 194 (2nd ed., 2016).

product will increase mortality among infants in the Countries. The Defendants discriminated against children in the countries by depriving them of their fundamental right to life under international law as recognized in the International Bill of Human Rights.⁵⁹ The Defendants also discriminated against these children by depriving them of their fundamental right to privacy of person and informed consent as codified in the Nuremberg Code⁶⁰ and the UNESCO Universal Declaration on Bioethics and Human Rights.⁶¹ The Defendants have violated international law and deprived millions of children of their fundamental rights by failing to duly inform the parents of the infants of the risks of mortality from this product.

2. *Crime Against Humanity of Murder (Article 7(1)(a))*

The foregoing conduct violates Article 7 (1)(a), the crime against humanity of murder, since the Defendants have caused the death⁶² of civilian children in the Countries as a part of their widespread and systematic plan to widely inject this product into all infants despite knowing that DTP causes increased mortality among infants.⁶³ For the Defendants to be found guilty of the crime against humanity of murder, specific identity of the victims is not required to be proven.⁶⁴

3. *Crime Against Humanity of Other Inhumane Acts (Article 7(1)(k))*

The foregoing conduct violates Article 7(1)(k), the crime of humanity of engaging in other inhumane acts. The Defendants inflicted great suffering and death to infants and great suffering and serious injury to the mental health of the parents and/or guardians of the killed infants by means of an inhumane act of having these parents participate in causing the deaths of their children. The Defendants took advantage of the lack of access to the proper information in the Countries and promoted the use of DTP with full knowledge that injecting infants in the Countries would increase mortality among infants in the Countries. The Defendants deprived the parents of the many infants in the Countries the right to give free and informed consent as mandated by

⁵⁹ The International Bill of Human Rights consists of the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights and its two Optional Protocols.

⁶⁰ Nuremberg Code *supra* note 14.

⁶¹ UNESCO Universal Declaration on Bioethics and Human Rights, Article 6(1), available at http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html (providing that “[a]ny preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.”).

⁶² Elements of Crimes, Article 7 (1)(a), Crime Against Humanity of Murder, note 7.

⁶³ See Elements of Crimes, Article 7 (1)(a), Crime Against Humanity of Murder.

⁶⁴ *Prosecutor v. Bemba*, Decision Pursuant to Article 61(7)(a) and (b) of the Rome Statute on the Charges of the Prosecutor Against Jean-Pierre Bemba Gombo, ICC-01/05-01/08-424, Jun. 15, 2009, ¶ 133 (available at <https://www.icc-cpi.int/Pages/record.aspx?docNo=ICC-01/05-01/08-3343>).

international human rights law.⁶⁵ Such deprivation is an inhumane act of similar gravity to the acts referred to in Article 7(1).⁶⁶

D. The ICC Has Jurisdiction *Ratione Materiae* Over the Alleged Crimes Because the Allegations Herein Constitute Violations of Article 8(2)(a) of the Rome Statute

Since February 6, 2018, the date UNICEF sent its letter regarding DTP and mortality to ICAN, it appears the following countries from the above list⁶⁷ have been involved in an international armed conflict: Georgia, Jordan, Moldova, and Palestine (the “**International Armed Conflict Countries**”).⁶⁸ The Defendants are guilty of war crimes in the International Armed Conflict Countries as laid out in Article 8 of the Rome Statute due to their conduct in relation to the International Armed Conflict Countries. Specifically, Defendants are guilty of the war crime of biological experiments (Article 8(2)(a)(ii)-3), the war crime of willful killing (Article 8(2)(a)(i)), and the war crime of willfully causing great suffering (Article 8(2)(a)(iii)).

It is submitted that the provisions of Articles 8(1) and 8(2)(a) of the Rome Statute are applicable with respect to the International Armed Conflict Countries since these states are either facing either an international armed conflict⁶⁹ or are under military occupation by another state.⁷⁰ Consequently, the civilian populations in the International Armed Conflict Countries enjoy protected status⁷¹ under the Geneva Convention Relative to the Protection of Civilian Persons in Time of War of 1949 (the “**Fourth Geneva Convention**”).⁷² The Court has jurisdiction with respect to the violations of Article 8(1) of the Rome Statute because the crimes alleged below have been committed as “part of a large-scale commission of such crimes.”⁷³ The evidence presented in this letter demonstrates the extent to which civilian children and their families in the International Armed Conflict Countries have been abused and impacted due to the Defendants’ actions during times of existing conflicts. The Defendants also meet the intent requirement because they were fully aware⁷⁴ of the existence and state of an armed conflict in the International

⁶⁵ See Nuremberg Code *supra* note 14; UNESCO Universal Declaration on Bioethics and Human Rights *supra* note 61.

⁶⁶ *Prosecutor v. Katanga et. al.*, Decision on Confirmation of Charges, ICC-01/04-01/07, Sept. 30, 2008, ¶ 448 (available at https://www.icc-cpi.int/CourtRecords/CR2008_05172.PDF).

⁶⁷ See *supra* § I (D).

⁶⁸ <http://www.rulac.org/browse/conflicts>.

⁶⁹ *Ibid.*

⁷⁰ *Ibid*; see also, Elements of Crime, note 34.

⁷¹ See Elements of Crime, note 35.

⁷² The Geneva Convention Relative to the Protection of Civilian Persons in Time of War, 75 U.N.T.S 287, Aug. 12, 1949, Article 2 (available at <https://www.icrc.org/en/doc/assets/files/publications/icrc-002-0173.pdf>) (the “**Fourth Geneva Convention**”).

⁷³ Rome Statute *supra* note 1, Article 8(1).

⁷⁴ See Elements of Crime, Article 8, Introduction, ¶ 3.

Armed Conflict Countries when they undertook extra measures to procure, supply, promote, and distribute DTP to civilian infants in these countries.⁷⁵

1. *War Crime of Biological Experiments (Article 8(2)(a)(ii)-3)*

The foregoing conduct also violates Article 8(2)(a)(ii)-3 since the Defendants subjected one or more infants in these countries to a biological experiment endangering their physical health without any therapeutic intent because, *inter alia*, DTP is a preventative product and not a therapeutic.⁷⁶ Subjecting the protected civilian infants to DTP amounts to a biological, medical or scientific experiment because DTP has not been subjected to a single randomized placebo-controlled trial to prove its safety and efficacy⁷⁷ and the Defendants had the best possible evidence reflecting that this product increases mortality in children, rather than decreasing it.⁷⁸ The intent of administering DTP is non-therapeutic in nature since it does not treat any condition but is rather considered preventative. Further, the Defendants' actions leading to increased mortality among protected infants are neither justified by medical reasons⁷⁹ nor was the methodical and systematic injection of DTP carried out in the best interests⁸⁰ of these children; rather, the Defendants' actions were to protect Defendants from the reputational, civil, and criminal consequences of admitting that DTP is increasing mortality.

2. *War Crime of Willful Killing (Article 8(2)(a)(i))*

The foregoing conduct violates Article 8(2)(a)(i) since the Defendants caused the deaths⁸¹ of civilian children in the International Armed Conflict Countries. The Defendants' conduct is reckless, if not willful,⁸² because they were aware that DTP would increase infant mortality; nevertheless, they engaged in extra measures to continue administering DTP to protected infants during the armed conflict without any regard to the potentially fatal impact of the biologic, and without duly informing the parents of the affected infants of the increased risk of mortality.

⁷⁵ See for example, UNICEF Immunization Program in Conflict Areas (available at <https://www.unicef.org/immunization/immunization-and-conflict>); UNICEF Press Release, Jul. 15, 2019 (available at <https://www.unicef.org/press-releases/20-million-children-missed-out-lifesaving-measles-diphtheria-and-tetanus-vaccines>); UNICEF Occupied Palestinian territory - Real Lives - Reaching the most vulnerable children in the State of Palestine (available at https://www.unicef.org/oPt/real_lives_11148.htm).

⁷⁶ Elements of Crimes, Article 8(2)(a)(ii)-3.

⁷⁷ See White Paper *supra* note 10 at 19.

⁷⁸ See *supra* § I (B).

⁷⁹ Elements of Crimes, Article 8(2)(a)(ii)-3.

⁸⁰ *Ibid.*

⁸¹ Elements of Crime, note 31.

⁸² M. Klamberg, COMMENTARY ON THE LAW OF THE INTERNATIONAL CRIMINAL COURT 68 (2017).

3. *War Crime of Willfully Causing Great Suffering (Article 8(2)(a)(iii))*

The foregoing conduct also violates Article 8(2)(a)(iii), since the Defendants inflicted great suffering and death to infants and great mental pain and suffering to the parents of the killed infants who unwittingly participated in causing the deaths of their children. The Defendants were, at the very least, reckless⁸³ as to their conduct by failing to inform the parents of the protected infants of the risks of increased mortality from DTP.

E. The ICC Has Jurisdiction *Ratione Materiae* Over the Alleged Crimes Because the Allegations Herein Constitute Violations of Article 8(2)(c) of the Rome Statute

Since February 6, 2018, the date UNICEF sent its letter regarding DTP and mortality to ICAN, it appears the following countries from the above list⁸⁴ have been involved in an armed conflict not of an international character: Afghanistan, Central African Republic, Democratic Republic of Congo, Kenya, Mali, Niger, Nigeria, and Senegal (the “**Non-International Armed Conflict Countries**”).⁸⁵ The Defendants are guilty of war crimes in the Non-International Armed Conflict Countries as laid out in Article 8 of the Rome Statute due to their conduct in relation to the Non-International Armed Conflict Countries. Specifically, Defendants are guilty of the war crime of medical or scientific experiments (Article 8(2)(e)(xi)-2), the war crime of murder (Article 8(2)(c)(i)-1), and the war crime of cruel treatment (Article 8(2)(c)(i)-3).

