SECTION: PIL

IN THE SUPREME COURT OF INDIA
(CIVIL ORIGINAL JURISDICTION)
WRIT PETITION (CIVIL) NO. 289 OF 2016

IN THE MATTER OF:

S. SRINIVASAN .... PETITIONER

VERSUS

UNION OF INDIA & ORS. ...RESPONDENTS

FILING INDEX

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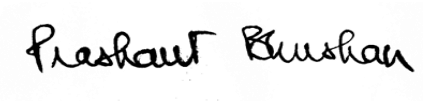

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONERS
301, NEW LAWYERS CHAMBERS
SUPREME COURT OF INDIA
NEW DELHI 110 001
CODE NO.: 515

NEW DEHI:
DATED: 20.07.2021

IN THE SUPREME COURT OF INDIA

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WRIT PETITION (CIVIL) NO. 289 OF 2016

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S. SRINIVASAN PETITIONER

VERSUS

UNIN OF INDIA & ORS. RESPONDENTS

PAPER BOOK

(FOR INDEX KINDLY SEE INSIDE)

(ADDITIONAL AFFIDAVIT ON BEHALF OF THE PETITIONER)

COUNSEL FOR THE PETITIONER**: PRASHANT BHUSHAN**

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IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 289/ 2016

(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF:

S. Srinivasan .....Petitioners

Versus

Union of India & Ors. .....Respondent

ADDITIONAL AFFIDAVIT ON BEHALF OF THE PETITIONER

I, S.Srinivasan, aged 67 years, S/o Shri S. Sourirajan, Managing Trustee of LOCOST (Low Cost Standard Therapeutics), Vadodara, R/o 1 Tejas Apts, 53 Haribhakti Colony, Old Padra RD, Vadodara 390007 Gujarat, presently at Vadodara, do hereby solemnly state and affirm as under:

NOTARY C. V. PATEL Area : Dist. Vadodara Reg. No. 13200 Valid up to 19/02/22 GOVT. OF INDIA

1. That I am the Petitioner in the aforementioned writ petition and being familiar with the facts and circumstances of the case, I am competent and fully authorized to swear this Affidavit.

2. That the Petitioner herein has filed the instant writ petition in public interest under Article 32 of the Constitution of India for the enforcement of rights under Article 14 and 21 of the Constitution of India seeking a writ directing the Respondents to make public the segregated data (centre-wise results) of the Rotavac clinical trial (phase III) that was conducted on 6799 infants at three centres namely Delhi, Pune and Vellore between 2011-2013 to gauge the safety and efficacy of the said vaccine with funding from the Government of India and so must be available under the Right to Information Act 2005.

3. That instead of providing the segregated data about the safety of the Randomised Control Trial as sought by the petitioner, the respondents had assured that they will carry out assessment of safety data at the Surveillance Stage. However, even in this, real surveillance of all vaccinated infants was not done. The respondents only observed cases of intussusception that came in a few selected hospitals and scrutinized if these infants with intussusception had received rotavirus vaccine. They looked at

NOTARY
C. V. PATEL
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Reg. No. 13260
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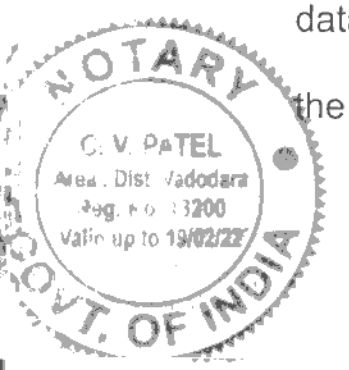
intussusception in 3 weeks after vaccination as intussusceptions caused by vaccination.

4. That the misleading surveillance data has since been published in an article 'Intussusception after Rotavirus Vaccine Introduction in India' published in New England Journal of Medicine issue dated 12.11.2020. A copy of the Article published in NEJM dated 12.11.2020 is annexed herewith as **Annexure P1** (page____to_____).

5. That the raw surveillance data used in the paper was received under RTI reply dated 11.12.2020. The data shows 589 infants who had come to hospital with intussusception were selected for self controlled case series analysis (SCCS). Out of 589, 212 infants had not received the vaccine and 377 infants had received at least one dose of the vaccine. A copy of the reply to the RTI dated 11.12.2020 issued by Translational Health Science and Technology Institute is annexed herewith as **Annexure P2** (page__to_____).

6. That Former Member of National Technical Advisory Group on Immunization in India (NTAGI), Dr. Jacob Puliyel studied the said data and determined that the data was misleadingly presented in the New England Journal of Medicine (NEJM).



7. That the surveillance data was analyzed and the following observations were made by Dr Puliyel in his letter to New England Journal of Medicine (NEJM):

"The SCCS compared a period when intussusceptions are usually low (3 weeks following immunization which is advised at 6,10 and 14 weeks of age) against a high susceptibility period which peaks between 20 weeks and 28 weeks. Unless intussusceptions in the low-risk period studied exceed the intussusceptions in the rest of the year, when the risk is higher, the safety signal is likely to be missed. This is a poor test of vaccine safety."

8. In other words, it is a known fact that majority of the cases of naturally occurring intussusception (not related to vaccine) occurs in infants after 4 months and such cases are not seen in infants below four months.

Without vaccination, intussusceptions are not expected in the period that were studied and all intussusceptions in this period must be attributed to vaccination.

9. That the analysis done by Dr Puliyel and sent to the NEJM demonstrates that the infants who got vaccinated, developed intussusception significantly earlier than unvaccinated infants showing that vaccine was causing the early intussusceptions.

10. That based on this data analysis there is clear indication that the administration of vaccine is leading to rise in the rate of early intussusception, as it's a side effect, in infants and the same observations with the data were sent to New England Journal of Medicine. The Editor of the journal subsequently demanded that the authors of the paper Dr. Gagandeep Kang give an explanation in light of the observations made by Dr. Puliyel. A copy of the letter dated 29.12.2020 sent to NEJM is annexed herewith as **Annexure P3**(page____to_____) & **Annexure P4**(page____to_____).

11. That despite a passage of six months, there has been no satisfactory response from Dr. Kang. This is evidenced by the email sent by the Editor of the NEJM to Dr Puliyel. A copy of the e-mail dated 20.05.2021 from NEJM to Dr. Puliyel is annexed herewith as **Annexure P5**(page____to____).

12. That, in summary, the post-marketing surveillance data, actually shows vaccinated infants developing intussusception early, but it seems to have been misleadingly reported that there was no safety risk of the vaccine. When confronted with the data by the Editor of the NEJM, the respondents have not provided satisfactory explanation for nearly 6 months now.

13. That it is clear from the correspondence that the new surveillance data is not reassuring in the least, and the vaccine is causing early intussusception. A definitive answer to this question of how many safety of the vaccine can only be made by disclosing the data of the RCT as requested by the petitioner in the instant writ petition.

14. That the respondents by concealing the segregated randomized trial data (funded by Government funds and so mandatorily to be provided under RTI) has put the lives of millions at risk of intussusception and death.

That the present surveillance data set is inadequate to clearly examine by how much vaccination increases the incidence of intussusception. In order to know how many cases of intussusception are caused by vaccination, evidence from randomised controlled trial in a segregated manner is crucial. This matter concerns the safety of infants who are being put at serious risk by delays and concealment of the randomized trial data. It is imperative that independent scientists are able to objectively look at the data. Like in the matter of the misleading surveillance data published in the NEJM, review by independent scientists can pick

up errors that have been made intentionally or unintentionally. This can save lives of infants.

In view of the above, it is humbly prayed that segregated data as sought by the petitioner be provided at the earliest.

For Low Cost Standard Therapeutics

Trustee

DEPONENT

VERIFICATION:

Verified at New Delhi on this 17th of July 2021 that the contents of the above Affidavit are true and correct to my knowledge; that no part of it is false and that nothing material has been concealed therefrom.

For Low Cost Standard Therapeutics

Trustee

DEPONENT

Reg. Sr. No. 02482
17 JUL 2021
Chiragkumar V. Patel
NOTARY
Government of India

NOTARIAL

MY COMMISSION EXPIRES
ON Dt. 19 - 02 - 2022

Solemnly Affirmed / Declared
Sworn Before me By

Chiragkumar V. Patel
NOTARY
Government of India
17 JUL 2021

NOTARY
V. PATEL
Dist. Vadodara
Reg. No. 13200
Valid up to 19/02/22
GOVT. OF INDIA

ORIGINAL ARTICLE

Intussusception after Rotavirus Vaccine Introduction in India

S.N. Reddy, N.P. Nair, J.E. Tate, V. Thiyagarajan, S. Giri, I. Praharaj, V.R. Mohan, S. Babji, M.D. Gupte, R. Arora, S. Bidari, S. Senthamizh, S. Mekala, K.B. Goru, B. Reddy, P. Pamu, R.P. Gorthi, M. Badur, V. Mohan, S. Sathpathy, H. Mohanty, M. Dash, N.K. Mohakud, R.K. Ray, P. Mohanty, G. Gathwala, S. Chawla, M. Gupta, R. Gupta, S. Goyal, P. Sharma, M.A. Mathew, T.J.K. Jacob, B. Sundaram, G.K.C. Purushothaman, P. Dorairaj, M. Jagannatham, K. Murugiah, H. Boopathy, R. Maniam, R. Gurusamy, S. Kumaravel, A. Shenoy, H. Jain, J.K. Goswami, A. Wakhlu, V. Gupta, G. Vinayagamurthy, U.D. Parashar, and G. Kang

ABSTRACT

BACKGROUND

A three-dose, oral rotavirus vaccine (Rotavac) was introduced in the universal immunization program in India in 2016. A prelicensure trial involving 6799 infants was not large enough to detect a small increased risk of intussusception. Postmarketing surveillance data would be useful in assessing whether the risk of intussusception would be similar to the risk seen with different rotavirus vaccines used in other countries.

METHODS

We conducted a multicenter, hospital-based, active surveillance study at 27 hospitals in India. Infants meeting the Brighton level 1 criteria of radiologic or surgical confirmation of intussusception were enrolled, and rotavirus vaccination was ascertained by means of vaccination records. The relative incidence (incidence during the risk window vs. all other times) of intussusception among infants 28 to 365 days of age within risk windows of 1 to 7 days, 8 to 21 days, and 1 to 21 days after vaccination was evaluated by means of a self-controlled case-series analysis. For a subgroup of patients, a matched case–control analysis was performed, with matching for age, sex, and location.

RESULTS

From April 2016 through June 2019, a total of 970 infants with intussusception were enrolled, and 589 infants who were 28 to 365 days of age were included in the self-controlled case-series analysis. The relative incidence of intussusception after the first dose was 0.83 (95% confidence interval [CI], 0.00 to 3.00) in the 1-to-7-day risk window and 0.35 (95% CI, 0.00 to 1.09) in the 8-to-21-day risk window. Similar results were observed after the second dose (relative incidence, 0.86 [95% CI, 0.20 to 2.15] and 1.23 [95% CI, 0.60 to 2.10] in the respective risk windows) and after the third dose (relative incidence, 1.65 [95% CI, 0.82 to 2.64] and 1.08 [95% CI, 0.69 to 1.73], respectively). No increase in intussusception risk was found in the case–control analysis.

CONCLUSIONS

The rotavirus vaccine produced in India that we evaluated was not associated with intussusception in Indian infants. (Funded by the Bill and Melinda Gates Foundation and others.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Kang at the Division of Gastrointestinal Sciences, Christian Medical College Vellore, Ida Scudder Rd., Vellore, Tamil Nadu 632004, India, or at gkang@cmcvellore.ac.in.

Drs. S.N. Reddy and Nair contributed equally to this article.