It is submitted that the provisions of Articles 8(1), 8(2)(c) and 8(2)(e) of the Rome Statute are applicable with respect to the Non-International Armed Conflict Countries, since these states are facing non-international armed conflicts⁸⁶ which meet the *Tadic* standard of armed conflict adopted by the Court⁸⁷ and are not merely internal disturbances as stipulated in the Rome Statute.⁸⁸ Consequently, the civilian populations in the Non-International Armed Conflict Countries enjoy protected status⁸⁹ under the Fourth Geneva Convention.⁹⁰ The Court has jurisdiction with respect to the violations of Article 8(1) of the Rome Statute because the crimes alleged below have been committed as “part of a large-scale commission of such crimes.”⁹¹ The evidence presented in this letter demonstrates the extent to which civilian children and their families in the Non-International Armed Conflict Countries have been abused and impacted due to the Defendants’ actions during times of existing conflicts. The Defendants also meet the intent requirement since they were fully

⁸³ *Ibid* at 70.

⁸⁴ *See supra* § I (D).

⁸⁵ <http://www.rulac.org/browse/conflicts>.

⁸⁶ *Ibid*.

⁸⁷ *See Prosecutor v. Dyllo*, Decision on the Confirmation of Charges, Pre-Trial Chamber I, ICC-01/04-01/06, Jan. 29, 2007 at ¶ 533 (available at <https://www.icc-cpi.int/pages/record.aspx?uri=266175>).

⁸⁸ Rome Statute *supra* note 1, Article 8(2)(d) and (f).

⁸⁹ *See Elements of Crimes*, note 35.

⁹⁰ Fourth Geneva Convention *supra* note 72, Article 2.

⁹¹ Rome Statute *supra* note 1, Article 8(1).

aware⁹² of the existence and state of armed conflicts in the Non-International Armed Conflict Countries when they undertook extra measures to procure, supply, promote, and distribute DTP to the civilian infants in these countries.⁹³

1. *War Crime of Medical or Scientific Experiments (Article 8(2)(e)(xi)-2)*

The foregoing conduct also violates Article 8(2)(e)(xi)-2 since the Defendants subjected one or more infants in these countries to a biological experiment, thus endangering their physical health, without therapeutic intent because, *inter alia*, DTP is a preventative product and not a therapeutic.⁹⁴ Subjecting the protected civilian infants who, in many cases were under the power of another party to the conflict,⁹⁵ to DTP amounts to a biological, medical or scientific experiment since DTP has not been subjected to a single randomized placebo-controlled trial to prove its safety and efficacy,⁹⁶ and the Defendants had the best possible evidence reflecting that this product increases mortality in children, rather than decreasing it.⁹⁷ The intent of administering DTP is non-therapeutic in nature since it does not treat any condition but is rather considered preventative. Further, the Defendants' actions leading to increased mortality among protected infants are neither justified by medical reasons⁹⁸ nor was the methodical and systematic injection of DTP carried out in the best interests⁹⁹ of these children, but rather was to protect Defendants from the reputational, civil, and criminal consequences of admitting that DTP is increasing mortality.

2. *War Crime of Murder (Article 8(2)(c)(i)-1)*

The foregoing conduct violates Article 8(2)(c)(i)-1 because the Defendants have killed one or more infants by administering DTP to them while they enjoyed protected civilian status and were not taking part in the hostilities.¹⁰⁰

3. *War Crime of Cruel Treatment (Article 8(2)(c)(i)-3)*

The foregoing conduct also violates Article 8(2)(c)(i)-3, since the Defendants inflicted great suffering and death to infants and great mental pain and suffering to the parents of the killed infants who unwittingly participated in causing the deaths of their children. The Defendants were,

⁹² See Elements of Crimes, Article 8, Introduction, ¶ 3.

⁹³ See *supra* note 75.

⁹⁴ M. Klamberg, *supra* note 82, at 114.

⁹⁵ Elements of Crimes, Article 8(2)(e)(xi)-2.

⁹⁶ See White Paper *supra* note 10 at 19.

⁹⁷ See *supra* § I (B).

⁹⁸ Elements of Crimes, Article 8(2)(e)(xi)-2.

⁹⁹ *Ibid.*

¹⁰⁰ Elements of Crimes, Article 8(2)(c)(i)-1

at the very least, reckless¹⁰¹ as to their conduct by failing to inform the parents of the protected infants of the risks of increased mortality from DTP.

III. THE PRESENT MATTER IS ADMISSIBLE UNDER ARTICLE 17 OF THE ROME STATUTE

We respectfully request confirmation that the Prosecutor intends to initiate an investigation of the serious crimes raised herein pursuant to Article 15(1) of the Rome Statute. The facts and evidence presented in this communication demonstrates there is a reasonable basis to believe that Defendants have committed the foregoing crimes that are within the jurisdiction of the Court.¹⁰² Further, as required under Article 53(1)(b), the facts demonstrated above satisfy the gravity and complementarity requirements of Article 17 for the Prosecutor to initiate her investigation.¹⁰³

A. The Present Complaint Satisfies the Gravity Threshold of Article 17(1)(D)

According to Article 17(1)(d) of the Rome Statute, the Prosecutor must assess whether the allegations contained are of “sufficient gravity to justify further action by the Court.”¹⁰⁴ The supplementary regulations of the Office of the Prosecutor provide that, while assessing the gravity of a complaint about the admissibility of the matter, the Prosecutor shall consider both the quantitative and the qualitative aspects of various factors¹⁰⁵ including the scale,¹⁰⁶ nature,¹⁰⁷ manner of commission,¹⁰⁸ and impact of the crimes.¹⁰⁹

The present matter meets the scale threshold because the facts presented above clearly demonstrate the sheer extent of the Defendants’ actions as UNICEF has procured tens of millions

¹⁰¹ M. Klamberg, *supra* note 82, at 112.

¹⁰² Rome Statute *supra* note 1, Article 53(1)(a).

¹⁰³ *See infra* §§ III(A), (B).

¹⁰⁴ The Office of the Prosecutor, *Policy Paper on Preliminary Examinations*, November 2013, at ¶ 59 (available at https://www.icc-cpi.int/iccdocs/otp/OTP-Policy_Paper_Preliminary_Examinations_2013-ENG.pdf) (the “Policy Paper”).

¹⁰⁵ *Ibid* at ¶ 61.

¹⁰⁶ *The scale of the crimes* – this refers to the number of direct and indirect victims, the extent of the damage caused by the crimes, in particular the bodily or psychological harm caused to the victims and their families, or their geographical or temporal spread. *Ibid* at ¶ 62.

¹⁰⁷ *The nature of the crimes* – this refers to the specific elements of each offense. *Ibid* at ¶ 63.

¹⁰⁸ *The manner of commission of the crimes* – this refers to the means employed to execute the crimes, the degree of participation and intent in their commission, the extent to which the crimes are systematic or result from a plan or organized policy or otherwise result from the abuse of power or official capacity, and elements of particular cruelty, including the vulnerability of the victims or motives involving discrimination. *Ibid* at ¶ 64.

¹⁰⁹ *The impact of the crimes* – this refers to the sufferings endured by the victims and their increased vulnerability; the terror subsequently instilled, or the social, economic and environmental damage inflicted on the affected communities. *Ibid* at ¶ 65.

of DTP doses for millions of children in the Countries.¹¹⁰ The facts alleged herein satisfy the specific elements of each alleged crime in the preceding section.

In regards to the manner of commission of the crimes, this communication sheds light on the systematic malfeasance by one of the world's leading child protection organizations which claims to advocate for the "protection of children's rights"¹¹¹ and "strives to establish children's rights as enduring ethical principles and international standards of behavior towards children."¹¹² Despite repeated requests from organizations, including ICAN and the Vaccine Science Foundation, expressing their concerns and providing clear scientific evidence regarding the increase of mortality from DTP, the Defendants have failed to rebut clear proof that their actions are causing the death of countless infants, let alone acknowledge the credible studies presented to them; nor have they taken action to either investigate the matter or otherwise disprove them. The Defendants have acted systematically with the requisite knowledge of the grave threats DTP poses in already vulnerable infant populations.

Finally, this communication also sheds light on the impact caused by the Defendants' oversight and their need to protect their reputes. Parents and families of countless children have had to endure the loss of their children's lives and have inadvertently contributed to such loss simply because the Defendants failed to warn these parents of the potential risks associated with DTP.

B. The Present Complaint Satisfies the Complementarity Requirement of Article 17(1)(A)-(C)

As determined by the ICC Appeals Chamber in *Katanga*¹¹³ the established test for the complementarity requirement to admissibility under Article 17(a)-(c) is the determination of whether there are any ongoing or whether there have been any relevant national investigations or prosecutions.¹¹⁴ Domestic inactivity is considered sufficient to make the case admissible.¹¹⁵

It is submitted that, to the best of our knowledge, the matters of UNICEF's procurement, supply, and distribution of DTP and its safety have not, and are not currently being, investigated by any of the Countries. If such investigations have been conducted or are ongoing, there are no public records to that effect. Thus, unless the Prosecutor determines otherwise, the presented case meets the complementarity test to admissibility.

¹¹⁰ See UNICEF Supply Division Update Diphtheria Tetanus and Pertussis Vaccine Supply Update, Oct. 2016 (available at <https://www.unicef.org/supply/sites/unicef.org/supply/files/2019-06/diphtheria-tetanus-and-pertussis-DTP-vaccine.pdf>).

¹¹¹ See UNICEF's Mission Statement (available at https://www.unicef.org/about/who/index_mission.html).

¹¹² *Ibid.*

¹¹³ *Prosecutor v. Katanga et. al.*, Judgement on the Appeal of Mr. Germain Katanga against the Oral Decision of Trial Chamber II of 12 June 2009 on the Admissibility of the Case, ICC-01/04-01/07-1497, Sept. 25, 2009 (available at <https://www.icc-cpi.int/pages/record.aspx?uri=746819>).

¹¹⁴ *Ibid* at ¶ 78.

¹¹⁵ The Policy Paper *supra* note 104 at ¶ 47.

IV. CONCLUSION

While medical interventions have saved countless lives, the graveyard of history is also replete with once lauded but later abandoned medical inventions and practices. When an issue with a medical procedure is identified, especially when it is killing children, immediate action is demanded. Unfortunately, it appears that political and economic considerations at UNICEF have clouded its clear moral and ethical duty to protect children from death caused by its administration of DTP.

We look forward to the response from the Prosecutor and pray for confirmation that she will proceed with an investigation pursuant to Article 15(1) of the Rome Statute. Upon confirmation that the Prosecutor will engage in an investigation *proprio motu*, we can provide the additional information and evidence needed for the Prosecutor to conduct her analysis and investigation pursuant to Article 15(2). It is our sincere hope that the mere existence of an investigation will finally move UNICEF to act to save the infants in developing countries who are dying each day due to its DTP program.

Thank you for the time taken to review this submission and for working toward protecting all children, especially the most disenfranchised, from premature death based on the actions of those in positions of power.

Respectfully submitted,



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Enclosure: Exhibits A - F

* Admitted to practice law in the Republic of India.

EXHIBIT A



Research Paper

The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment



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ABSTRACT

Background: We examined the introduction of diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau in the early 1980s.

Methods: The child population had been followed with 3-monthly nutritional weighing sessions since 1978. From June 1981 DTP and OPV were offered from 3 months of age at these sessions. Due to the 3-monthly intervals between sessions, the children were allocated by birthday in a 'natural experiment' to receive vaccinations early or late between 3 and 5 months of age. We included children who were <6 months of age when vaccinations started and children born until the end of December 1983. We compared mortality between 3 and 5 months of age of DTP-vaccinated and not-yet-DTP-vaccinated children in Cox proportional hazard models.

Results: Among 3–5-month-old children, having received DTP (\pm OPV) was associated with a mortality hazard ratio (HR) of 5.00 (95% CI 1.53–16.3) compared with not-yet-DTP-vaccinated children. Differences in background factors did not explain the effect. The negative effect was particularly strong for children who had received DTP-only and no OPV (HR = 10.0 (2.61–38.6)). All-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19)).

Conclusion: DTP was associated with increased mortality; OPV may modify the effect of DTP.

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1. Introduction

Individually randomized studies to measure impact on child survival of different vaccines were not conducted when the Expanded Program on Immunization (EPI) was introduced in low-income countries in the 1970s. The disease-protective effects were well documented, so the main issue was at which age to introduce the vaccine most effectively (The Expanded Programme on Immunization, 1982). Except for measles vaccine (MV), surprisingly few studies examined the introduction of vaccines and their impact on child survival (Aaby et al., 1983, 2003a; Holt et al., 1990; The Kasongo Project Team, 1981). One trial of measles-vaccinated and measles-unvaccinated communities in Congo showed a larger than expected reduction in child mortality (Aaby et al., 1981); this observation was subsequently corroborated by community "trials" and before-after studies in several countries (Aaby et al. 1984, 1993, 2003a; Holt et al., 1990; Kapoor and Reddaiah, 1991).

Hence, a vaccine may have non-specific effects (NSEs) on susceptibility to other infections (Aaby et al., 1995). WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs of BCG, diphtheria-tetanus-pertussis (DTP) and MV and recommended further research (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP (Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the "unvaccinated" children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in

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the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the “unvaccinated” were therefore not frail children.

2. Methods

2.1. Background

Bandim Health Project (BHP) has followed an urban community with a demographic surveillance system since December 1978, and took part in the introduction of vaccines well before a full-fledged national program was implemented with UNICEF support in 1986 (Aaby et al., 1984, 2004a).

2.2. Demographic Surveillance

In 1978–1979, under-five mortality was nearly 500/1000. Since malnutrition was assumed to be the main cause, a study was initiated to determine why children were malnourished (Aaby et al., 1983). However, severe malnutrition was not evident, and to understand the high mortality we started a health and demographic surveillance system (HDSS). The area was mapped and a census conducted. Four health workers were employed to identify pregnant women, encourage women to attend ante-natal clinics, and to follow children with anthropometric measurements to assess growth patterns and detect malnourished children. Each health worker followed a population of 1500–2000 individuals. The health workers were supervised by an expatriate nurse.

For each sub-district in Bandim, the responsible health worker kept a list of children under three years of age. BHP had no computerized surveillance system until 1990 but kept an A5 card (“BHP card”) for each child, where weights and vaccination dates were noted. The child’s growth card was kept by the mother.

The Bandim population was very mobile. It was important to maintain contact with the natal village for ceremonial purposes and to secure rice. Furthermore, mothers were not supposed to have sexual relations during breastfeeding (Jakobsen et al., 2004). Breastfeeding was prolonged in Guinea-Bissau. Thus, many women stayed in the rural areas with their natal family while breastfeeding. These cultural

traditions introduced variability in the participation in weighing and vaccination sessions.

2.3. Anthropometry

We arranged quarterly weighing sessions in each sub-district. The responsible health worker advised mothers the day before a community weighing. The following morning, the weight was measured and noted on the child’s growth card and the BHP card. When the World Food Program provided supplementary feeding this was given to families with malnourished children.

2.4. Vaccinations

There was no community vaccination program in 1981 except that we had organized a few measles vaccination campaigns (Aaby et al., 1984). Mothers could take their children to the Mother and Child Health Program in town. However, this clinic was mainly attended by the urban elite. Few children were vaccinated before BHP organized vaccination sessions (Table 1).

In June 1981, BHP started to provide vaccinations at the quarterly weighing sessions. A health center nurse accompanied the weighing team and vaccinated eligible children. DTP and OPV were provided from 3 months and MV from 9 months of age. OPV-at-birth was not given then. The three DTP and OPV doses could be given with an interval of one month but since we only arranged weighing every three months, most children had longer intervals between doses. DTP was administered intramuscularly and OPV as an oral drop. When both vaccines were administered at the same session OPV was usually given first and then DTP; the children would usually start crying after DTP due to the pain of the injection and it would therefore have complicated the administration of OPV to give DTP first. There were several periods where either OPV or DTP was missing (Fig. 1). BCG was rarely provided at the weighing sessions since most nurses were not trained to administer intra-dermal vaccination. A total of 269 children may have been BCG vaccinated as they had a vaccination date on their card (N = 192) or were noted to have received BCG but no date given (N = 77).

The expatriate nurse sometimes organized additional vaccination sessions in which the children were not weighed. During these sessions,

Table 1
Median age of vaccination and coverage for BCG, DTP and OPV of study cohort.

	1980	1981	1982	1983	1981–1983
Median age in days (N vaccines)					
BCG	9 (4)	48.5 (50)	34 (46)	25 (68)	33 (164)
DTP1	97 (12)	127 (147)	121 (164)	117 (278)	121 (589)
OPV1	98 (12)	118 (185)	121.5 (170)	117 (225)	118 (580)
MV	181 (5)	141 (53)	157 (2)	110 (1)	141.5 (56)
Coverage at 6 months of age					
BCG	1.7% (5/289)	3.5% (12/342)	23.7% (72/304)	17.4% (57/327)	14.5% (141/973)
DTP1	4.2% (12/289)	31.3% (107/342)	61.2% (186/304)	73.1% (239/327)	54.7% (532/973)
DTP3	2.4% (7/289)	0.9% (3/342)	4.3% (13/304)	4.0% (13/327)	3.0% (29/973)
OPV1	4.2% (12/289)	43.0% (147/342)	62.5% (190/304)	69.7% (228/327)	58.1% (565/973)
OPV3	2.4% (7/289)	2.0% (7/342)	4.3% (13/304)	4.0% (13/327)	3.4% (33/973)
MV	2.8% (8/289)	15.2% (52/342)	0.7% (2/304)	0% (0/327)	5.5% (54/973)
Coverage at one year of age					
BCG	2.6% (3/116)	2.4% (7/294)	15.4% (51/332)	17.4% (46/264)	11.7% (104/890)
DTP1	2.6% (3/116)	32.7% (96/294)	71.1% (236/332)	83.0% (219/264)	61.9% (551/890)
DTP3	2.6% (3/116)	4.4% (13/294)	18.4% (61/332)	43.2% (114/264)	21.1% (188/890)
OPV1	2.6% (3/116)	37.4% (110/294)	77.4% (257/332)	84.8% (224/264)	66.4% (591/890)
OPV3	2.6% (3/116)	12.2% (36/294)	32.5% (108/332)	44.3% (117/264)	29.3% (261/890)
MV	15.5% (18/116)	68.0% (200/294)	34.0% (113/332)	51.1% (135/264)	50.3% (448/890)

Notes: The inclusion criteria for the cohort in Table 1 are the same as for our study cohort: weight examination after 15 days of age and contribute time between 91 and 183 days of age. Median age: ‘year’ means the year the vaccination was given, and median age is the median age at time of vaccination with a given vaccine among children vaccinated before turning 6 months. E.g. the 4 BCG vaccines in the 1980 column were given in 1980 to children with a median age of 9 days. Coverage: ‘year’ means the year when the child turned exactly 1 year (or 6 months) old and coverage was assessed. Only children surviving to 1 year (or 6 months) of age were assessed for coverage. Children turning 1 year in 1984 were thus not presented in the table.