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Postlicensure studies of rotavirus vaccines have shown varying risks of intussusception in different settings worldwide. The association of intussusception with rotavirus vaccination was identified in 1998, when RotaShield (Wyeth–Lederle Vaccines), the first licensed rotavirus vaccine, was withdrawn because of an increased risk of intussusception.[1,2] Subsequent, large, prelicensure trials of the second-generation rotavirus vaccines Rotarix (GlaxoSmithKline Biologicals) and RotaTeq (Merck) did not show an increased risk of intussusception in clinical trials involving 65,000 to 70,000 infants.[3,4] However, postmarketing surveillance of Rotarix in Australia, Brazil, England, Mexico, and the United States showed one to six excess cases of intussusception per 100,000 vaccinated children.[5-10] Postmarketing surveillance of RotaTeq in Australia and the United States showed one to seven excess cases of intussusception per 100,000 vaccinated children.[6,10]

Despite the hypothesis that intussusception might be an adverse event associated with all rotavirus vaccines,[11] the World Health Organization (WHO) recommended the introduction of rotavirus vaccine into childhood vaccination programs because the projected incidences of rotavirus infection and deaths due to diarrhea that were averted were greater than the incidence of additional intussusception, resulting in a favorable risk–benefit ratio.[12] Recently, our understanding of the safety of rotavirus vaccination in specific populations was further informed by the finding that in seven low-income African countries and South Africa, where vaccine efficacy has been lower than that in high-income countries, there was no increased risk of intussusception after Rotarix vaccination.[13,14]

The vaccine we studied, Rotavac (Bharat Biotech International), is an oral monovalent, live, attenuated rotavirus vaccine that contains a naturally occurring bovine–human reassortant 116E strain (G9P[11]).[15,16] The vaccine is administered in a three-dose series at 6, 10, and 14 weeks of age, concurrent with other childhood vaccines. It had an efficacy of 56% against severe rotavirus gastroenteritis in a multicenter, phase 3 clinical trial in India and was licensed in 2014.[17] That trial, in which 6799 infants were randomly assigned in a 2:1 ratio to receive vaccine or placebo, was not large enough to detect a small increased risk of intussusception.[17] This vaccine was introduced into the Universal Immunization Programme of India[18] in 4 states in 2016, in 5 additional states in 2017, in 1 additional state in 2018, and in 10 additional states in 2019.[19] More than 100 million doses of vaccine have been administered to Indian infants.

There are limited background data on intussusception in India. Two studies have shown a general incidence of 18 intussusception cases per 100,000 infants and 20 cases per 100,000 infants.[20,21] The Indian National Technical Advisory Group on Immunization and the WHO recommended the monitoring of vaccine safety after the introduction of the vaccine into the immunization program[22]; in response to this recommendation, we established the Indian Intussusception Surveillance Network.[23] Because the vaccine on which we now report has been prequalified by the WHO, safety data are important for India, for the Gavi Alliance, and for countries considering the introduction of rotavirus vaccines.

METHODS

STUDY SITES

Active surveillance for intussusception was conducted at 27 participating hospitals (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org) that could carry out sentinel surveillance (called sentinel hospitals here) in 10 states in India in which half the population of India resides. Surveillance started in 4 states in April 2016 and was expanded concurrently with vaccine introduction. Detailed information about the methods is provided in the protocol, which has been published previously[23] and is available at NEJM.org.

All the infants who were younger than 2 years of age and who met level 1 diagnostic certainty for intussusception according to the Brighton Collaboration criteria were eligible for recruitment as study participants. Level 1 criteria of the Brighton Collaboration require the confirmation of intussusception by radiologic findings (specifically, if the intussusception was reduced by pneumatic or hydrostatic methods or by contrast enema) or during surgery or at autopsy (Table S2).[24] Surveillance staff completed paper case-report forms with information about patients' sociodemographic and clinical characteristics, treatment, and outcomes and obtained copies of ultrasonographic images and reports and treatment notes. Information about rotavirus vaccination status and a copy of the vaccination record

were obtained from the parents or guardians, and the dates of the first, second, and third vaccinations were recorded. For children who were unvaccinated or partially vaccinated, we contacted the child's health subcenter or primary health center to verify vaccination status.

We performed a matched case–control analysis that included a subgroup of patients with intussusception (case patients) and control infants, who were matched for age (date of birth within a window of ±30 days), sex, and location (same state of residence) and who had been admitted with illness unrelated to the gastrointestinal tract within 30 days before or after the admission of the matched case patient. Copies of the vaccination card and vaccination information were obtained for control infants as they were for the case patients. All case-report forms were sent to the central data management team at Christian Medical College Vellore and entered into an audit trail–enabled SQL database, in which data cleaning and query resolution from sites were managed and validated against documents for 10% of all the case-report forms.

STUDY OVERSIGHT

This study was approved by the institutional review board of Christian Medical College Vellore and by the institutional ethics committees of all the participating hospitals. Written informed consent was obtained from the parents or guardians of all enrolled infants and control participants.

Three authors designed the study, two authors led the data acquisition with all the investigators and wrote the first draft of the manuscript, and four authors analyzed the data. The last author, who made the decision to submit the manuscript for publication, vouches for the accuracy of the data and for the fidelity of the study to the protocol.

STATISTICAL ANALYSIS

We calculated that 160 case patients would need to be enrolled[25] for the study to have 80% power to detect a relative incidence of 2, within a 21-day risk window after the administration of any dose of vaccine, at a 5% level of significance; to detect a relative incidence of 2 after the first dose, the sample size was increased to 263 case patients.[25] We used the self-controlled case-series method to assess the risk of intussusception after vaccine administration. We used conditional Poisson regression analysis to calculate the relative incidence by comparing the incidence in the risk windows (i.e., 1 to 7 days, 8 to 21 days, and 1 to 21 days after each dose of vaccine) with the incidence in all other observational periods (non–risk periods) for each case patient, as required for self-controlled case-series analysis.[23,26,27] We used the pseudolikelihood method[27] to allow the contraindication of vaccination after an episode of intussusception, and event ascertainment was independent of vaccination status.

Considering the minimum and maximum ages at which rotavirus vaccine was administered, we restricted the analysis to children who were 28 to 365 days of age at the time of symptom onset. Children with a recurrent episode of intussusception were excluded from the study. Children with a verified vaccination history were included in the self-controlled case-series analysis, and children for whom vaccination history was based only on report from a parent or guardian or who had received a different rotavirus vaccine were excluded. Unvaccinated children were included in the analysis in order to adjust for the background incidence of intussusception according to age. Age was controlled in the model with the use of 14-day windows. The confidence interval estimates were derived by means of bootstrapping with 1000 iterations.

For all the children, we attempted follow-up at approximately 18 months of age. During follow-up, data were obtained regarding the vital status of the child (alive or dead), the incidence of repeat intussusception, and the receipt of additional doses of rotavirus vaccine after the intussusception.

The matched case–control analysis involved a subgroup of infants with intussusception from the self-controlled case-series analysis for whom matched control participants were enrolled. Rotavirus vaccination status with confirmed vaccination was needed for both the case patient and the matched control in order for the pair to be included. We used conditional logistic regression to assess the ratio of the odds that case patients and controls who were matched for age, sex, and location were vaccinated during the same risk window. A reference date was created for controls, which was the date on which the control participant was the same age as the re-

spective case patient at the time of symptom onset. Exposure to the vaccine with the first, second, or third dose in the risk windows of 1 to 7 days, 8 to 21 days, and 1 to 21 days before the reference date was determined. The matched odds ratios are reported as point estimates with 95% confidence intervals.

In sensitivity analyses for both the self-controlled case-series analysis and the matched case–control analysis, we used the date of admission instead of the date of symptom onset. All the statistical analyses were performed with the use of Stata software, version 13.1 (StataCorp).

RESULTS

CHARACTERISTICS AND CLINICAL FEATURES OF THE PATIENTS

A total of 970 children younger than 2 years of age with intussusception meeting the Brighton level 1 case definition were enrolled (Table S1). Of these, 258 children were excluded from the analysis because they were younger than 28 days of age or older than 365 days of age. Of the 712 children who were 28 to 365 days of age, 46 did not have a copy of the vaccination card and 40 had received a vaccine other than the one under study. Rotavirus vaccination status could not be verified by the health subcenter or primary health center for 37 children. Thus, 589 children with intussusception were included in the self-controlled case-series analysis (Fig. S1).

The median age of these 589 patients was 7 months (interquartile range, 5 to 9). Intussusception was more common among male infants than among female infants (ratio, 2:1). Blood in stools and vomiting were the most common symptoms (in 481 patients [82%] and 438 patients [74%], respectively). Other than constipation and blood in stools, there were no significant differences between vaccinated children and unvaccinated children. Ileocolic intussusception, which was seen in 498 children (85%), was the most common type of intussusception; ileoileal intussusception was observed in 33 children (6%). The treatment methods were hydrostatic or pneumatic reduction (in 200 children [34%]), surgical reduction (in 321 [54%]), and intestinal resection (in 68 [12%]). There were six deaths; the case fatality rate was 1%. (Details are provided in Tables S3 and S4.)

VACCINE COVERAGE AND VACCINATION TIMING

Among these 589 children, 289 (49%) had received all three doses of vaccine, 55 (9%) had received two doses, and 33 (6%) had received one dose; 212 children (36%) had not received any dose of vaccine. The median ages of the patients at the administration of the first, second, and third doses were, respectively, 8 weeks (interquartile range, 7 to 9), 13 weeks (interquartile range, 12 to 14), and 18 weeks (interquartile range, 16 to 20). Of the 377 children who had received the first dose of rotavirus vaccine, 330 (88%) had also received oral polio vaccine on the same day. Of the 344 and 289 children who had received the second and third doses of rotavirus vaccine, 300 (87%) and 240 (83%), respectively, had also received the second and third doses of oral polio vaccine on the same day. The third dose of vaccine is scheduled to be administered at 14 weeks of age, but children presented at a median age of 18 weeks, which overlapped with the peak age of intussusception (Fig. 1).

FOLLOW-UP IN THE SELF-CONTROLLED CASE-SERIES ANALYSIS

We were able to recontact 455 of the 589 children at a median age of 16 months (interquartile range, 13 to 22). Of those 455 children, 8 (2%) had a repeat episode of intussusception, and 7 (2%) died after hospital discharge. The deaths occurred between 4 months and 15 months after discharge; none of the deaths were due to intussusception. Although further doses of the vaccine are contraindicated after intussusception by the manufacturer, parents or guardians reported that 22 of 300 children (7%) who had not completed their rotavirus immunization series had received at least one dose of rotavirus vaccine after intussusception (Table S5).

RISK OF INTUSSUSCEPTION AFTER VACCINATION

Self-Controlled Case-Series Analysis

After the first dose of vaccine, 2 cases of intussusception occurred in the risk window of 1 to 7 days after receipt of the vaccine and 2 cases in the risk window of 8 to 21 days. After the second dose of vaccine, 4 cases of intussusception occurred in the risk window of 1 to 7 days and 15 cases in the risk window of 8 to 21 days. After the third dose of vaccine, 15 cases occurred in the risk window of 1 to 7 days and 22

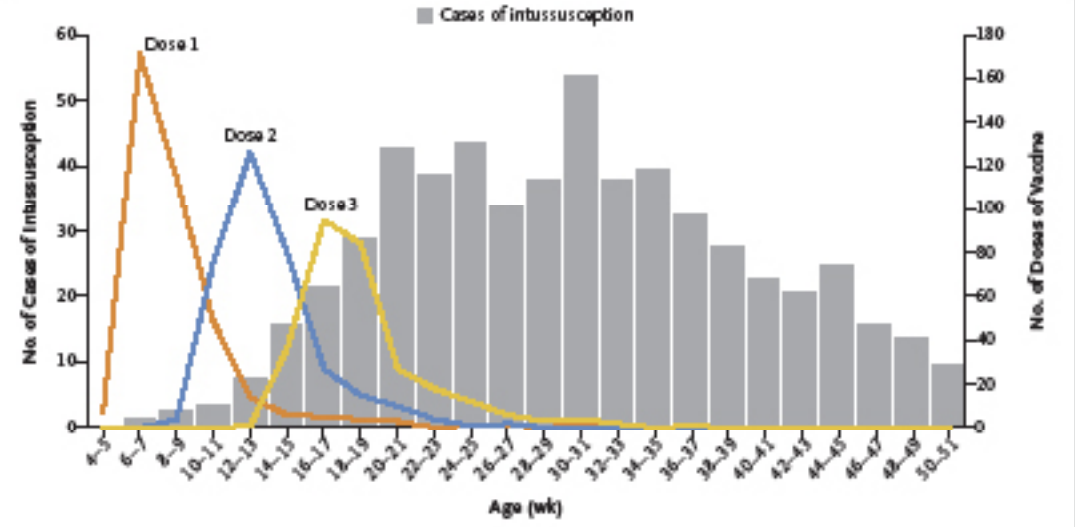

Figure 1. Age at Immunization and at Onset of Intussusception, April 2016 through June 2019.