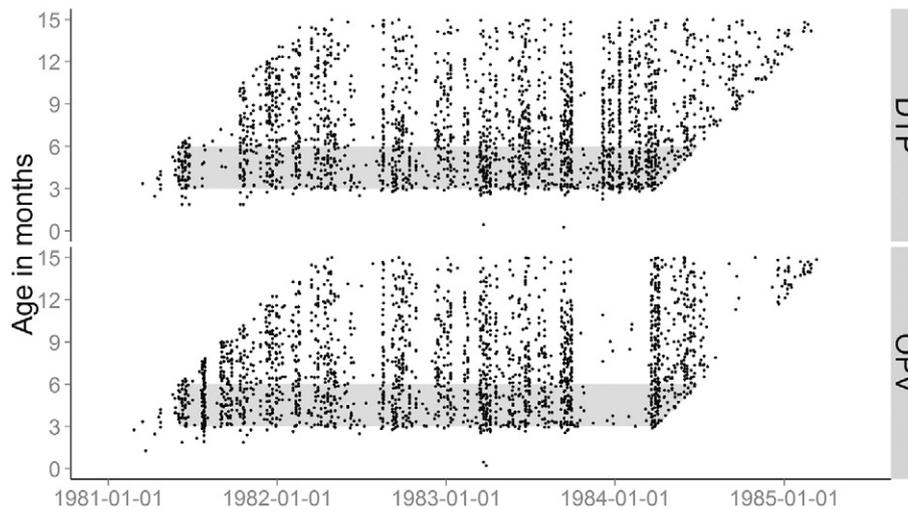
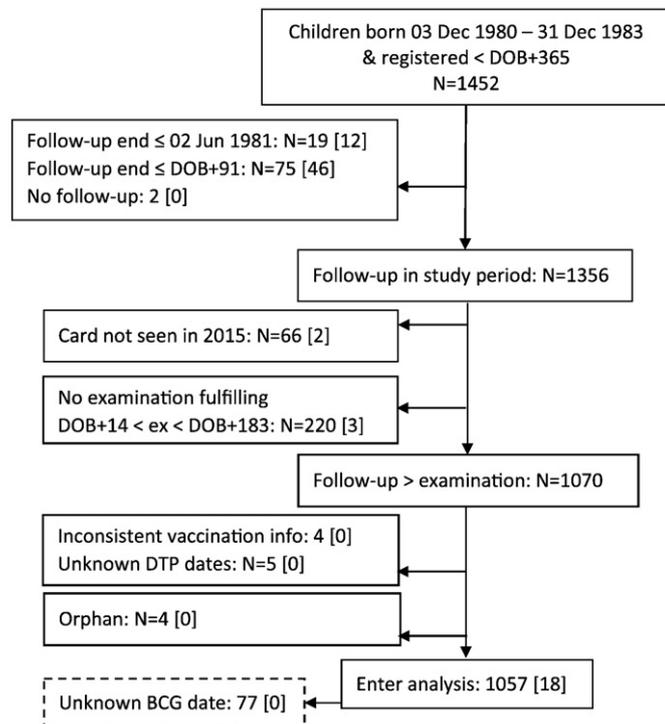


Fig. 1. Each vaccination of the specified type is plotted according age of the recipient and date of vaccination.

vaccinations were noted on the BHP cards. Both nurses and mothers thought that sick children should not be vaccinated; the BHP card often indicated that the child was 'sick', 'malnourished' or 'orphan' as an explanation of why an age-eligible child had not been vaccinated.

2.5. Data Control

When a computerized system became available in 1990–1991, weights and vaccinations from the BHP cards were entered. For the present analysis, all information on dates of visit, weights and vaccination dates was checked against the original cards. A few cards were not available or could no longer be found (Fig. 2).



Notes: DOB=date of birth; [] indicates the number of deaths before 6 months of age in the group.

Fig. 2. Flowchart of study population and children included in the analyses. Notes: DOB = date of birth; [] indicates the number of deaths before 6 months of age in the group.

2.6. The Study Cohort

We included children born from December 3, 1980 as they would become eligible for vaccination before 6 months of age (Fig. 2). Few children were vaccinated with BCG (Table 1). Children who travelled and never attended any session were not included in the 'unvaccinated' group. Children weighed within a fortnight of their birth to obtain a birth weight were only included if they took part in a subsequent community weighing session. Furthermore, we excluded orphans since they were not breastfed and were likely to have different care. The cohort is depicted in Supplementary Fig. 1.

2.7. Natural Experiment for 3–5-month-old Children

Though not individually randomized, the present study is a natural experiment with limited bias in group allocation: With 3-monthly intervals between weighing sessions, children were allocated by their birthday to receive their first vaccinations early or late between 3 and 5 months of age (Fig. 3). We therefore compared 3–5-month-old children who had received DTP (\pm OPV) vaccinations early with children who had not yet received these vaccinations. Since there were no healthy "unvaccinated" children after 6 months of age unless they had travelled, we censored follow-up of all children at 6 months of age (Fig. 3).

Sick children were not vaccinated, in the main analysis we therefore censored 'unvaccinated' children who attended a weighing session but did not receive a vaccination (Fig. 3). Since the censoring of sick children could have introduced a bias, we also conducted an intention-to-treat analysis in which the censored children were transferred to the DTP group. Hence, in this analysis we compared the mortality of the intended-DTP-vaccinated group and the not yet DTP-vaccinated group.

Children were included from 91 days of age if they had been examined in a weighing session before 91 days; if they were only seen in a weighing session after 3 months of age they were only included from the day seen. DTP was not administered elsewhere and the follow-up time of children was therefore counted as DTP-unvaccinated time in the survival analysis until BHP provided the vaccine. Time as DTP-unvaccinated also came from children who did not turn up at the weighing sessions between 3 and 5 months of age but had been seen before 3 months of age and therefore were part of the community cohort (Fig. 3). Hence, the DTP-vaccinated and DTP-unvaccinated children were all children from the same cohort of children born in Bandim and their allocation depended on the timing of their birth date, the timing of the weighing sessions and their travelling pattern. We

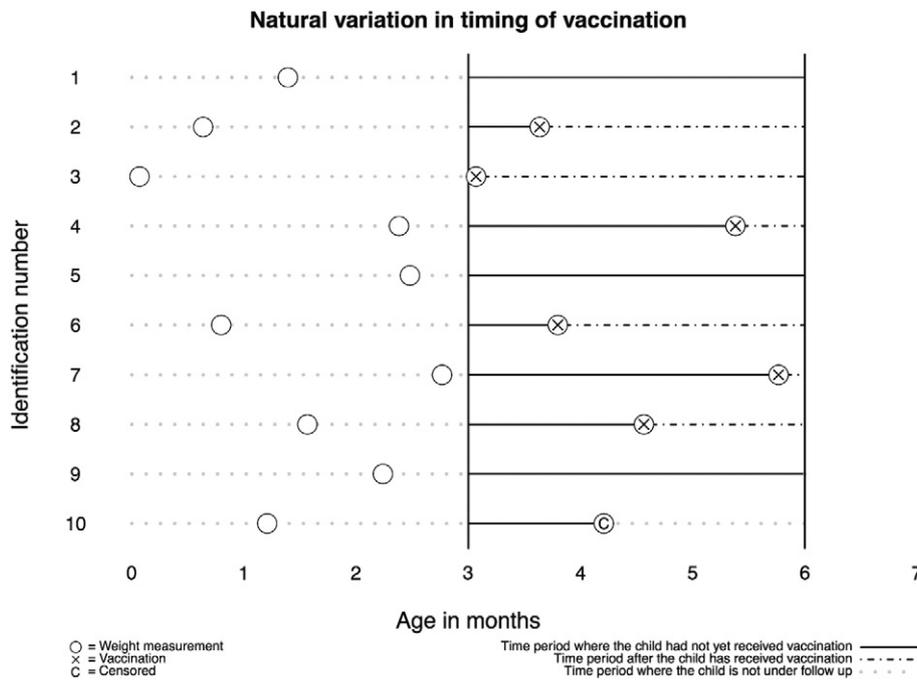


Fig. 3. Natural experiment study design. Note: Children were weighed every third month. After 3 months of age they received DTP and OPV on weighing days if they were healthy. Children who attended but were not vaccinated at a weighing session after 3 months of age were censored in the survival analysis comparing DTP-vaccinated and unvaccinated children.

compared the background factors for the children who were DTP vaccinated, attended a weighing session between 3 and 5 months but were not vaccinated and those who did not attend a weighing session (Table 2).

We also examined the mortality of children who due to logistic reasons had received DTP-only. Absences and travelling patterns are unlikely to differ between children who at their first vaccination had received DTP1 + OPV versus DTP1-only; these two groups were equally likely to receive subsequent vaccinations both with respect to timing of subsequent vaccinations and coverage (data available on request).

2.8. Statistical Methods

First possible enrolment date was June 2, 1981, when DTP and OPV vaccinations were introduced. Different vaccination groups were compared using a Cox proportional hazard model with age as underlying time.

Children were classified according to their most recent vaccination (Supplementary Table 1). We ignored BCG vaccinations in the main analysis because we gave few BCG vaccinations (Table 1) and some children had received BCG at the maternity ward without proper documentation as some children had a BCG scar but no vaccination card. To avoid survival bias, we used a landmark approach (Jensen et al., 2007); hence, a child's vaccination status was only updated from the day the information was collected. Due to the additional vaccination sessions organized by the expatriate nurse some “unvaccinated” children received a vaccine before the weighing session where they changed status to “vaccinated”; it is noted in the footnote to Table 3 how many had received such vaccinations. As a sensitivity analysis we also did an analysis including the additional vaccination sessions as landmarks. For the remainder of this paper, we will refer to these landmarks as vaccination-days-without-weighing.

The WHO z-score for weight-for-age was used to assess nutritional status. Control for sub-district, ethnic group and twinning did not change the results (data not shown). There was no obvious clustering

Table 2
Background factors children in the main analysis of vaccination and mortality between 3 and 5 months of age.

	DTP-vaccinated at 3–5 months	Attended weighing session at 3–5 months, not vaccinated	Did not attend weighing session at 3–5 months
Number	662	186	209
Male sex	52.1%	53.2%	54.1%
Twin	2.7%	2.2%	2.9%
Birth weight (SD)	3.23 (0.025)	3.28 (0.061)	3.22 (0.051)
Ethnic group			
• Pepel	46.8%	54.8%	45.0%
• Balanta	11.8%	13.4%	16.3%
• Other ethnic groups	41.4%	31.7%	38.8%
Mean weight-for-age z-score (SD) at examination before 3 months of age	−0.30 (0.037)	−0.34 (0.084)	−0.43 (0.066)
Follow-up time (person-years) between 3 and 5 months;			
[Median number of days of follow]	All time 135.5 [92]	36.8 [86]	47.4 [92]
	As DTP vaccinated 73.3	1.8	2.0
	As unvaccinated 62.2	35.1	45.4
Mean number (SD) of weighing sessions per year between 6 and 11 months of age	2.7 (0.03)	2.2 (0.07)	1.6 (0.08)

Table 3
Mortality rate and hazard rate (HR) for children from 3 months of age until first examination without vaccination or 6 months of age. Natural experiment.

Age group 3–5 months	Mortality rate (deaths/person-years)		HR (95% CI) for DTP vs unvaccinated	
All				
Unvaccinated (N = 651)	4.5 (5/111.4)	DTP (\pm OPV) (N = 462)	17.4 (11/63.1)	5.00 (1.53–16.3)
		DTP only (N = 101)	35.2 (5/14.2)	10.0 (2.61–38.6)
		DTP + OPV (N = 361)	12.3 (6/48.9)	3.52 (0.96–12.9)
Girls				
Unvaccinated (N = 313)	1.9 (1/51.9)	DTP (\pm OPV) (N = 222)	13.3 (4/30.1)	9.98 (0.81–123.0)
		DTP only (N = 44)	16.2 (1/6.2)	12.0 (0.56–257.2)
		DTP + OPV (N = 178)	12.5 (3/23.9)	9.50 (0.73–124.0)
Boys				
Unvaccinated (N = 338)	6.7 (4/59.5)	DTP (\pm OPV) (N = 240)	21.2 (7/33.0)	3.93 (1.01–15.3)
		DTP only (N = 57)	49.8 (4/8.0)	8.93 (2.01–39.7)
		DTP + OPV (N = 183)	12.0 (3/24.9)	2.21 (0.44–11.0)

Notes: There were no deaths due accidents in this age group. BCG is disregarded in the analysis. Hence, the unvaccinated children have not received DTP, OPV or MV but may have received BCG. Of the 651 unvaccinated children, 219 received DTP and/or OPV before their first weighing examination. These children counted as 'unvaccinated' until their first weighing examination. Of the 462 children who received DTP (\pm OPV), 177 received an additional DTP or OPV before 6 months of age. The OPV-only is not presented in the table because there were no deaths and very little follow-up time in this age group.

of deaths and control for season and calendar time did not change estimates (data not shown).

There were 18 deaths between 3 and 5 months of age: 3 had cough and respiratory infections as the main symptom, 3 had fever (presumed malaria), 2 were due to diarrhea, 5 had diarrhea and vomiting, 1 was a sudden death, and 4 had no information on cause.

2.9. Ethics

The study of nutritional status was planned by SAREC (Swedish Agency for Research Collaboration with Developing Countries) and the Ministry of Health in Guinea-Bissau.

3. Results

Of 1356 children registered in Bandim and followed to 3 months of age (Fig. 2), 286 were never weighed, had no card or their card was lost. An additional 13 children had inconsistent information, vaccinations marked with a cross but without dates or were orphans. Hence, 1057 children were included in the study cohort. The median ages for DTP1 and OPV1 were 121 and 118 days, respectively (Table 1). The vaccination coverage at 6 months of age was 55% for DTP1; 3% got DTP3 (Table 1). Coverage for MV was only 6%. Of the DTP1, OPV1 and MV vaccinations noted on the BHP card 90–95% had been administered by the BHP.

For children examined after 91 days, a one-unit increase in w/a z-score was associated with an odds ratio of 1.07 (0.93–1.24) for receiving a vaccination at that weighing session.

3.1. Natural Experiment with 3–5-month-old Children

There were no marked differences in background factors for the three groups of children who were DTP vaccinated at 3–5 months of age, those who attended a weighing session but were not vaccinated, and those who did not attend a weighing session at 3–5 months of age (Table 2). Birth weight was similar in the three groups. Weight-for-age z-score before 3 months of age did not differ for the three groups (Table 2). Those who did not attend a weighing session at 3–5 months of age were significantly less likely to attend later weighing sessions during infancy, the mean number of visits being lower for those not attending than for those being DTP-vaccinated ($p < 0.001$) (Table 2); hence, they are likely to have travelled more than those who were DTP-vaccinated.

In the main experiment depicted in Fig. 3, DTP vaccination (\pm OPV) compared with 'DTP-unvaccinated' was associated with a HR of 5.00 (1.53–16.3) (Table 3); the HR was 9.98 (0.81–123) for girls and 3.93 (1.01–15.3) for boys. If we also included vaccinations given on vaccinations-days-without-weighing in the landmark analysis, DTP (\pm OPV) compared with unvaccinated was associated with a HR of 3.90 (1.20–

12.3). When DTP had been given alone without OPV the HR was 10.0 (2.61–38.6) (Table 3). The difference between DTP-only children and DTP-plus-OPV does not reflect differences in follow-up and other vaccinations since the time to DTP2 and prevalence of DTP2 was the same for DTP-only and DTP-plus-OPV vaccinated children (data not shown). If we excluded the 269 children who may have been BCG vaccinated results were similar (Supplementary Table 2).

If the analysis was conducted as an intention-to-treat analysis in which the children weighed but not vaccinated were not censored but transferred to the DTP group, the intended-DTP-vaccinated group had a HR of 3.92 (1.20–12.8) compared with the not-yet vaccinated group (Supplementary Table 3).

3.2. Secondary Analyses

Since the introduction of DTP and OPV apparently was associated with increased mortality, we examined what happened to infant mortality from 3 to 12 months of age after the introduction of these vaccines. The mortality rate for all 3–11 months old children increased 2-fold (HR = 2.12 (1.07–4.19)) from 1980, before vaccinations, to 1982–1983, after the introduction of DTP and OPV (Table 4).

4. Discussion

4.1. Main Observations

DTP vaccinations were associated with increased infant mortality even though there was no vaccine-induced herd immunity. When unvaccinated controls were normal children who had not yet been eligible for vaccination, mortality was 5 times higher for DTP-vaccinated children. Co-administration of OPV with DTP may have reduced the negative effects of DTP.

4.2. Strength and Weaknesses

The present analysis assessed DTP and child survival in a "natural experiment" in which the children were allocated by the timing of their birth and community weighing sessions and the group allocation was therefore not influenced by the usual selection biases to the same extent as most other studies of DTP (Aaby et al., 2016). To assure that the censoring from the main analysis of children who were not vaccinated had not produced the unexpected strong result we made an intention-to-treat analysis but this did not change the result. If anything the unvaccinated children had slightly worse nutritional status before 3 months of age than the children who were subsequently DTP vaccinated ($p = 0.09$) (Table 2); the unvaccinated children travelled more than the DTP vaccinated children. These biases would tend to favor rather than increase mortality in the DTP group and the

Table 4
Mortality rates (deaths/100 person-years) between 3 and 11 months of age by study year.

Mortality rate	1980	1981	1982	1983	HR (95% CI) for 1982–1983 versus 1980
Children aged 3–11 months	4.7 (10/211.8) (N = 547)	7.2 (18/250.8) (N = 678)	8.0 (19/237.1) (N = 632)	12.1 (30/247.5) (N = 638)	2.12 (1.07–4.19)

Notes: Event recorded as accidents were not removed from this analysis.

estimates from the natural experiment may therefore still be conservative.

The estimated effects of DTP and OPV are unlikely to have been influenced by other vaccinations since very few had received other vaccines; if the children who may have received BCG were censored in the analysis the result was essentially the same (Supplementary Table 2).

The 3-monthly community examinations assured that we had follow-up information for all children and relatively accurate information on the time of death. Some children were excluded because a BHP card could not be found and we did not know whether they had been vaccinated or were travelling. Most likely, BHP cards may never have been made because the child was not coming for examination, or the card may have disappeared at community examinations, at the later handling of BHP cards by field workers or data entry clerks, or due to mice. However, the few missing cards are unlikely to have affected the main analysis as the mortality rate in this group was similar to the general mortality rate (Fig. 2).

To assure comparability of vaccinated and unvaccinated groups, also with respect to travelling, we included only children who had been weighed in Bandim in connection with the 3-monthly community examinations. This meant that children who mostly stayed outside the area were not included in the analysis; these children had no access to community vaccinations and they lived elsewhere where the mortality risk might have been quite different, e.g. due to a higher risk of malaria infection.

The present study was not a planned trial. The study would have been a cleaner natural experiment if vaccinations had only been administered at the weighing sessions. However, the expatriate nurse did organize additional vaccinations and some ‘unvaccinated’ children had therefore already received a vaccination before coming for a weighing session. These ‘misclassifications’ do not explain the increased mortality in the DTP group. The estimate for DTP-vaccinated (\pm OPV) compared with DTP-unvaccinated children was 4-fold higher mortality when we included these additional landmarks in the analysis.

4.3. Comparison with Previous Studies of DTP and OPV

There is only one other study of the introduction of DTP. In rural Guinea-Bissau, DTP (\pm OPV) was associated with 2-fold higher mortality (Aaby et al., 2004a). All studies that documented vaccination status and followed children prospectively indicate that DTP has negative effects; a meta-analysis of the eight studies found 2-fold higher mortality for DTP-vaccinated compared with DTP-unvaccinated, mostly BCG-vaccinated controls (Aaby et al., 2016) (Appendix A).

The negative effect of DTP was much worse in this natural experiment than has been reported in previous studies of DTP. This is presumably due to the “unvaccinated” control children in previous studies having been a frail subgroup too frail to get vaccinated. Previous studies have not been able to compare DTP-vaccinated children with “normal” controls. Hence, most previous studies have probably underestimated the negative effect of DTP.

The potentially differential effects of DTP and OPV have only been examined in few studies. However, we have recently been able to document marked beneficial NSEs of OPV. In an RCT, OPV at birth (OPV0) reduced infant mortality by 32% (0–57%) before the children received campaign-OPV (Lund et al., 2015). In Bissau campaign-OPV reduced

the mortality rate by 19% (5–32%) (submitted). When DTP was missing for several months in Bissau, we showed that the all-cause case-fatality at the pediatric ward was 3-fold lower if the children had OPV-only as their most recent vaccination rather than the recommended combination of DTP and OPV (Aaby et al., 2004b). Thus, OPV may have modified the negative effect of DTP.

This pattern was also seen when DTP was first introduced in the rural areas of Guinea-Bissau in 1984 (Aaby et al., 2004a). OPV was not used the first year and the HR for DTP versus unvaccinated was 5.00 (0.63–39.7). In the period from 1985 to 1987, when DTP and OPV were nearly always administered together, the MRR was 1.90 (0.91–3.97). In the present study, the hazard ratio was 10.0 (2.61–38.6) for DTP-only but 3.52 (0.96–12.9) for children who received DTP and OPV simultaneously (Table 3). Based on these two studies of the introduction of DTP, the HR compared with DTP-unvaccinated children was significantly different for children who had received DTP-only (HR = 8.14 (2.63–15.2)) and for children who received both DTP and OPV (HR = 2.21 (1.16–4.19)) (test of interaction, $p = 0.049$). Hence, simultaneous administration of DTP and OPV may have alleviated the negative non-specific effect of DTP.