Gray bars indicate the numbers of intussusception cases according to the age at symptom onset in the infants who were included in the self-controlled case-series analysis. Colored lines indicate the specified doses of rotavirus vaccine administered, according to the infants' age at immunization. Data are from 27 hospitals in 10 states in India.

cases in the risk window of 8 to 21 days (Fig. 2). The risk of intussusception in the 1-to-7-day window (relative incidence, 0.83; 95% confidence interval [CI], 0.00 to 3.00) and in the 8-to-21-day window (relative incidence, 0.35; 95% CI, 0.00 to 1.09) after receipt of the first dose was not higher than the background risk. The risk of intussusception in the 1-to-7-day and 8-to-21-day windows after the second and third doses and the risk in the 1-to-21-day window after any dose were also not higher than the background risk (Table 1).

Matched Case–Control Analysis

The case–control analysis included 162 patients with intussusception who were matched for age, sex, and location with control participants who had a recorded vaccination history (Fig. S2). The odds of intussusception in the 1-to-7-day risk window (matched odds ratio, 1.00; 95% CI, 0.12 to 78.49) and in the 8-to-21-day risk window (matched odds ratio, 0.00; 95% CI, 0.00 to 1.51) after the first dose did not differ significantly among case patients and control participants. Similarly, the odds of intussusception in the 1-to-7-day and the 8-to-21-day windows after the second and third doses, or in the 1-to-21-day window after any dose, did not differ significantly among case patients and control participants (Table 2).

In analyses that used the date of admission instead of the date of symptom onset, the odds ratios did not differ significantly in all the risk windows in both the self-controlled case-series analysis and the matched case-control analysis (Tables S6 and S7). Similar risk estimates were also obtained with the self-controlled case-series analysis that was restricted to include only the 162 infants with intussusception who were included in the matched case–control analysis (Table S8).

DISCUSSION

An increased risk of intussusception was not detected in any risk window after the receipt of any dose of the rotavirus vaccine under study (Rotavac) among children in India in either the self-controlled case-series analysis or the case–control analysis. The results of our postmarketing, active surveillance study provide evidence that there was no adverse safety signal associated with this vaccine in the Indian population.

Our findings differ from those of postlicensure studies of Rotarix or RotaTeq in high-income and middle-income countries that showed a low-

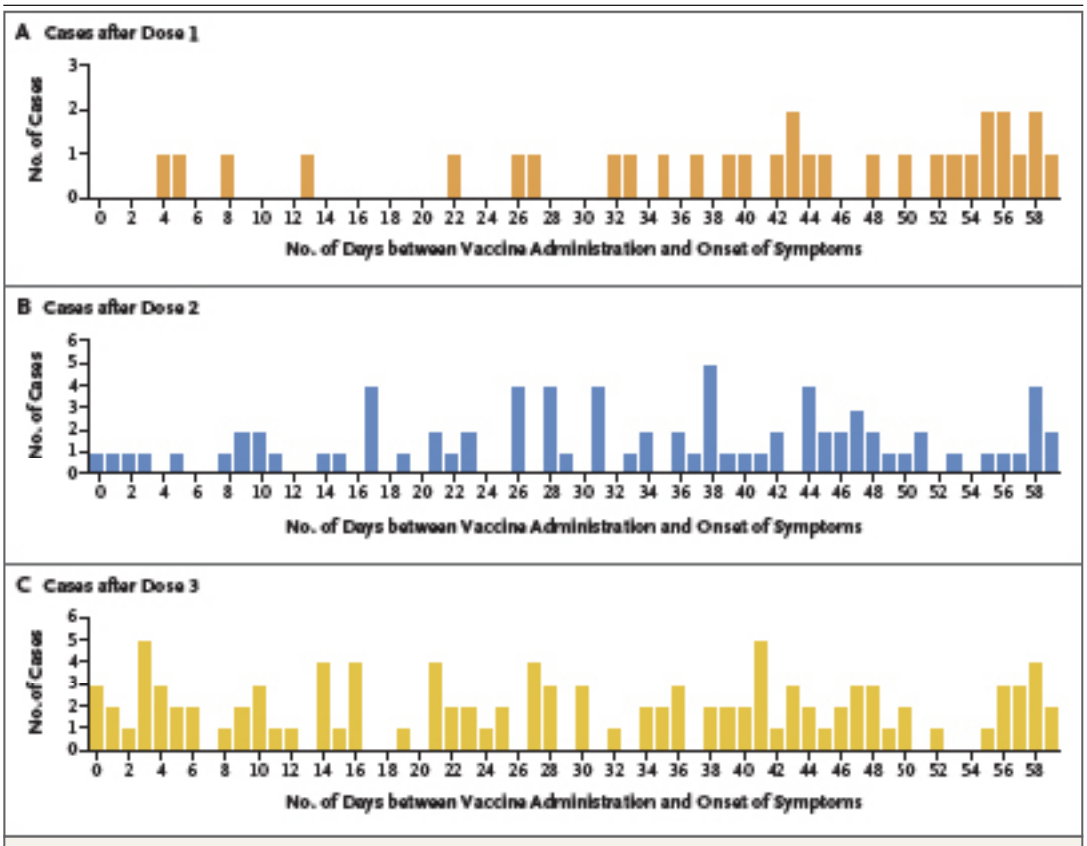

Figure 2. Cases of Intussusception after Rotavirus Vaccine Dose Administration, April 2016 through June 2019.

Shown are the distributions of cases of intussusception during the 59 days after the administration of the first, second, and third doses of rotavirus vaccine. An additional 345 cases occurred more than 59 days after the first dose, an additional 265 cases occurred more than 59 days after the second dose, and an additional 181 cases occurred more than 59 days after the third dose.

level risk of intussusception after rotavirus vaccination. Studies from Australia, England, Mexico, Singapore, and the United States showed an increase in the risk of intussusception by a factor of 2.6 to 8.4 in the 21 days after any dose of Rotarix vaccination.[6-10,28] Studies from Australia and the United States have shown that RotaTeq vaccination was associated with an increase in the risk of intussusception by a factor of 2.6 to 9 in the 21 days after vaccination.[6,10] Conversely, our findings appear to be similar to reports from sub-Saharan Africa and South Africa that did not show an increased risk of intussusception after the administration of a different rotavirus vaccine (Fig. 3).[13,14]

There are no defined criteria on which the risk of intussusception among individual children or in populations can be predicted, although the wide variation in background rates of intussusception indicate that there may be population-based predictors.[29] The earlier ages at which rotavirus vaccines are administered in low-income settings (at 6, 10, and 14 weeks), in contrast to the ages of vaccination in high-income countries (at 2, 4, and 6 months), may be one reason for this lack of association. In addition, the coadministration of rotavirus vaccine with oral poliovirus vaccine may decrease vaccine rotavirus replication in the intestinal epithelium,[30] thus reducing the likelihood of triggering an intussusception. In Brazil, no increased risk of intussusception was found after the administration of the first dose of Rotarix vaccine, a situation in which the rotavirus vaccine was coadministered with oral polio vaccine.[5] In our study, 88%, 87%, and 83% of the infants received the first, second, and third doses, respectively, of rotavirus vaccine and oral polio vaccine on the same day,

Table 1. Relative Incidence of Intussusception in Risk Windows after the First, Second, and Third Doses of Rotavirus Vaccine.*

Dose and Risk Window	No. of Cases	Relative Incidence (95% CI)
Dose 1		
Days 1–7	2	0.83 (0.00–3.00)
Days 8–21	2	0.35 (0.00–1.09)
Days 1–21	4	0.52 (0.08–1.27)
Dose 2		
Days 1–7	4	0.86 (0.20–2.15)
Days 8–21	15	1.23 (0.60–2.10)
Days 1–21	19	1.13 (0.61–1.94)
Dose 3		
Days 1–7	15	1.65 (0.82–2.64)
Days 8–21	22	1.08 (0.69–1.73)
Days 1–21	37	1.24 (0.81–1.82)

* Shown is the relative incidence of intussusception in the risk windows after the first, second, and third doses of Rotavac vaccine in 589 Indian infants who were 28 to 365 days of age and who had a confirmed history of having received or not received rotavirus vaccination. Relative incidence was calculated by the self-controlled case-series method. Of the 589 children included in the analysis, 377 (64%) had been vaccinated with one or more doses, and 212 (36%) had not received any dose of the rotavirus vaccine under study. The date of intussusception was defined as the date of symptom onset.

Table 2. Matched Odds of Intussusception in Risk Windows after Rotavirus Vaccination in Case–Control Pairs of Indian Infants.*

Dose and Risk Window	No. of Cases	No. of Controls	Matched Odds Ratio (95% CI)
Dose 1			
1–7 days	1	1	1.00 (0.12–78.49)
8–21 days	1	5	0.00 (0.00–1.51)
1–21 days	2	6	0.00 (0.00–1.51)
Dose 2			
1–7 days	1	1	1.00 (0.01–78.49)
8–21 days	3	3	1.00 (0.07–13.79)
1–21 days	4	4	1.00 (0.13–7.46)
Dose 3			
1–7 days	6	3	2.50 (0.41–26.25)
8–21 days	7	7	1.00 (0.26–3.74)
1–21 days	13	10	1.40 (0.49–4.42)

* Shown are the matched odds of intussusception in the risk windows after the first, second, and third doses of rotavirus vaccine in 162 case–control pairs of Indian infants. The infants were matched for age, sex, and location and had a confirmed rotavirus vaccination history with the vaccine under study. The date of intussusception onset was defined as the date of symptom onset.

and no increased risk of intussusception was found after any dose.

The safety findings regarding the two different rotavirus vaccines in Africa[13,14] and India (the current study) are interesting in the context of reduced vaccine performance in these geographic settings. The immunogenicity and efficacy of oral vaccines, including rotavirus vaccines, are lower in low-resource communities than in high-income countries.[30,31] Factors, such as inhibition by higher levels of maternal antibodies in serum or breast milk and the coadministration of oral polio vaccine, that lower the effective titers of vaccine virus, thus reducing vaccine virus replication and hence immunogenicity, might also lower the risk of intussusception. Other factors, such as micronutrient deficiencies, malnutrition, environmental enteropathy, and early and constant exposure to other gut pathogens, are also proposed to affect mucosal and systemic responses to vaccination[30-32] and could be responsible for the lower background and vaccine-associated intussusception rates in low-resource settings.

Our large, active surveillance study of intussusception, with high-quality countrywide data on intussusception and its management and consequences, including a case fatality rate, adds safety data to the literature on a relatively new vaccine that has been prequalified by the WHO. Death occurred in 1% of the Indian infants who were hospitalized with intussusception, whereas in a similar study in Africa, 12% of the children with intussusception died.[13]

Our study has certain limitations, which include the exclusion of 12% of eligible infants who had inconclusive evidence of vaccination, an inability of the study to assess an association between intussusception and nutritional status, and a lack of estimates of community-based incidence and case fatality rates. However, background rates of intussusception are not needed for a self-controlled case-series analysis because case patients act as their own control and were identified independent of their vaccination status. Given the large sample size, the study was adequately powered to detect small increases in risk in a 1-week or 3-week window after vaccination and showed none. A limitation of the case–control analysis is the relatively smaller size, because

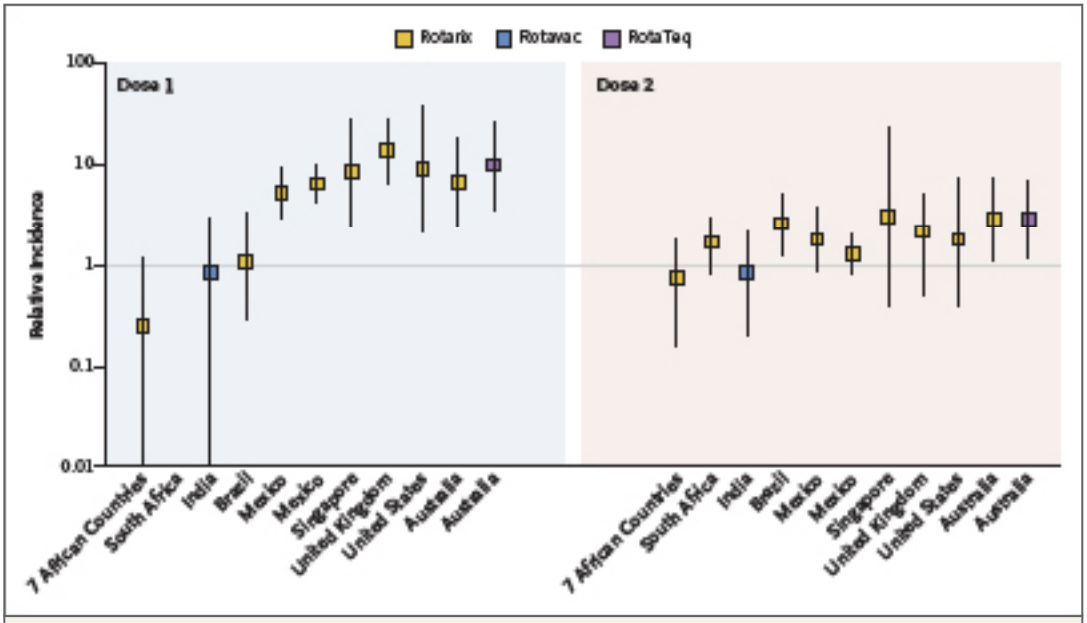

Figure 3. Relative Incidence Estimates of Intussusception after Two Doses of Licensed Rotavirus Vaccine, According to Country.