5. Conclusions

DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the performance of national vaccination programs.

It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee to which SAGE delegated the follow-up studies of the NSEs of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study may remain the closest we will ever come to a RCT of the NSEs of DTP.

Funding

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Conflict of Interest

Nothing to declare

Contributions

CSB and PA proposed the study. PA collected the original data. AR is responsible for the demographic surveillance system. SWM and PA cleaned the data. SWM and AA conducted the statistical analyses. The first draft was written by PA; all authors contributed to the final version of the paper. PA and SWM will act as guarantors of the study.

Independence

The funding agencies had no role in the study design, data collection, data analysis, data interpretation, or the writing of the report.

Data Sharing

Through request to the authors

Appendix A. The DTP Controversy

The issue of DTP vaccination and child mortality in high mortality areas was raised 15 years ago when a study from rural Guinea-Bissau showed 1.84-fold higher mortality for children who had received DTP1 vaccination (Aaby et al., 2016; Kristensen et al., 2000). All subsequent prospective studies have supported a negative effect (Aaby et al., 2016). Furthermore, DTP may have a negative effect when given simultaneously with or after MV (Aaby et al., 2003b, 2012). For example, the negative effect of high-titer measles vaccination (HTMV) in girls, which led to the global withdrawal of HTMV, was due to DTP being administered after MV because HTMV had been given early at 4–5 months of age (Aaby et al., 2003b).

DTP has not been shown to have beneficial effects in RCTs or natural experiments. The current policy for DTP has only been examined by reanalyses of existing data sets collected for other purposes. All such studies have had methodological problems related to different forms of frailty and survival bias (Aaby et al., 2012). These studies have updated follow-up time for DTP-vaccinated children who survived but children who died without their vaccination status being documented were classified as “unvaccinated”. Such procedures give a misleading high mortality rate in the unvaccinated group, and the comparison of DTP-vaccinated survivors and “unvaccinated” children will therefore give a beneficial estimate for DTP (Aaby et al., 2016). If the mortality rate of unvaccinated children is unnaturally increased, the HR of unvaccinated children versus children who have received at least one vaccine may indicate how much bias there might be in the study, and we have called this HR the “bias-index”. All studies with prospective follow-up have had a bias index below 2.0 (Aaby et al., 2016); in the present study the bias index was 0.41 (0.15–1.15) in the 3–5 months age group (Supplementary Table 2). In studies with survival bias and unnaturally high mortality in the unvaccinated group, the bias index has been 3–8 times higher (Aaby et al., 2016).

SAGE recently reviewed the potential NSEs of BCG, MV and DTP (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014). The reviewers indicated that the majority of studies showed a deleterious effect of DTP but they concluded that the results were inconsistent because two studies showed a beneficial effect. The beneficial effect in these studies was not surprising because the mortality rate in the unvaccinated group was unnaturally high, and the bias index was 3.40 (2.93–3.95) and 7.52 (5.15–10.97), respectively (Aaby et al., 2016).

SAGE's working group on non-specific effects of vaccines further emphasized that the overall effect remains unclear because DTP has been given in combination with other vaccines and under

circumstances where the burden of the target diseases has been reduced to a very low level. However, several previous studies have shown that the negative effect of DTP-plus-OPV was not due to OPV (Aaby et al., 2004a,b, 2012). OPV has probably reduced the overall negative effect of DTP. Previous studies have indicated that DTP (\pm OPV) was associated with a 2-fold higher mortality than DTP-unvaccinated children (Aaby et al., 2016). Since pertussis did not account for >5–6% of infant deaths in the only existing African study of the impact of pertussis on child mortality (Mahieu et al., 1978), it is not surprising that DTP is also associated with a strong negative effect prior to vaccine-induced herd immunity (Aaby et al., 2012).

Appendix B. Supplementary Data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.ebiom.2017.01.041>.

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EXHIBIT B



VIA FEDEX

December 5, 2017

UNICEF House
Dr. Anthony Lake
Executive Director
3 United Nations Plaza
New York, NY 10017
Telephone: +1(212) 32 67 490
Facsimile: +1(212) 32 67 477

Re: Deaths caused by DTP

Dear Dr. Lake,

UNICEF has been instrumental in vaccination campaigns in many countries, including their prior and ongoing DTP vaccination campaign. We write to bring to your attention an alarming study, published this year, which found that children vaccinated with DTP were 10 times more likely to die in the first six months of life than those children that were unvaccinated.¹ A copy of this study is enclosed.

Dr. Peter Aaby, the lead author of this study, is renowned for studying and promoting vaccines in Africa with over 300 published studies.² Dr. Aaby, after concluding that children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated, states:

“All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.”³

¹ A copy of this study can also be found here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

² <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

This study also found that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.⁴ This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.⁵

Unlike most vaccine safety studies in which subjects are not well matched, Dr. Aaby's study is reliable because the subjects were accurately matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. (This issue is explained in detail in a publication by vaccine safety scientists at the U.S. Centers for Disease Control.⁶) Dr. Aaby's study is the only study looking at death from DTP specifically designed to avoid this error.

When an extremely well-designed study from accomplished vaccine proponents at the Research Centre for Vitamins and Vaccines and Institute of Clinical Research at the University of Southern Denmark/Odense University Hospital finds that children receiving a certain product are dying at 10 times the rate of children not receiving that product, prudence dictates pausing the distribution of that product. Please confirm that UNICEF has ceased distributing DTP and kindly advise what research UNICEF is undertaking regarding deaths from DTP vaccine, including identifying the families killed by this vaccine in order to provide them with reparations.

We also note that continued vaccination with DTP without disclosing the findings in Dr. Aaby's study would violate the Nuremberg Code which provides that:

"The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."⁷

The Nuremberg Code thus draws a sharp line when stating that no human being should receive a medical procedure and/or product without informed consent. Failing to advise

⁴ Ibid.

⁵ Ibid.

⁶ <https://www.ncbi.nlm.nih.gov/pubmed/1415136>

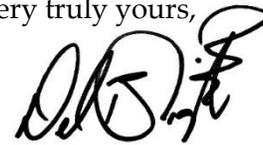
⁷ <https://history.nih.gov/research/downloads/nuremberg.pdf>

the findings of Dr. Aaby's study to parents prior to administering the DTP vaccine would violate this basic human right.

While medical interventions have saved countless lives, the graveyard of history is also replete with once lauded but later abandoned medical inventions and practices. When an issue with a medical procedure is identified, especially when it is killing children, immediate action is necessary. We hope that political and economic considerations will not cloud the clear moral and ethical duty to protect children from death from DTP vaccine.

If UNICEF does not intend to cease distribution of DTP vaccine or at least confirm that parents of children receiving this vaccine are advised of Dr. Aaby's findings, we intend to take appropriate legal action. We look forward to receiving a timely response to this letter so that we can follow-up with all member states cc'd on this communication with regard to what actions UNICEF intends to take in response to Dr. Aaby's extremely concerning finding that children receiving DTP vaccine had a death rate 10 times that of children that were not vaccinated.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', with a stylized flourish at the end.

Del Bigtree

cc: See Appendix A (*Countires Using DTP Vaccine*)

Enclosure: Mogensen S.W., Andersen A., Rodrigues A., Benn C.S., Aaby P., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, EBioMedicine. 2017;17:192–198.

EXHIBIT C

Date 6 February 2018

Dear Mr Bigtree

Many thanks for your message expressing interest in learning more regarding the safety and effectiveness of the DTP vaccine. I was asked by our outgoing Executive Director, Anthony Lake to prioritize the response to your letter, as he was preparing to leave office, and he asked me to convey his apologies for not responding himself.

I would like to assure you that we take the issue of vaccine safety very seriously. Vaccine safety, along with the safety of all health interventions, are closely followed and monitored by ourselves, in close association with technical agencies like the World Health Organization (WHO). The wellbeing of children, as you are aware, is central to the mandate of UNICEF and we do not compromise in any way in fulfilling this mandate.

There are various independent and multidisciplinary expert bodies at global and national level, which regularly review the evidence on the impact of vaccines and on its safety profile and provide advice to WHO and UNICEF. Notably, the Strategic Advisory Group of Experts (SAGE) is the principal advisory group to WHO for vaccines and immunization (established in 1999). It is charged with advising on overall global policies and strategies, ranging from vaccines (impact and safety) and technology, research and development, to delivery of immunization and its linkages with other health interventions. The Global Advisory Committee on Vaccine Safety (GACVS) responds to vaccine safety issues of potential global importance (established in 1999). The GACVS provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short or long term national immunization programmes. The Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC) provides independent advice on matters related to implementation research and their relevance to immunization policies and practices, and reviews best practices relating to methods for conducting and reporting on quantitative immunization and vaccines-related research (including vaccine impact and safety evaluations).

Some authors have suggested that some of the vaccines routinely administered to infants and children also affect the risk of illness and death from conditions other than the specific infectious diseases they are designed to prevent. The hypotheses concerning these "non-specific effects" of vaccines include that, under some circumstances, some vaccines (for example, measles and Bacillus Calmette-Guérin (BCG)) lower subsequent risk, whereas others (such as DTP) increase subsequent risk of illness and death from other causes. It is further postulated that the magnitude of these effects depends on other factors, including gender and vitamin A supplementation status. The potential for non-specific vaccine effects has led some authors to question whether the vaccination schedules currently recommended by WHO should be adjusted.

WHO with the support of several independent experts has been reviewing and discussing evidence around the non-specific effects of vaccines and immunization programmes since 2001. In 2012, SAGE requested that WHO review the evidence concerning the possible non-specific effects of routine infant vaccines on mortality. A working group was established in March 2013 to review data on non-specific mortality effects and assess whether current evidence is sufficient to inform adjustments in policy recommendations, or if further scientific

investigation is required. A systematic review was conducted to evaluate the non-specific effects on all-cause mortality, in children under 5, of Bacillus Calmette-Guérin (BCG), diphtheria-tetanus-pertussis (DTP), and standard titre measles containing vaccines (MCV); to examine internal validity of the studies; and to examine any modifying effects of gender, age, vaccine sequence, and co-administration of vitamin A.