The relative incidence estimates were calculated by means of self-controlled case-series analyses. Errors bars indicate 95% confidence intervals. Data from studies outside India are from previous studies.[13,14] The seven countries in Africa were Ethiopia, Ghana, Kenya, Malawi, Tanzania, Zambia, and Zimbabwe. In South Africa, there were no cases of intussusception in the 1-to-7-day risk window after the administration of the first dose.

control participants were enrolled for only a subgroup of case patients, and the analysis was adjusted for sex but not for other potential confounders. Nonetheless, the risk estimates from the self-controlled case-series analysis and the case–control analysis were similar except for the wider confidence intervals in the case–control analysis.

In this postmarketing, active surveillance study, we found that Rotavac, an oral rotavirus vaccine produced in India, was not associated with intussusception in the population studied.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC).

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No potential conflict of interest relevant to this article was reported.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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APPENDIX

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Haryana, India

No. THS/6.8.0/5270

11th December, 2020

To,
Dr. Jacob Puliyel,
Flat 6A, 7 Raj Narayan Marg,
Delhi-110054

Dear Dr. Puliyel,

Subject:- Information required under the RTI Act, 2005.

With reference to your RTI appeal received in this office on 23rd November, 2020, the reply to the query is given below:-

The appellate authority has said that the data will be provided after it has been published in a peer reviewed journal. This is now published on 12 November 2020 in the NEJM.

I am enclosing postal orders for Rs. 38 (Rs. 40 actually) as stipulated in the order of the appellate authority quoted above.

Under the RTI request dated 30/12/19 forwarded to you No. Z. 33013/01/2020-IMM please provide me the following expeditiously.

Anonymised raw data on all 598 cases of Level 1 IS cases who received Rotavac/Rotasure in the Sentinel Surveillance by THSTI.

Reply: The information obtained from the Principal Investigator (PI) concerned is enclosed.

In case you are not satisfied with the reply given above, you may contact the appellate authority whose address is given below:-

Dr. Nisheeth Agarwal
Professor & Appellate Authority
Translational Health Science and Technology Institute
NCR Biotech Science Cluster, 3rd Milestone,
Faridabad – Gurgaon Expressway, PO box #04,
Faridabad – 121001

Yours sincerely,

A. Krishnamohan

(Dr. Krishnamohan Atmakuri)
Assistant Professor & PIO

S.No	Date of birth	Date of 1st dose Rotavirus vaccine	Date of 2nd dose Rotavirus vaccine	Date of 3rd dose Rotavirus vaccine	Date of intussusception
1	11/17/2018	12/22/2018	3/2/2019		3/30/2019
2	1/23/2017				8/30/2017
3	2/21/2017				6/18/2017
4	11/3/2018				6/4/2019
5	4/5/2016				3/1/2017
6	9/29/2017	12/14/2017	2/22/2018	3/22/2018	7/14/2018
7	2/19/2017				8/29/2017
8	3/17/2018				7/5/2018
9	1/23/2018	3/24/2018	4/24/2018	5/25/2018	8/26/2018
10	11/2/2017				2/21/2018
11	11/13/2016				10/10/2017
12	2/28/2017				8/15/2017
13	2/15/2017				8/9/2017
14	11/11/2017	1/10/2018	2/14/2018	3/14/2018	6/17/2018
15	9/27/2018	11/13/2018	1/5/2019	2/1/2019	3/31/2019
16	6/26/2017	8/16/2017	11/15/2017	1/3/2018	6/18/2018
17	4/19/2016	7/20/2016	8/17/2016		9/1/2016
18	10/16/2016	12/5/2016	1/9/2017	2/6/2017	4/14/2017
19	7/24/2017	9/20/2017	10/20/2017	11/22/2017	1/17/2018
20	4/18/2017	6/7/2017	7/15/2017		8/1/2017
21	9/1/2017	10/25/2017	12/13/2017	1/10/2018	1/13/2018
22	3/4/2019	4/18/2019	5/16/2019		6/24/2019
23	7/3/2017				11/22/2017
24	8/15/2018	10/1/2018	12/4/2018		12/26/2018
25	6/8/2015				6/6/2016
26	4/8/2018	5/23/2018	8/18/2018	10/3/2018	11/15/2018
27	11/12/2018	1/9/2019	2/13/2019		3/16/2019
28	4/17/2017	6/7/2017	7/5/2017	8/9/2017	9/26/2017
29	10/24/2016	12/28/2016	1/25/2017	2/22/2017	3/10/2017
30	10/3/2018	11/19/2018	12/19/2018	1/23/2019	5/2/2019
31	2/9/2016	4/6/2016	5/12/2016	6/1/2016	10/20/2016

32	3/22/2017	5/17/2017	6/28/2017	7/26/2017	8/11/2017
33	6/27/2017	8/17/2017	9/22/2017	10/26/2017	2/3/2018
34	5/2/2017				1/22/2018
35	3/6/2018	5/10/2018	6/14/2018	7/12/2018	12/16/2018
36	5/28/2017	7/12/2017	8/12/2017	9/27/2017	2/18/2018
37	7/8/2018	9/6/2018	10/20/2018		10/20/2018
38	3/7/2018	4/26/2018	7/3/2018	8/7/2018	1/11/2019
39	1/30/2017	4/5/2017			6/5/2017
40	6/12/2016	8/3/2016	10/5/2016	11/5/2016	11/19/2016
41	11/1/2017				4/25/2018
42	5/19/2018				11/4/2018
43	11/4/2018	12/20/2018	1/22/2019	2/22/2019	2/25/2019
44	10/16/2018	12/15/2018	1/9/2019		3/11/2019
45	12/21/2016				8/8/2017
46	4/19/2017	6/7/2017	7/5/2017	8/2/2017	10/2/2017
47	5/19/2016	7/6/2016	8/10/2016	9/14/2016	9/17/2016
48	10/23/2017				3/9/2018
49	2/12/2018	4/11/2018	5/2/2018	6/6/2018	7/24/2018
50	11/28/2017	1/18/2018	3/8/2018	4/5/2018	5/5/2018
51	10/18/2017	1/10/2018	2/14/2018	3/14/2018	3/14/2018
52	5/28/2016	8/3/2016	10/5/2016	11/23/2016	3/6/2017
53	8/8/2018	9/19/2018	10/17/2018	11/16/2018	2/9/2019
54	10/4/2018	4/11/2019			6/21/2019
55	10/11/2017	12/6/2017	1/17/2018	2/21/2018	9/8/2018
56	2/14/2018				1/10/2019
57	5/5/2017				3/16/2018
58	2/12/2018	4/4/2018	5/2/2018	6/6/2018	8/28/2018
59	10/17/2017	12/6/2017	1/24/2018	2/28/2018	3/9/2018
60	5/28/2017	7/18/2017	9/5/2017	10/3/2017	3/31/2018
61	6/10/2017				2/4/2018
62	5/9/2018	7/10/2018	8/23/2018	9/26/2018	12/6/2018
63	3/17/2017				12/27/2017
64	1/22/2017				11/24/2017

65	6/27/2017				10/5/2017
66	3/24/2019	5/16/2019	6/27/2019		7/14/2019
67	3/14/2017	5/3/2017	6/7/2017	7/21/2017	12/16/2017
68	10/15/2016				5/2/2017
69	1/1/2016				11/7/2016
70	12/13/2018	2/7/2019	3/7/2019	4/11/2019	7/19/2019
71	9/11/2018	11/1/2018	12/6/2018	2/7/2019	3/1/2019
72	8/12/2018	11/1/2018			2/7/2019
73	7/4/2018	8/23/2018	10/11/2018		2/5/2019
74	9/4/2018	10/17/2018	11/14/2018	12/19/2018	4/9/2019
75	10/8/2018				5/16/2019
76	8/17/2017	11/9/2017	12/14/2017	2/8/2018	3/27/2018
77	10/5/2016	12/14/2016	1/11/2017	2/8/2017	2/18/2017
78	12/19/2017	2/26/2018	3/27/2018	4/26/2018	7/13/2018
79	11/18/2017	1/2/2018	2/7/2018	3/7/2018	6/16/2018
80	12/16/2017	2/21/2018	4/18/2018		5/14/2018
81	12/8/2018	1/31/2019	3/7/2019	5/16/2019	6/21/2019
82	10/3/2018	11/24/2018	12/22/2018	1/25/2019	5/17/2019
83	5/22/2018				1/27/2019
84	1/23/2016				6/14/2016
85	10/25/2016				9/25/2017
86	4/5/2017				3/21/2018
87	9/3/2017	10/25/2017	11/22/2017	12/20/2017	4/16/2018
88	8/15/2016	10/19/2016	11/16/2016	12/21/2016	1/2/2017
89	7/10/2018	9/17/2018	10/15/2018	11/19/2018	4/29/2019
90	4/8/2016				11/3/2016
91	1/17/2017	3/8/2017	4/12/2017	5/10/2017	6/29/2017
92	9/25/2018	11/15/2018	12/20/2018	1/24/2019	5/28/2019
93	10/18/2018	12/3/2018	1/4/2019		5/6/2019
94	4/21/2016				11/20/2016
95	7/3/2017	8/16/2017	9/13/2017	10/11/2017	2/4/2018
96	9/9/2017	11/2/2017	12/13/2017	1/10/2018	5/11/2018
97	6/29/2018	9/19/2018	10/17/2018	11/22/2018	1/19/2019

98	12/6/2017	1/17/2018	2/20/2018	3/21/2018	7/20/2018
99	5/8/2018	12/11/2018			2/2/2019
100	10/18/2017	11/16/2017	12/21/2017	1/18/2018	8/29/2018
101	7/5/2018	8/20/2018	9/20/2018	11/21/2018	11/27/2018
102	12/6/2017	1/24/2018	2/28/2018	3/28/2018	7/11/2018
103	10/10/2018	12/6/2018	1/3/2019	3/28/2019	6/15/2019
104	5/16/2017				3/5/2018
105	9/5/2017	11/15/2017	12/20/2017	1/17/2018	4/20/2018
106	12/8/2017	2/3/2018	3/7/2018		3/10/2018
107	8/12/2017	10/4/2017	11/4/2017	12/13/2017	2/6/2018
108	5/9/2017				2/7/2018
109	6/24/2016	8/17/2016	9/21/2016	10/19/2016	4/2/2017
110	9/24/2017	11/9/2017	12/14/2017	1/18/2018	6/13/2018
111	8/1/2018				5/26/2019
112	10/20/2017				8/11/2018
113	6/29/2017	8/28/2017	10/9/2017		1/26/2018
114	6/23/2017				3/26/2018
115	6/3/2017	7/26/2017	8/30/2017	10/7/2017	2/4/2018
116	6/29/2017	9/6/2017	10/4/2017	11/1/2017	11/24/2017
117	5/15/2017	10/5/2017			12/11/2017
118	12/31/2016				10/26/2017
119	11/4/2018	1/2/2019	2/27/2019	3/28/2019	5/8/2019
120	9/22/2016				5/14/2017
121	12/20/2018	2/21/2019	3/22/2019	4/25/2019	6/27/2019
122	10/25/2018	12/12/2018	1/9/2019	2/13/2019	5/23/2019
123	5/31/2016	8/3/2016	9/7/2016	10/5/2016	5/29/2017
124	7/27/2017				3/5/2018
125	9/10/2018	11/21/2018	12/19/2018	1/16/2019	4/22/2019
126	8/21/2017	10/12/2017			12/28/2017
127	4/30/2018	6/20/2018	7/25/2018	9/12/2018	11/24/2018
128	4/27/2019				7/21/2019
129	10/31/2018	12/19/2018	1/30/2019	3/6/2019	7/1/2019
130	2/15/2018	4/24/2018	6/7/2018		12/10/2018

131	8/15/2015				5/8/2016
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133	1/25/2016				10/3/2016
134	10/28/2018	1/17/2019	3/14/2019		5/27/2019
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136	10/6/2017	11/22/2017	1/11/2018	2/8/2018	5/11/2018
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148	2/21/2019	7/3/2019			7/7/2019
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164	5/19/2016				1/7/2017
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229	9/18/2017				6/6/2018

230	4/25/2017	6/16/2017	7/16/2017	8/31/2017	9/1/2017
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239	12/3/2017				4/13/2018
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418	11/17/2017				6/6/2018
419	3/9/2018	5/7/2018	6/4/2018	7/2/2018	11/13/2018
420	9/28/2017	11/17/2017	12/21/2017	2/6/2018	5/20/2018
421	9/29/2017	12/13/2017			4/24/2018
422	9/6/2018	10/27/2018	11/24/2018	12/24/2018	2/20/2019
423	10/6/2016	11/23/2016	12/28/2016	1/25/2017	6/9/2017
424	2/28/2017	4/12/2017	5/24/2017		7/3/2017
425	1/2/2016	2/17/2016	3/28/2016	5/6/2016	11/6/2016
426	7/3/2017				4/19/2018
427	8/31/2016	11/16/2016	12/21/2016	1/18/2017	7/30/2017

428	12/23/2016				8/23/2017
429	3/11/2017	5/6/2017	6/3/2017	7/1/2017	2/10/2018
430	8/10/2018	9/26/2018	10/31/2018	11/28/2018	12/20/2018
431	7/26/2017	12/21/2017	1/25/2018	2/21/2018	7/1/2018
432	6/22/2016				1/20/2017
433	3/1/2017				8/2/2017
434	11/26/2017	1/17/2018	2/28/2018	3/21/2018	6/19/2018
435	10/13/2017	12/8/2017	1/12/2018	2/21/2018	2/27/2018
436	12/30/2017	3/8/2018	4/4/2018	5/5/2018	8/27/2018
437	4/22/2017				12/29/2017
438	7/18/2016	9/28/2016	10/26/2016	11/23/2016	3/31/2017
439	3/4/2016	4/17/2016	6/23/2016	8/4/2016	1/1/2017
440	11/11/2017				2/20/2018
441	4/18/2016				3/21/2017
442	7/11/2017				3/31/2018
443	11/25/2017	1/17/2018	2/28/2018	3/28/2018	9/11/2018
444	12/27/2017	2/18/2018	3/19/2018	4/19/2018	7/7/2018
445	8/2/2017				3/25/2018
446	11/23/2016	12/28/2016	1/28/2017	3/1/2017	7/8/2017
447	8/25/2018	10/10/2018	11/21/2018	12/26/2018	4/15/2019
448	7/23/2017				10/29/2017
449	7/3/2017				2/18/2018
450	5/18/2018				2/28/2019
451	9/27/2018	11/16/2018	12/19/2018	2/6/2019	5/30/2019
452	7/9/2016	9/21/2016	11/9/2016	12/21/2016	5/15/2017
453	1/14/2018				6/5/2018
454	11/21/2017	1/17/2018	2/21/2018	3/21/2018	4/26/2018
455	7/25/2018	9/20/2018	10/25/2018	12/5/2018	5/22/2019
456	8/25/2017				5/5/2018
457	6/28/2017				3/12/2018
458	3/18/2018	5/2/2018	6/13/2018	7/11/2018	10/9/2018
459	7/31/2016				1/27/2017
460	5/16/2016	9/7/2016			12/8/2016

461	11/9/2017	2/21/2018	3/21/2018		4/4/2018
462	1/15/2018	3/6/2018	4/4/2018	5/2/2018	6/30/2018
463	8/8/2017	10/4/2017	11/8/2017		2/28/2018
464	7/5/2018				5/31/2019
465	2/15/2019	4/2/2019			4/15/2019
466	7/29/2017				1/20/2018
467	4/1/2018	5/16/2018	7/11/2018		8/1/2018
468	4/7/2018				1/17/2019
469	9/5/2016	11/15/2016	12/14/2016	1/16/2017	5/5/2017
470	10/15/2016	11/22/2016	12/21/2016	1/26/2017	3/7/2017
471	8/31/2017				5/20/2018
472	12/8/2017	2/14/2018	3/21/2018	5/2/2018	7/12/2018
473	9/10/2016				7/12/2017
474	9/25/2017				4/6/2018
475	10/23/2017	12/13/2017	2/14/2018	4/18/2018	7/2/2018
476	8/10/2017				5/10/2018
477	6/15/2018	8/16/2018	9/19/2018	10/25/2018	6/4/2019
478	6/17/2016				10/19/2016
479	11/6/2017	1/10/2018	2/21/2018	3/21/2018	6/19/2018
480	9/5/2018				2/20/2019
481	11/11/2018	1/2/2019	2/6/2019	3/13/2019	4/3/2019
482	9/17/2016				1/17/2017
483	1/12/2018				8/1/2018
484	4/24/2017	7/12/2017	8/9/2017	9/13/2017	10/17/2017
485	3/27/2018				9/21/2018
486	5/3/2018	6/20/2018	7/23/2018	8/23/2018	9/19/2018
487	2/2/2017				8/28/2017
488	4/27/2018				4/22/2019
489	4/3/2017				1/19/2018
490	6/19/2017				9/7/2017
491	8/14/2017				5/2/2018
492	2/3/2017				12/14/2017
493	10/8/2017				6/4/2018

494	8/12/2017				6/17/2018
495	12/10/2017	1/24/2018	2/28/2018	4/4/2018	5/31/2018
496	2/7/2017				9/23/2017
497	3/26/2018	6/6/2018	7/4/2018	8/1/2018	1/22/2019
498	4/19/2018	6/28/2018	7/26/2018	8/23/2018	11/21/2018
499	5/7/2018				4/3/2019
500	3/8/2018	5/10/2018	6/14/2018	7/12/2018	12/2/2018
501	8/9/2018				3/24/2019
502	3/19/2018	5/7/2018	6/8/2018	7/8/2018	7/24/2018
503	7/1/2016				2/26/2017
504	8/5/2016				11/22/2016
505	7/3/2017				10/31/2017
506	2/27/2018	5/10/2018	6/14/2018	7/12/2018	11/22/2018
507	10/7/2017				5/10/2018
508	5/8/2018	7/4/2018	8/1/2018	10/3/2018	1/6/2019
509	3/13/2017	5/5/2017	6/9/2017	7/10/2017	2/24/2018
510	10/13/2016				4/22/2017
511	4/3/2017				2/10/2018
512	10/26/2017	2/14/2018			7/15/2018
513	11/27/2018	1/23/2019	3/6/2019	4/3/2019	6/14/2019
514	1/29/2018	3/14/2018	4/11/2018	5/16/2018	6/26/2018
515	11/26/2017	2/1/2018	3/8/2018	5/10/2018	5/12/2018
516	8/5/2016				4/14/2017
517	1/29/2018	3/21/2018	4/25/2018		9/7/2018
518	2/2/2018	4/4/2018	5/23/2018		8/13/2018
519	6/6/2018	7/28/2018	8/25/2018	9/28/2018	3/28/2019
520	11/16/2017	1/10/2018	2/14/2018		4/23/2018
521	7/26/2017	9/13/2017	10/12/2017	11/13/2017	12/10/2017
522	6/20/2018	8/3/2018			11/13/2018
523	5/15/2018				4/22/2019
524	11/6/2018				5/12/2019
525	2/16/2017	4/20/2017	5/18/2017	7/20/2017	11/22/2017
526	2/17/2017				10/29/2017

527	8/30/2018	11/5/2018	12/5/2018	1/16/2019	2/9/2019
528	10/6/2017				4/11/2018
529	3/17/2017	5/8/2017	6/9/2017	7/10/2017	1/5/2018
530	12/4/2015				10/16/2016
531	7/11/2017	9/7/2017	10/5/2017	11/2/2017	12/16/2017
532	3/17/2018	5/5/2018	6/6/2018	7/18/2018	9/22/2018
533	8/12/2018				3/2/2019
534	8/1/2017	9/21/2017	10/26/2017	12/7/2017	1/14/2018
535	2/7/2017	4/13/2017	5/14/2017	7/24/2017	12/9/2017
536	7/10/2017	8/23/2017	9/27/2017	10/25/2017	12/21/2017
537	11/16/2016				10/24/2017
538	5/30/2018				11/8/2018
539	12/28/2017				3/24/2018
540	5/20/2017	8/21/2017			10/27/2017
541	10/26/2017	12/13/2017			12/18/2017
542	8/24/2017				2/20/2018
543	3/10/2019				4/27/2019
544	2/15/2016	4/12/2016	5/18/2016	6/14/2016	1/11/2017
545	4/29/2017				2/7/2018
546	7/17/2017				1/27/2018
547	2/9/2018	4/4/2018	5/2/2018	6/6/2018	6/20/2018
548	1/20/2018	3/14/2018	5/19/2018	6/16/2018	8/16/2018
549	1/16/2018				3/1/2018
550	9/16/2018	12/10/2018	1/5/2019		1/6/2019
551	6/20/2017				3/14/2018
552	1/12/2018				3/21/2018
553	10/14/2017				3/31/2018
554	12/3/2017	1/24/2018	2/28/2018		3/10/2018
555	4/8/2017				12/19/2017
556	7/17/2018				1/11/2019
557	3/18/2017	10/23/2017			1/22/2018
558	10/5/2018	12/12/2018	1/12/2019		1/29/2019
559	10/8/2017	11/24/2017	12/28/2017	1/25/2018	3/14/2018

560	9/4/2016	10/13/2016	12/10/2016		12/12/2016
561	1/2/2017	2/23/2017			3/27/2017
562	8/1/2017	9/19/2017	10/18/2017		12/5/2017
563	4/3/2018	5/28/2018	6/28/2018	8/2/2018	9/17/2018
564	5/15/2018	7/7/2018	8/18/2018		10/16/2018
565	10/7/2018	12/6/2018	1/9/2019	2/14/2019	5/10/2019
566	7/6/2018	8/22/2018	9/24/2018	10/24/2018	3/20/2019
567	5/16/2018	7/11/2018	8/8/2018		10/19/2018
568	10/3/2017				5/3/2018
569	4/5/2018	6/13/2018	7/11/2018	8/8/2018	9/13/2018
570	2/10/2017	3/26/2017	4/29/2017	5/30/2017	9/26/2017
571	2/16/2017				9/15/2017
572	1/7/2019	3/20/2019	4/17/2019	5/15/2019	6/18/2019
573	7/7/2016	9/3/2016	10/4/2016		10/13/2016
574	4/27/2018				10/13/2018
575	11/7/2015				6/9/2016
576	2/8/2017	4/5/2017	5/6/2017	6/3/2017	1/4/2018
577	11/24/2018	3/8/2019	4/12/2019	6/14/2019	7/3/2019
578	2/20/2018	4/26/2018	5/24/2018	6/21/2018	7/18/2018
579	10/8/2016	12/3/2016	2/3/2017	3/15/2017	5/20/2017
580	6/23/2016	9/3/2016	10/1/2016	11/5/2016	11/6/2016
581	12/11/2018				2/13/2019
582	10/22/2016				1/19/2017
583	5/26/2017				5/20/2018
584	5/2/2017	6/19/2017	7/20/2017	8/25/2017	12/29/2017
585	9/24/2017				5/4/2018

586	9/11/2018	11/7/2018	12/9/2018	1/2/2019	2/14/2019
587	7/4/2018	8/21/2018	9/26/2018		10/15/2018
588	12/22/2018	2/6/2019	3/13/2019		6/5/2019
589	6/6/2017	9/27/2017			2/10/2018

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ANNEXURE: P3

Regarding my earlier letter to the Editor (manuscript ID is 20-33556):

One year before the recent publication on the rotavirus vaccine in the NEJM (1), the authors had published a White Paper using the same data (2). Under the Indian 'Right to Information Act 2005', I have now been provided with the dataset from the study and a scanned copy is attached. Analysis of the data used in the self-controlled case-series casts a shadow of doubt on the assertion that 'oral rotavirus vaccine produced in India, was not associated with intussusception in the population studied.'