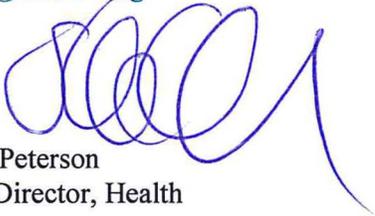
In 2014 SAGE reviewed the outcomes of this review and concluded that, regarding the possible non-specific effect of DTP on all-cause mortality, the available data neither exclude nor confirm the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality. Randomized controlled trials did not contribute any evidence on non-specific effects of DTP. Evidence was largely from observational studies considered at a high risk of bias. Further, SAGE stated that further observational studies are unlikely to contribute to policy decisions. SAGE considered that the non-specific effects on all-cause mortality warranted further research. SAGE recommended that the IVIR- AC be tasked with providing advice on which priority research questions need to be addressed to inform policy decisions, and what kinds of studies and study designs would provide answers to these questions. SAGE concluded that the evidence does not support a change in policy for DTP, and emphasized the benefit of DTP in preventing disease and the importance of the current recommendation.

In conclusion, I would like to reiterate that UNICEF (and WHO) takes the issue of vaccine safety very seriously and for several decades has reviewed the evidence to guide policy decisions. While available evidence does not support a change in DTP vaccination policy, there is substantial evidence on the benefits of DTP (and pentavalent) vaccines in preventing disease and on the substantial risk for unvaccinated population DTP vaccines as evidenced by diphtheria, pertussis and tetanus cases and deaths that we are seeing today. In a number of locations globally, we are experiencing diphtheria outbreaks with high case fatality, which is a direct result of these children not receiving the recommended doses of vaccines in their childhood. Diphtheria, Tetanus and Pertussis were among the leading causes of childhood death in the pre-vaccine era causing several hundred thousand cases each year.

I hope my message provides you with the information that you were seeking. I am copying representatives of our member states who are included in your original message.

Please do not hesitate to contact us if you have further queries or require clarifications. The appropriate point of contact in our office is Dr. Robin Nandy, Principal Advisor and Chief of Immunizations and he can be contacted at rnandy@unicef.org

Sincerely,



Dr. Stefan Peterson
Associate Director, Health
UNICEF Headquarters

EXHIBIT D



VIA FEDEX

March 15, 2018

UNICEF House
Henrietta H. Fore, Executive Director
Dr. Stefan Peterson, Associate Director, Health
3 United Nations Plaza
New York, NY 10017
Telephone: (212) 326-7490
Facsimile: (212) 326-7477

Re: *DTP Vaccine is Killing More Children Than it Saves & is Only Used in Developing Countries*

Dear Ms. Fore and Dr. Peterson,

Thank you for your response dated February 6, 2018 to our letter of December 5, 2017¹ which detailed the disturbing results of a seminal study, published February 1, 2017, which found that DTP vaccine² is killing more children than it is saving (the “**2017 Study**”). The 2017 Study was the only item discussed in our letter and a copy of that study was also enclosed with our letter. Yet, in response, you did not address that study. We therefore write again to emphasize the need for UNICEF to quickly join all developed nations and cease administration of DTP vaccine.

A. Dr. Aaby’s 2017 Study Establishes the Danger of Administering DTP Vaccine

The primary author of the 2017 Study is internationally respected vaccine researcher Dr. Peter Aaby.³ In his rigorous 2017 Study, Dr. Aaby and his colleagues found that the children receiving DTP vaccine were *10 times more likely to die* in the first 6 months of life than the unvaccinated children.⁴ The 2017 Study was therefore forced to conclude:

¹ Copies of these letters are available at <http://www.icandecide.org/>

² “DTP vaccine” is also commonly referred to as “DTwP vaccine” or so-called “whole cell pertussis vaccine,” as opposed to “DTaP vaccine” or so-called “acellular pertussis vaccine.”

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/pdf/main.pdf>

⁴ [Ibid.](#)

“All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.”⁵

This 2017 Study was published in an Elsevier peer-reviewed journal which collaborates with The Lancet and was funded by the Ministry of Foreign Affairs, Denmark and the European Union.⁶ As you know, Dr. Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.⁷ Dr. Aaby, among other things, in 1978, established and continues to direct the Bandim Health Project, a Health and Demographic Surveillance System site in Guinea-Bissau.⁸ In 2000, he was awarded the Novo Nordisk Prize, the most important Danish award within health research.⁹ In 2009, the Danish Ministry of Foreign Affairs selected Dr. Aaby as a leader in the fight against global poverty.¹⁰

Instead of addressing the 2017 Study, your response points to a 2014 review by SAGE regarding the possible non-specific effect of DTP vaccine on all-cause mortality. The 2014 SAGE review pre-dates the 2017 Study by three years and at that time concluded, as stated in your letter, that “the available data neither excludes nor confirm[s] the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality.” Even though your letter does not cite or provide a copy of the 2014 SAGE review, links to same are footnoted here.¹¹ Dr. Aaby expressly created the 2017 Study to address many of the weaknesses in prior DTP vaccine studies identified by the 2014 SAGE review. By addressing the concerns raised by SAGE, the 2017 Study’s results should be considered highly reliable, providing clear evidence DTP vaccine is killing more children than it saves.

The 2014 SAGE review identified 16 studies that compared death rates between children receiving DTP vaccine and children not receiving DTP vaccine.¹² SAGE found that a “majority of studies indicated a negative effect of DTP,” meaning a majority of the

⁵ [Ibid.](#)

⁶ [Ibid.](#)

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>

⁸ <https://www.bandim.org/>

⁹ <http://novonordiskfonden.dk/en/content/novo-nordisk-prize>

¹⁰ <https://www.bandim.org/press>

¹¹ http://www.who.int/immunization/sage/meetings/2014/april/1_NSE_Backgroundpaper_final.pdf;
http://www.who.int/immunization/sage/meetings/2014/april/3_NSE_Epidemiology_review_Report_to_SAGE_14_Mar_FINAL.pdf

¹² [Ibid.](#)

studies SAGE reviewed found that DTP vaccine killed more children than it saved.¹³ For example, one study found that children receiving DTP vaccine were between 154% and 1,219% more likely to die than those that did not receive DTP vaccine.¹⁴ SAGE, however, chose to give virtually no weight to these studies, despite their being conducted by WHO respected vaccine experts, because SAGE stated: (i) these studies were not “randomized” (*i.e.*, children were not randomly assigned to either receive or not receive DTP vaccine, hence potentially introducing bias¹⁵), (ii) “OPV [Oral Polio Vaccine] was administered concomitantly with DTP in most included studies” and hence it “was not possible to separate any possible effects of DTP from OPV in the available studies,” and (iii) these studies were often conducted in communities with existing “herd immunity,” which could have introduced further bias.¹⁶

Dr. Aaby designed the 2017 Study to address these three issues.¹⁷ It rectified the “randomized” issue by comparing children vaccinated solely based on birthdates, thereby creating a random grouping.¹⁸ It corrected the “OPV with DTP” issue by comparing children with no vaccines and those only receiving DTP.¹⁹ And it addressed the “herd immunity” issue by looking at death rates at the time of the introduction of DTP vaccination.²⁰ As explained in the introduction to the 2017 Study:

WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs [Non-Specific Effects] of ... diphtheria-tetanus-pertussis (DTP) ... and recommended further research (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP

¹³ [Ibid.](#)

¹⁴ [Ibid.](#)

¹⁵ For example, unvaccinated children often do not receive vaccines because they are very frail, malnourished or sick, and hence more likely to die irrespective of vaccination, hence the unvaccinated group is often sicker than the vaccinated group, thus making the vaccine appear safer. By randomly picking which children receive or do not receive DTP vaccine, a researcher can avoid this type of bias.

¹⁶ See footnote 11.

¹⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/pdf/main.pdf>

¹⁸ [Ibid.](#)

¹⁹ [Ibid.](#)

²⁰ [Ibid.](#)

(Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the “unvaccinated” children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the “unvaccinated” were therefore not frail children.²¹

The 2017 Study also explains why it is the best study and evidence that modern science will likely obtain to determine whether DTP vaccine kills more children than it saves:

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee [Immunization and Vaccines Related Implementation Research Advisory Committee] to which SAGE delegated the follow-up studies of the NSEs [Non-Specific Effects] of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study [the 2017 Study] may remain the closest we will ever come to a RCT [Randomized Controlled Trial] of the NSEs of DTP.²²

The 2017 Study therefore represents the closest and best data UNICEF is likely ever going to have regarding whether DTP kills more children than it saves. And as a reminder, this

²¹ [Ibid.](#)

²² [Ibid.](#)

study found that children receiving DTP in the first six months of life *died at ten times the rate* of those children that received no vaccines in the first six months of life.²³ And it concluded that “All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.”²⁴

Your letter states that the “wellbeing of children, . . . is central to the mandate of UNICEF and we do not compromise in any way in fulfilling this mandate.” If so, the 2017 Study shows why DTP vaccine presents a danger to the “wellbeing of children” receiving it and UNICEF’s mandate dictates that you should, at least, pause supporting the use of DTP vaccine until UNICEF has evidence to demonstrate children receiving the vaccine do not die at a greater rate than children not receiving this vaccine.

B. UNICEF Should Join Every Developed Nation in Stopping Use of DTP Vaccine

There is a lesson in the fact that every single developed country in the world has long-ago phased out using DTP vaccine.²⁵ The following are just a few examples of the nations that have ceased all use of the DTP vaccine, and the year in which they were phased out:

- Japan in 1981
- South Korea in 1989
- New Zealand in 1994
- Sweden in 1996
- Australia in 1996
- United States in 1997
- Canada in 1998
- China in 2008

Yet, UNICEF continues to promote and distribute this vaccine to developing countries.²⁶ Given the findings of the 2017 study, UNICEF’s continued use of DTP vaccine, in the face of developed nations’ shunning of this vaccine, is very troubling.