Among the 589 infants selected for the self-controlled case-series analysis (SCCS), 212 had not received the vaccine and 377 received at least one dose of the vaccine. The SCCS compared a period when intussusceptions are usually low (3 weeks following immunization which is advised at 6,10 and 14 weeks of age) against a high susceptibility period which peaks between 20 weeks and 28 weeks (3). Unless intussusceptions in the low-risk period studied exceed the intussusceptions in the rest of the year, when the risk is higher, the safety signal is likely to be missed. This is a poor test of vaccine safety.

If vaccination is merely a coincidental event and it does not disturb the normal incidence of intussusceptions in the population, the mean age of intussusception would be the same in the vaccinated and the unvaccinated. We found that there was a significant lowering of the mean age intussusception among the vaccinated [- 205.4 days (SD 65.8) compared to 223.3 days (SD 74.1) in the unvaccinated (95% CI -29.5 to – 6.3 $p = 0.003$) (Data in Excel sheets attached and can be used as supplementary file)]

It is not unreasonable to surmise that vaccination may have been responsible for early intussusceptions which caused the shift in the mean age of intussusception. The data-set does not allow us to examine whether vaccination increases the incidence of intussusception. It is possible that vaccination merely lowered the age of developing intussusception among those susceptible to it. To be able to say if there is an increase in intussusception caused by the vaccine, evidence from randomized control trials are needed. Data from an RCT using this vaccine in Vellore India has not been made available yet (4). It is hoped that this will be published immediately, as it concerns the safety of infants. The Indian rotavirus vaccine is a relatively inexpensive vaccine

and the NEJM paper is likely to be used for applying for more international licenses for use of this vaccine in developing countries with a paucity of facilities to diagnose and treat intussusceptions.

The data utilized here was provided to me by the authors after I had sent you the earlier letter. This submission is different from what was previously submitted and it is outside the 3-week deadline for responses. I will be grateful for an early decision on the suitability of this material (after editing) for publication in the NEJM.

Jacob Puliyel MD

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		1st dose		2nd dose		3rd dose		Intussusception						intussusception by age					
S.No	Date of birth	Date	Age in Days	Date2	Age in Days3	Date4	Age in Days5	Date6	Age in Days7	Days since D1	Days since D2	Days since D3	Min(dsd1,dsd1,dsd1)	without vaccination	with vaccination				
1	11/17/2018	12/22/2018	35	3/2/2019	105			3/30/2019	133	98	28		28		133				
2	1/23/2017							8/30/2017	219	219				219					
3	2/21/2017							6/18/2017	117	117				117					
4	11/3/2018							6/4/2019	213	213				213					
5	4/5/2016							3/1/2017	330	330				330					
6	9/29/2017	12/14/2017	76	2/22/2018	146	3/22/2018	174	7/14/2018	288	212	142	114	114		288				
7	2/19/2017							8/29/2017	191	191				191					
8	3/17/2018							7/5/2018	110	110				110					
9	1/23/2018	3/24/2018	60	4/24/2018	91	5/25/2018	122	8/26/2018	215	155	124	93	93		215				
10	11/2/2017							2/21/2018	111	111				111					
11	11/13/2016							10/10/2017	331	331				331					
12	2/28/2017							8/15/2017	168	168				168					
13	2/15/2017							8/9/2017	175	175				175					
14	11/11/2017	1/10/2018	60	2/14/2018	95	3/14/2018	123	6/17/2018	218	158	123	95	95		218				
15	9/27/2018	11/13/2018	47	1/5/2019	100	2/1/2019	127	3/31/2019	185	138	85	58	58		185				
16	6/26/2017	8/16/2017	51	11/15/2017	142	1/3/2018	191	6/18/2018	357	306	215	166	166		357				
17	4/19/2016	7/20/2016	92	8/17/2016	120			9/1/2016	135	43	15		15		135				
18	10/16/2016	12/5/2016	50	1/9/2017	85	2/6/2017	113	4/14/2017	180	130	95	67	67		180				
19	7/24/2017	9/20/2017	58	10/20/2017	88	11/22/2017	121	1/17/2018	177	119	89	56	56		177				
20	4/18/2017	6/7/2017	50	7/15/2017	88			8/1/2017	105	55	17		17		105				
21	9/1/2017	10/25/2017	54	12/13/2017	103	1/10/2018	131	1/13/2018	134	80	31	3	3		134				
22	3/4/2019	4/18/2019	45	5/16/2019	73			6/24/2019	112	67	39		39		112				
23	7/3/2017							11/22/2017	142	142				142					
24	8/15/2018	10/1/2018	47	12/4/2018	111			12/26/2018	133	86	22		22		133				
25	6/8/2015							6/6/2016	364	364				364					
26	4/8/2018	5/23/2018	45	8/18/2018	132	10/3/2018	178	11/15/2018	221	176	89	43	43		221				
27	11/12/2018	1/9/2019	58	2/13/2019	93			3/16/2019	124	66	31		31		124				
28	4/17/2017	6/7/2017	51	7/5/2017	79	8/9/2017	114	9/26/2017	162	111	83	48	48		162				
29	10/24/2016	12/28/2016	65	1/25/2017	93	2/22/2017	121	3/10/2017	137	72	44	16	16		137				
30	10/3/2018	11/19/2018	47	12/19/2018	77	1/23/2019	112	5/2/2019	211	164	134	99	99		211				
31	2/9/2016	4/6/2016	57	5/12/2016	93	6/1/2016	113	10/20/2016	254	197	161	141	141		254				
32	3/22/2017	5/17/2017	56	6/28/2017	98	7/26/2017	126	8/11/2017	142	86	44	16	16		142				
33	6/27/2017	8/17/2017	51	9/22/2017	87	10/26/2017	121	2/3/2018	221	170	134	100	100		221				
34	5/2/2017							1/22/2018	265	265				265					
35	3/6/2018	5/10/2018	65	6/14/2018	100	7/12/2018	128	12/16/2018	285	220	185	157	157		285				
36	5/28/2017	7/12/2017	45	8/12/2017	76	9/27/2017	122	2/18/2018	266	221	190	144	144		266				
37	7/8/2018	9/6/2018	60	10/20/2018	104			10/20/2018	104	44	0		0		104				
38	3/7/2018	4/26/2018	50	7/3/2018	118	8/7/2018	153	1/11/2019	310	260	192	157	157		310				
39	1/30/2017	4/5/2017	65					6/5/2017	126	61			61		126				
40	6/12/2016	8/3/2016	52	10/5/2016	115	11/5/2016	146	11/19/2016	160	108	45	14	14		160				
41	11/1/2017							4/25/2018	175	175				175					
42	5/19/2018							11/4/2018	169	169				169					
43	11/4/2018	12/20/2018	46	1/22/2019	79	2/22/2019	110	2/25/2019	113	67	34	3	3		113				
44	10/16/2018	12/15/2018	60	1/9/2019	85			3/11/2019	146	86	61		61		146				
45	12/21/2016							8/8/2017	230	230				230					
46	4/19/2017	6/7/2017	49	7/5/2017	77	8/2/2017	105	10/2/2017	166	117	89	61	61		166				
47	5/19/2016	7/6/2016	48	8/10/2016	83	9/14/2016	118	9/17/2016	121	73	38	3	3		121				
48	10/23/2017							3/9/2018	137	137				137					
49	2/12/2018	4/11/2018	58	5/2/2018	79	6/6/2018	114	7/24/2018	162	104	83	48	48		162				
50	11/28/2017	1/18/2018	51	3/8/2018	100	4/5/2018	128	5/5/2018	158	107	58	30	30		158				
51	10/18/2017	1/10/2018	84	2/14/2018	119	3/14/2018	147	3/14/2018	147	63	28	0	0		147				

52	5/28/2016	8/3/2016	67	10/5/2016	130	11/23/2016	179	3/6/2017	282	215	152	103	103		282				
53	8/8/2018	9/19/2018	42	10/17/2018	70	11/16/2018	100	2/9/2019	185	143	115	85	85		185				
54	10/4/2018	4/11/2019	189					6/21/2019	260	71			71		260				
55	10/11/2017	12/6/2017	56	1/17/2018	98	2/21/2018	133	9/8/2018	332	276	234	199	199		332				
56	2/14/2018							1/10/2019	330	330				330					
57	5/5/2017							3/16/2018	315	315				315					
58	2/12/2018	4/4/2018	51	5/2/2018	79	6/6/2018	114	8/28/2018	197	146	118	83	83		197				
59	10/17/2017	12/6/2017	50	1/24/2018	99	2/28/2018	134	3/9/2018	143	93	44	9	9		143				
60	5/28/2017	7/18/2017	51	9/5/2017	100	10/3/2017	128	3/31/2018	307	256	207	179	179		307				
61	6/10/2017							2/4/2018	239	239				239					
62	5/9/2018	7/10/2018	62	8/23/2018	106	9/26/2018	140	12/6/2018	211	149	105	71	71		211				
63	3/17/2017							12/27/2017	285	285				285					
64	1/22/2017							11/24/2017	306	306				306					
65	6/27/2017							10/5/2017	100	100				100					
66	3/24/2019	5/16/2019	53	6/27/2019	95			7/14/2019	112	59	17		17		112				
67	3/14/2017	5/3/2017	50	6/7/2017	85	7/21/2017	129	12/16/2017	277	227	192	148	148		277				
68	10/15/2016							5/2/2017	199	199				199					
69	1/1/2016							11/7/2016	311	311				311					
70	12/13/2018	2/7/2019	56	3/7/2019	84	4/11/2019	119	7/19/2019	218	162	134	99	99		218				
71	9/11/2018	11/1/2018	51	12/6/2018	86	2/7/2019	149	3/1/2019	171	120	85	22	22		171				
72	8/12/2018	11/1/2018	81					2/7/2019	179	98			98		179				
73	7/4/2018	8/23/2018	50	10/11/2018	99			2/5/2019	216	166	117		117		216				
74	9/4/2018	10/17/2018	43	11/14/2018	71	12/19/2018	106	4/9/2019	217	174	146	111	111		217				
75	10/8/2018							5/16/2019	220	220				220					
78	8/17/2017	11/9/2017	84	12/14/2017	119	2/8/2018	175	3/27/2018	222	138	103	47	47		222				
77	10/5/2016	12/14/2016	70	1/11/2017	98	2/8/2017	126	2/18/2017	136	66	38	10	10		136				
78	12/19/2017	2/26/2018	69	3/27/2018	98	4/26/2018	128	7/13/2018	206	137	108	78	78		206				
79	11/18/2017	1/2/2018	45	2/7/2018	81	3/7/2018	109	6/16/2018	210	165	129	101	101		210				
80	12/16/2017	2/21/2018	67	4/18/2018	123			5/14/2018	149	82	26		26		149				
81	12/8/2018	1/31/2019	54	3/7/2019	89	5/16/2019	159	6/21/2019	195	141	106	36	36		195				
82	10/3/2018	11/24/2018	52	12/22/2018	80	1/25/2019	114	5/17/2019	226	174	146	112	112		226				
83	5/22/2018							1/27/2019	250	250				250					
84	1/23/2016							6/14/2016	143	143				143					
85	10/25/2016							9/25/2017	335	335				335					
86	4/5/2017							3/21/2018	350	350				350					
87	9/3/2017	10/25/2017	52	11/22/2017	80	12/20/2017	108	4/16/2018	225	173	145	117	117		225				
88	8/15/2016	10/19/2016	65	11/16/2016	93	12/21/2016	128	1/2/2017	140	75	47	12	12		140				
89	7/10/2018	9/17/2018	69	10/15/2018	97	11/19/2018	132	4/29/2019	293	224	196	161	161		293				
90	4/8/2016							11/3/2016	209	209				209					
91	1/17/2017	3/8/2017	50	4/12/2017	85	5/10/2017	113	6/29/2017	163	113	78	50	50		163				
92	9/25/2018	11/15/2018	51	12/20/2018	86	1/24/2019	121	5/28/2019	245	194	159	124	124		245				
93	10/18/2018	12/3/2018	46	1/4/2019	78			5/6/2019	200	154	122		122		200				
94	4/21/2016							11/20/2016	213	213				213					
95	7/3/2017	8/16/2017	44	9/13/2017	72	10/11/2017	100	2/4/2018	216	172	144	116	116		216				
96	9/9/2017	11/2/2017	54	12/13/2017	95	1/10/2018	123	5/11/2018	244	190	149	121	121		244				
97	6/29/2018	9/19/2018	82	10/17/2018	110	11/22/2018	146	1/19/2019	204	122	94	58	58		204				
98	12/6/2017	1/17/2018	42	2/20/2018	76	3/21/2018	105	7/20/2018	226	184	150	121	121		226				
99	5/8/2018	12/11/2018	217					2/2/2019	270	53			53		270				
100	10/18/2017	11/16/2017	29	12/21/2017	64	1/18/2018	92	8/29/2018	315	286	251	223	223		315				
101	7/5/2018	8/20/2018	46	9/20/2018	77	11/21/2018	139	11/27/2018	145	99	68	6	6		145				
102	12/6/2017	1/24/2018	49	2/28/2018	84	3/28/2018	112	7/11/2018	217	168	133	105	105		217				
103	10/10/2018	12/6/2018	57	1/3/2019	85	3/28/2019	169	6/15/2019	248	191	163	79	79		248				
104	5/16/2017							3/5/2018	293	293				293					
105	9/5/2017	11/15/2017	71	12/20/2017	106	1/17/2018	134	4/20/2018	227	156	121	93	93		227				