C. Industrial and Financial Considerations Should Not Stand in the Way of Protecting Children from Harm

We understand that UNICEF has declared that a “healthy industry is vital to ensure uninterrupted and sustainable supply of vaccines” and has extensive financial arrangements and a “long standing relationship with” pharmaceutical companies

²³ [Ibid.](#)

²⁴ [Ibid.](#)

²⁵ http://www.who.int/immunization/monitoring_surveillance/data/en/

²⁶ [Ibid.](#)

producing vaccines.²⁷ Indeed, in 2016 alone, UNICEF purchased over \$1.6 billion dollars of vaccine products from these companies and spent an equally significant sum paying companies for their distribution, in total amounting to over a third of UNICEF's budget.²⁸ We nonetheless are sure that these political and economic considerations will not cloud UNICEF's judgment when evaluating its clear moral and ethical duty to protect children from death from DTP vaccine.

D. Continued Use of DTP Vaccine Raises Issues Regarding the Basic Human Right of Informed Consent

Also, previously noted, distributing and administering the DTP vaccine without disclosing the dangers of DTP vaccine, as found in the 2017 Study, and that all developed countries have phased out DTP vaccine, would violate the Nuremberg Code, which provides:

"The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."²⁹

The Nuremberg Code thus makes clear no human being should receive a medical procedure and/or product without informed consent. Failing to, at least, advise parents about the increased risk of death from DTP vaccine prior to administering this vaccine to their child would violate this basic human right.

As with our last letter, we again enclose a copy of the 2017 Study. We suggest you review this study carefully. You and every member of the UNICEF staff involved in the procurement, distribution and promotion of DTP vaccine should be aware of its findings, should receive a copy of the 2017 Study and of this correspondence. Continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study's unmistakable findings would violate various laws designed to protect children from harm.

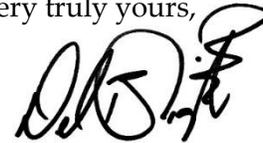
²⁷ https://www.unicef.org/supply/index_vaccines.html; https://www.unicef.org/supply/index_57476.html

²⁸ https://www.unicef.org/supply/index_vaccines.html

²⁹ <https://history.nih.gov/research/downloads/nuremberg.pdf>

In light of the 2017 Study, we believe an open and frank discussion within UNICEF regarding DTP vaccine will lead the organization to conclude that it must now join the developed world in ceasing to use DTP vaccine. If UNICEF will not take immediate action on this issue, then the countries that are copied on this communication are encouraged to take domestic action based on the 2017 Study, which reflects what is likely the best evidence that can be produced with regard to whether DTP vaccine kills more children than it saves.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', written in a cursive style.

Del Bigtree

cc: See Appendix A (*Countries Using DTP Vaccine*)

Enclosure: Mogensen S.W., Andersen A., Rodrigues A., Benn C.S., Aaby P., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, *EBioMedicine*. 2017;17:192–198.

EXHIBIT E



VIA FEDEX

July 26, 2018

UNICEF House
Henrietta H. Fore, Executive Director
Dr. Stefan Peterson, Associate Director, Health
3 United Nations Plaza
New York, NY 10017
Telephone: (212) 326-7490
Facsimile: (212) 326-7477

Re: *DTP Vaccine is Killing More Children Than it Saves*

Dear Ms. Fore and Dr. Peterson,

Our opening letter of December 5, 2017 detailed the disturbing results of a rigorous and seminal study, published February 1, 2017, which again found that DTP vaccine¹ is killing more children than it is saving (the “**2017 Study**”). A copy of the 2017 Study is attached as **Exhibit A** and a copy of our opening letter of December 5, 2017 letter is attached as **Exhibit B**.

You responded to our opening letter on February 6, 2018, a copy of which is attached as **Exhibit C**. We responded to this letter on March 15, 2018 noting that, amazingly, your response did not address the 2017 Study and that the information it did provide in fact supported the conclusion of the 2017 Study. Hence, we urged UNICEF to quickly join all developed nations and cease administration of DTP vaccine. A copy of our March 15, 2018 response letter is attached as **Exhibit D**.

Despite the passage of over four months, UNICEF has failed to respond to our March 15, 2018 letter and it has now been over eight months since we brought to your attention the fact that UNICEF is purchasing, distributing and widely promoting a vaccine for which, as is plain from our letter exchange, the best available evidence clearly demonstrates it is killing far more children than it is saving.

As you are likely also already acutely aware, on the heels of our last letter, Dr. Aaby and his renown vaccine advocate colleagues published an article on March 19, 2018, in the journal *Frontiers in Public Health*, entitled *Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?* (the “**2018 Study**”). A copy of this article is attached as **Exhibit E**.

¹ “DTP vaccine” is also commonly referred to as “DTwP vaccine” or so-called “whole cell pertussis vaccine,” as opposed to “DTaP vaccine” or so-called “acellular pertussis vaccine.”

As you will recall, the 2017 Study found that babies younger than six months of age receiving DTP vaccine died at ten times the rate as babies in the same age range that did not receive any vaccines. (Exhibit A.) The 2018 Study looked at children between six and thirty-five months of age and compared DTP-vaccinated children that were generally healthier and had better nutritional status with non-DTP-vaccinated children who generally were unhealthier and had worse nutritional status. (Exhibit E.) The incredible result:

Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.

(Exhibit E.) The children in developing countries which still use DTP vaccine would be better served if UNICEF and the WHO took the following advice from the 2018 Study:

Given the threat from diphtheria, tetanus, and pertussis and the less-effective acellular pertussis vaccine used in many countries, it is understandable that there has been reluctance in accepting that DTP could have negative effects for overall health in low-income countries. However, the studies from low-income countries have been consistent in showing deleterious effect of DTP. ...

In the current global immunization system, the coverage for the third dose of DTP (DTP3) is used as the main performance indicator for national immunization programs. This will clearly lead to an emphasis on increasing the coverage for DTP3 more than the coverage for other vaccines. Given that all studies, including the present one, suggest that DTP is associated with increased female mortality, this is really an illogical position. We need to use program performance indicators which are positively associated with better child survival.

(Exhibit E.)

In our letter from March 2018, we stated that you and every member of the UNICEF staff involved in the procurement, distribution and promotion of DTP vaccine should be aware of the 2017 Study's findings as well as receive a copy of the 2017 Study and of our prior correspondence. We also asserted that continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study's unmistakable findings would violate various laws designed to protect children from harm.

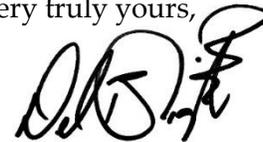
It has now been over eight months since we provided you, on two occasions, a copy of the 2017 Study. Yet, despite your verbose response in February 2018, you have failed to provide even a single argument to contest the 2017 Study's methodology or conclusions. In fact, you have failed

to address this study altogether. And you have also failed to indicate that UNICEF will, at the least, as required by the Nuremberg Code, assure that parents are being advised of the increased risk of death from DTP vaccine prior to administering this vaccine to their child.

Copies of this letter with all exhibits will be distributed directly to all members of UNICEF that we can identify that are involved in the purchase, distribution and promotion of DTP vaccine. For all UNICEF individuals receiving this letter, please take notice that your continued distribution of this for-profit product violates various laws, including various international human rights law. Furthermore, absent forthwith confirmation from UNICEF that it has either ceased distribution of DTP vaccine or has evidentiary support for why the 2017 Study and 2018 Study are incorrect, we intend to take appropriate remedial action, including referral to the International Criminal Court, against all individuals at UNICEF involved in continued purchase, distribution and promotion of a product that the best available evidence makes clear is killing far more children than it is saving.

We also hereby repeat the call to all countries that are copied on this communication to take domestic actions based on the 2017 Study and 2018 Study to protect babies in their country from increased rates of death from a for-profit product that all developed countries have long ago ceased using due to its serious adverse reactions.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', with a stylized flourish at the end.

Del Bigtree

cc: See Appendix A (*Countries Using DTP Vaccine*)

Enclosures

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EXHIBIT F

VACCINE SCIENCE FOUNDATION



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Dear Dr. Lake,

Please find enclosed an expert report by Peter C. Gøtzsche, Professor, DrMedSci, MSc on the effect of the DTP vaccine on total mortality in low-income countries. Gøtzsche analyzed the WHO's 2014 systematic review of the non-specific effects of BCG, DTP, and measles related vaccines. He then conducted a review of the literature and analyzed any studies published after the WHO report which assessed the effect of DTP vaccine on total mortality. According to the available evidence, Gøtzsche came to the conclusion that "it is likely that the DTP vaccine increases total mortality in low-income countries."¹

This echoes the conclusion by Peter Aaby – the scientist credited for the discovery of non-specific effects of vaccines - that "all currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections."² Dr. Aaby's recent study, the first ever naturally randomized comparison of mortality between children receiving DTP and those that are unvaccinated, found that children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.²

As a leading agency for vaccine procurement, UNICEF plays a vital role in increasing the accessibility of vaccinations worldwide, and provides crucial support for the WHO's Global Vaccine Action Plan (GVAP). Among other targets, the GVAP calls for nations to reach 90 percent or greater coverage of the DTP3 vaccine.³ If Gøtzsche's conclusion is correct, this is a counterproductive strategy to reduce child mortality rates in low-income countries.

The Vaccine Science Foundation proudly supports UNICEF's goal of reducing child mortality worldwide. For this reason, the Vaccine Science Foundation urges you to read the expert report *Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*, to ensure that UNICEF can productively engage in its goal of reducing child mortality.

The Vaccine Science Foundation respectfully requests that UNICEF explain whether it accepts the conclusion of the attached expert report. If it does, please explain the actions it intends to take. If it does not, please explain the basis for rejecting the conclusion of this report. The Vaccine Science Foundation welcomes publishing on its website any evidence or response that UNICEF believes is relevant to addressing the concern raised by the enclosed expert report, and any actions it intends given the findings in this report.

Please send a response to info@vaccinescience.org within sixty days so that the Vaccine Science Foundation can post it publicly on the vaccinescience.org website next to the paper *Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*.

We look forward to hearing from you.

Vaccine Science Foundation

References:

1. <https://vaccinescience.org/expert-report-effect-of-dtp-vaccines-on-mortality-in-children-in-low-income-countries/>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>
3. https://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/