106	12/8/2017	2/3/2018	57	3/7/2018	89			3/10/2018	92	35	3		3		92				
107	8/12/2017	10/4/2017	53	11/4/2017	84	12/13/2017	123	2/6/2018	178	125	94	55	55		178				
108	5/9/2017							2/7/2018	274	274				274					
109	6/24/2016	8/17/2016	54	9/21/2016	89	10/19/2016	117	4/2/2017	282	228	193	165	165		282				
110	9/24/2017	11/9/2017	46	12/14/2017	81	1/18/2018	116	6/13/2018	262	216	181	146	146		262				
111	8/1/2018							5/26/2019	298	298				298					
112	10/20/2017							8/11/2018	295	295				295					
113	6/29/2017	8/28/2017	60	10/9/2017	102			1/26/2018	211	151	109		109		211				
114	6/23/2017							3/26/2018	276	276				276					
115	6/3/2017	7/26/2017	53	8/30/2017	88	10/7/2017	126	2/4/2018	246	193	158	120	120		246				
116	6/29/2017	9/6/2017	69	10/4/2017	97	11/1/2017	125	11/24/2017	148	79	51	23	23		148				
117	5/15/2017	10/5/2017	143					12/11/2017	210	67			67		210				
118	12/31/2016							10/26/2017	299	299				299					
119	11/4/2018	1/2/2019	59	2/27/2019	115	3/28/2019	144	5/8/2019	185	126	70	41	41		185				
120	9/22/2016							5/14/2017	234	234				234					
121	12/20/2018	2/21/2019	63	3/22/2019	92	4/25/2019	126	6/27/2019	189	126	97	63	63		189				
122	10/25/2018	12/12/2018	48	1/9/2019	76	2/13/2019	111	5/23/2019	210	162	134	99	99		210				
123	5/31/2016	8/3/2016	64	9/7/2016	99	10/5/2016	127	5/29/2017	363	299	264	236	236		363				
124	7/27/2017							3/5/2018	221	221				221					
125	9/10/2018	11/21/2018	72	12/19/2018	100	1/16/2019	128	4/22/2019	224	152	124	96	96		224				
126	8/21/2017	10/12/2017	52					12/28/2017	129	77			77		129				
127	4/30/2018	6/20/2018	51	7/25/2018	86	9/12/2018	135	11/24/2018	208	157	122	73	73		208				
128	4/27/2019							7/21/2019	85	85				85					
129	10/31/2018	12/19/2018	49	1/30/2019	91	3/6/2019	126	7/1/2019	243	194	152	117	117		243				
130	2/15/2018	4/24/2018	68	6/7/2018	112			12/10/2018	298	230	186		186		298				
131	8/15/2015							5/8/2016	267	267				267					
132	8/5/2017	10/5/2017	61	12/7/2017	124	1/4/2018	152	4/2/2018	240	179	116	88	88		240				
133	1/25/2016							10/3/2016	252	252				252					
134	10/28/2018	1/17/2019	81	3/14/2019	137			5/27/2019	211	130	74		74		211				
135	2/13/2017	4/12/2017	58					5/19/2017	95	37			37		95				
136	10/6/2017	11/22/2017	47	1/11/2018	97	2/8/2018	125	5/11/2018	217	170	120	92	92		217				
137	1/1/2018	2/13/2018	43	3/14/2018	72	4/21/2018	110	7/7/2018	187	144	115	77	77		187				
138	6/26/2016	8/17/2016	52	10/12/2016	108	11/16/2016	143	5/20/2017	328	276	220	185	185		328				
139	7/24/2018							12/7/2018	136	136				136					
140	5/3/2017	7/11/2017	69	8/11/2017	100	9/11/2017	131	10/22/2017	172	103	72	41	41		172				
141	2/17/2018	4/11/2018	53	7/4/2018	137	8/1/2018	165	8/9/2018	173	120	36	8	8		173				
142	2/5/2018	4/7/2018	61	5/5/2018	89	7/16/2018	161	10/12/2018	249	188	160	88	88		249				
143	7/17/2017	10/5/2017	80	12/7/2017	143	1/4/2018	171	7/15/2018	363	283	220	192	192		363				
144	10/18/2017	1/25/2018	99	3/22/2018	155	5/24/2018	218	6/3/2018	228	129	73	10	10		228				
145	12/5/2017	2/8/2018	65	3/8/2018	93	4/12/2018	128	5/10/2018	156	91	63	28	28		156				
146	10/31/2017	12/21/2017	51	1/18/2018	79	2/15/2018	107	6/1/2018	213	162	134	106	106		213				
147	2/6/2016							9/12/2016	219	219				219					
148	2/21/2019	7/3/2019	132					7/7/2019	136	4			4		136				
149	11/4/2017	1/10/2018	67	2/28/2018	116	3/28/2018	144	5/19/2018	196	129	80	52	52		196				
150	7/11/2017	11/23/2017	135	12/28/2017	170	1/25/2018	198	3/13/2018	245	110	75	47	47		245				
151	10/3/2017	12/2/2017	60	2/2/2018	122			3/3/2018	151	91	29		29		151				
152	2/5/2018							10/20/2018	257	257				257					
153	2/13/2018							11/15/2018	275	275				275					
154	5/24/2017							10/8/2017	137	137				137					
155	12/20/2018	2/19/2019	61	3/14/2019	84	4/11/2019	112	7/26/2019	218	157	134	106	106		218				
156	7/31/2017							12/16/2017	138	138				138					
157	10/7/2018							5/1/2019	206	206				206					
158	12/11/2015							5/10/2016	151	151				151					
159	8/20/2017	10/7/2017	48	11/4/2017	76	12/2/2017	104	2/25/2018	189	141	113	85	85		189				

160	5/14/2018	8/6/2018	84	9/6/2018	115	10/13/2018	152	12/20/2018	220	136	105	68	68		220				
161	4/18/2018							9/26/2018	161	161				161					
162	9/16/2018	11/21/2018	66	12/18/2018	93	1/16/2019	122	3/14/2019	179	113	86	57	57		179				
163	10/11/2015							7/18/2016	281	281				281					
164	5/19/2016							1/7/2017	233	233				233					
165	5/28/2018	7/18/2018	51	8/29/2018	93	9/21/2018	116	9/21/2018	116	65	23	0	0		116				
166	2/15/2017							9/25/2017	222	222				222					
167	9/29/2017	11/15/2017	47					2/4/2018	128	81			81		128				
168	9/1/2017							6/24/2018	296	296				296					
169	7/15/2018							12/9/2018	147	147				147					
170	1/19/2017							8/15/2017	208	208				208					
171	3/12/2017	5/3/2017	52	6/21/2017	101			6/30/2017	110	58	9		9		110				
172	7/9/2018							11/25/2018	139	139				139					
173	10/29/2017	1/6/2018	69	2/3/2018	97	3/3/2018	125	5/16/2018	199	130	102	74	74		199				
174	5/8/2017	6/21/2017	44	7/19/2017	72	8/16/2017	100	10/4/2017	149	105	77	49	49		149				
175	8/18/2017	11/10/2017	84	12/11/2017	115	1/10/2018	145	3/29/2018	223	139	108	78	78		223				
176	10/11/2018							3/21/2019	161	161				161					
177	6/13/2018	8/1/2018	49	9/5/2018	84	10/10/2018	119	12/28/2018	198	149	114	79	79		198				
178	10/29/2016	12/14/2016	46	1/11/2017	74	4/7/2017	160	6/21/2017	235	189	161	75	75		235				
179	12/11/2017	2/21/2018	72	4/23/2018	133	5/30/2018	170	7/25/2018	226	154	93	56	56		226				
180	7/14/2018	9/19/2018	67	10/24/2018	102	12/5/2018	144	12/10/2018	149	82	47	5	5		149				
181	6/21/2017	8/23/2017	63	9/20/2017	91	10/25/2017	126	12/7/2017	169	106	78	43	43		169				
182	4/28/2016	9/14/2016	139					10/6/2016	161	22			22		161				
183	8/25/2017	10/9/2017	45	11/6/2017	73	12/7/2017	104	2/4/2018	163	118	90	59	59		163				
184	7/23/2017							4/20/2018	271	271				271					
185	5/20/2017	7/5/2017	46	8/2/2017	74	10/4/2017	137	1/14/2018	239	193	165	102	102		239				
186	12/29/2016							9/2/2017	247	247				247					
187	10/5/2017	12/5/2017	61					6/16/2018	254	193			193		254				
188	12/10/2018	1/29/2019	50	3/8/2019	88	4/24/2019	135	6/5/2019	177	127	89	42	42		177				
189	6/27/2017	9/6/2017	71	10/4/2017	99	11/1/2017	127	11/6/2017	132	61	33	5	5		132				
190	1/17/2018	3/14/2018	56	5/9/2018	112	6/13/2018	147	7/13/2018	177	121	65	30	30		177				
191	10/5/2018							4/18/2019	195	195				195					
192	5/23/2017	7/12/2017	50	8/19/2017	88	9/22/2017	122	10/3/2017	133	83	45	11	11		133				
193	6/8/2018	8/1/2018	54	9/5/2018	89	10/3/2018	117	11/10/2018	155	101	66	38	38		155				
194	6/3/2018	8/8/2018	66	10/15/2018	134	11/14/2018	164	12/5/2018	185	119	51	21	21		185				
195	9/8/2016	11/15/2016	68	12/14/2016	97	1/16/2017	130	1/31/2017	145	77	48	15	15		145				
196	9/21/2016	11/9/2016	49	12/14/2016	84	1/11/2017	112	1/25/2017	126	77	42	14	14		126				
197	5/8/2016	6/22/2016	45	7/27/2016	80	8/24/2016	108	11/13/2016	189	144	109	81	81		189				
198	1/31/2018	3/21/2018	49	4/25/2018	84	5/24/2018	113	8/29/2018	210	161	126	97	97		210				
199	10/10/2017	1/24/2018	106	2/28/2018	141			3/21/2018	162	56	21		21		162				
200	1/10/2017	3/10/2017	59	4/12/2017	92	5/12/2017	122	6/8/2017	149	90	57	27	27		149				
201	12/12/2018	1/30/2019	49	3/6/2019	84	4/10/2019	119	4/13/2019	122	73	38	3	3		122				
202	8/30/2015							7/15/2016	320	320				320					
203	3/8/2018	4/21/2018	44	5/19/2018	72	6/20/2018	104	7/30/2018	144	100	72	40	40		144				
204	12/8/2018	2/20/2019	74					6/12/2019	186	112			112		186				
205	9/24/2018	3/8/2019	165					4/20/2019	208	43			43		208				
206	10/15/2017	12/6/2017	52	1/3/2018	80	2/7/2018	115	3/14/2018	150	98	70	35	35		150				
207	3/26/2016							9/17/2016	175	175				175					
208	9/9/2017							8/18/2018	343	343				343					
209	8/3/2017							6/7/2018	308	308				308					
210	5/8/2016	7/6/2016	59	8/3/2016	87	9/7/2016	122	11/7/2016	183	124	96	61	61		183				
211	12/30/2017	2/14/2018	46	3/14/2018	74	4/11/2018	102	9/6/2018	250	204	176	148	148		250				
212	10/31/2017	12/10/2017	40	1/15/2018	76	2/13/2018	105	5/15/2018	196	156	120	91	91		196				
213	1/23/2019							4/20/2019	87	87				87					

214	4/25/2016	6/15/2016	51	7/20/2016	86	8/18/2016	115	11/22/2016	211	160	125	96	96		211				
215	11/27/2018							4/23/2019	147	147				147					
216	9/5/2018	10/24/2018	49	11/29/2018	85	12/26/2018	112	2/11/2019	159	110	74	47	47		159				
217	5/30/2017	7/19/2017	50	8/15/2017	77	9/20/2017	113	4/1/2018	306	256	229	193	193		306				
218	4/26/2018							10/16/2018	173	173				173					
219	6/5/2017							3/27/2018	295	295				295					
220	8/27/2017	10/25/2017	59	12/9/2017	104	2/28/2018	185	3/28/2018	213	154	109	28	28		213				
221	11/1/2018							3/24/2019	143	143				143					
222	4/17/2017	6/14/2017	58	7/12/2017	86	9/13/2017	149	11/28/2017	225	167	139	76	76		225				
223	8/10/2018	10/12/2018	63	11/11/2018	93	1/4/2019	147	1/8/2019	151	88	58	4	4		151				
224	8/22/2015							8/1/2016	345	345				345					
225	2/20/2018	4/10/2018	49					7/8/2018	138	89			89		138				
226	8/12/2015							4/20/2016	252	252				252					
227	11/8/2017	1/17/2018	70	2/21/2018	105	4/17/2018	160	8/1/2018	266	196	161	106	106		266				
228	8/31/2017	10/25/2017	55	11/29/2017	90			12/16/2017	107	52	17		17		107				
229	9/18/2017							6/6/2018	261	261				261					
230	4/25/2017	6/16/2017	52	7/16/2017	82	8/31/2017	128	9/1/2017	129	77	47	1	1		129				
231	6/26/2017	8/2/2017	37	9/5/2017	71	10/16/2017	112	6/8/2018	347	310	276	235	235		347				
232	10/18/2016	12/21/2016	64	1/13/2017	87	2/15/2017	120	6/26/2017	251	187	164	131	131		251				
233	9/16/2017							4/30/2018	226	226				226					
234	9/20/2016	11/9/2016	50	12/14/2016	85	1/11/2017	113	3/20/2017	181	131	96	68	68		181				
235	10/10/2016	11/23/2016	44	12/28/2016	79	1/25/2017	107	3/5/2017	146	102	67	39	39		146				
236	10/6/2017							7/2/2018	269	269				269					
237	3/23/2017							9/23/2017	184	184				184					
238	1/15/2018	2/21/2018	37	3/21/2018	65			3/26/2018	70	33	5		5		70				
239	12/3/2017							4/13/2018	131	131				131					
240	11/14/2016	2/15/2017	93	2/18/2017	96	3/18/2017	124	6/6/2017	204	111	108	80	80		204				
241	12/30/2017	2/21/2018	53	4/4/2018	95	5/9/2018	130	7/22/2018	204	151	109	74	74		204				
242	11/19/2016	1/4/2017	46	3/1/2017	102	4/5/2017	137	7/22/2017	245	199	143	108	108		245				
243	8/2/2017	10/28/2017	87	12/5/2017	125			3/17/2018	227	140	102		102		227				
244	7/31/2018	10/12/2018	73	11/9/2018	101	12/14/2018	136	3/8/2019	220	147	119	84	84		220				
245	3/9/2017	5/3/2017	55	6/28/2017	111			7/8/2017	121	66	10		10		121				
246	5/1/2018	7/6/2018	66	8/7/2018	98	10/4/2018	156	1/16/2019	260	194	162	104	104		260				
247	6/6/2017	7/24/2017	48	8/23/2017	78	9/20/2017	106	4/25/2018	323	275	245	217	217		323				
248	11/15/2017	1/9/2018	55	2/12/2018	89	3/14/2018	119	6/23/2018	220	165	131	101	101		220				
249	9/21/2017							4/19/2018	210	210				210					
250	10/5/2018	12/8/2018	64	1/12/2019	99	3/6/2019	152	3/27/2019	173	109	74	21	21		173				
251	7/19/2017	10/4/2017	77	12/8/2017	142			1/3/2018	168	91	26		26		168				
252	7/26/2017							2/13/2018	202	202				202					
253	8/31/2017	11/22/2017	83	1/10/2018	132	5/9/2018	251	6/28/2018	301	218	169	50	50		301				
254	8/2/2016	10/5/2016	64	1/4/2017	155	2/1/2017	183	2/10/2017	192	128	37	9	9		192				
255	10/23/2018	12/14/2018	52	1/18/2019	87			5/3/2019	192	140	105		105		192				
256	12/24/2018	2/28/2019	66					5/5/2019	132	66			66		132				
257	6/26/2017	8/16/2017	51	9/20/2017	86			3/29/2018	276	225	190		190		276				
258	3/8/2016	4/20/2016	43	5/18/2016	71	6/15/2016	99	7/30/2016	144	101	73	45	45		144				
259	9/18/2016	11/16/2016	59	12/21/2016	94	1/18/2017	122	4/11/2017	205	146	111	83	83		205				
260	5/17/2017	7/8/2017	52	8/12/2017	87	9/9/2017	115	1/5/2018	233	181	146	118	118		233				
261	9/16/2016							7/26/2017	313	313				313					
262	2/27/2018	4/11/2018	43	5/9/2018	71	6/6/2018	99	6/20/2018	113	70	42	14	14		113				
263	10/13/2016	12/3/2016	51	1/18/2017	97	2/22/2017	132	7/3/2017	263	212	166	131	131		263				
264	5/5/2018							10/22/2018	170	170				170					
265	9/23/2018	11/9/2018	47	12/12/2018	80	1/30/2019	129	5/4/2019	223	176	143	94	94		223				
266	4/2/2017	5/29/2017	57	7/25/2017	114	9/29/2017	180	12/27/2017	269	212	155	89	89		269				
267	8/28/2018	11/1/2018	65	12/6/2018	100	1/3/2019	128	7/19/2019	325	260	225	197	197		325				

268	1/12/2018	2/28/2018	47	3/28/2018	75	4/25/2018	103	10/3/2018	264	217	189	161	161		264				
269	10/27/2016	1/4/2017	69	2/1/2017	97	3/1/2017	125	3/1/2017	125	56	28	0	0		125				
270	11/2/2017	12/19/2017	47	1/20/2018	79			2/15/2018	105	58	26		26		105				
271	8/28/2016	10/19/2016	52	11/16/2016	80	12/21/2016	115	1/25/2017	150	98	70	35	35		150				
272	2/6/2017	3/22/2017	44	4/26/2017	79			6/3/2017	117	73	38		38		117				
273	12/25/2016	2/12/2017	49	3/12/2017	77	4/11/2017	107	11/30/2017	340	291	263	233	233		340				
274	1/12/2017	3/22/2017	69	5/3/2017	111	6/21/2017	160	10/18/2017	279	210	168	119	119		279				
275	12/23/2015							7/18/2016	208	208				208					
276	2/25/2016	4/13/2016	48	5/14/2016	79	6/11/2016	107	9/1/2016	189	141	110	82	82		189				
277	9/10/2017							5/16/2018	248	248				248					
278	9/26/2016	11/16/2016	51	12/21/2016	86	1/18/2017	114	2/12/2017	139	88	53	25	25		139				
279	1/4/2016	4/27/2016	114	5/28/2016	145			6/20/2016	168	54	23		23		168				
280	3/4/2018	4/18/2018	45	5/16/2018	73	6/20/2018	108	8/20/2018	169	124	96	61	61		169				
281	3/21/2017							9/3/2017	166	166				166					
282	5/23/2016	7/13/2016	51					8/8/2016	77	26			26		77				
283	11/28/2016	2/1/2017	65	4/5/2017	128	5/10/2017	163	9/2/2017	278	213	150	115	115		278				
284	5/22/2018							9/2/2018	103	103				103					
285	4/29/2018							8/5/2018	98	98				98					
286	9/2/2017	11/8/2017	67	12/14/2017	103	1/10/2018	130	1/14/2018	134	67	31	4	4		134				
287	9/22/2016							6/24/2017	275	275				275					
288	5/10/2017	7/11/2017	62	8/17/2017	99	9/18/2017	131	12/1/2017	205	143	106	74	74		205				
289	6/2/2017	7/19/2017	47	9/6/2017	96	11/8/2017	159	1/11/2018	223	176	127	64	64		223				
290	11/29/2018	1/16/2019	48	2/20/2019	83	3/27/2019	118	4/26/2019	148	100	65	30	30		148				
291	6/1/2018							9/30/2018	121	121				121					
292	5/6/2018	7/3/2018	58	10/9/2018	156			1/6/2019	245	187	89		89		245				
293	3/15/2016	6/22/2016	99	8/24/2016	162	10/24/2016	223	1/17/2017	308	209	146	85	85		308				
294	7/26/2018	9/20/2018	56	10/25/2018	91	12/13/2018	140	4/8/2019	256	200	165	116	116		256				
295	6/18/2018	8/10/2018	53	9/12/2018	86	10/17/2018	121	11/9/2018	144	91	58	23	23		144				
296	6/12/2017	8/28/2017	77	10/1/2017	111	11/1/2017	142	3/15/2018	276	199	165	134	134		276				
297	1/31/2017	3/15/2017	43	5/17/2017	106	6/21/2017	141	8/21/2017	202	159	96	61	61		202				
298	3/22/2018							6/20/2018	90	90				90					
299	4/26/2018	6/13/2018	48	7/18/2018	83	8/29/2018	125	3/2/2019	310	262	227	185	185		310				
300	8/23/2017	10/7/2017	45	11/4/2017	73	12/2/2017	101	7/4/2018	315	270	242	214	214		315				
301	9/22/2016							3/1/2017	160	160				160					
302	8/12/2018	9/14/2018	33	10/7/2018	56	12/26/2018	136	3/25/2019	225	192	169	89	89		225				
303	10/6/2018	11/22/2018	47	12/27/2018	82	2/7/2019	124	7/19/2019	286	239	204	162	162		286				
304	7/28/2017							4/10/2018	256	256				256					
305	9/6/2017	11/8/2017	63	12/8/2017	93	1/10/2018	126	6/10/2018	277	214	184	151	151		277				
306	10/27/2018	12/27/2018	61	1/24/2019	89	3/28/2019	152	4/29/2019	184	123	95	32	32		184				
307	10/12/2018							3/19/2019	158	158				158					
308	7/12/2016	9/16/2016	66	11/16/2016	127	12/16/2016	157	12/20/2016	161	95	34	4	4		161				
309	9/2/2018	11/21/2018	80	12/19/2018	108	1/16/2019	136	3/23/2019	202	122	94	66	66		202				
310	11/28/2017	2/1/2018	65	3/4/2018	96			3/30/2018	122	57	26		26		122				
311	8/16/2018							2/25/2019	193	193				193					
312	1/23/2018	3/8/2018	44	6/7/2018	135	8/26/2018	215	9/16/2018	236	192	101	21	21		236				
313	1/4/2018	3/17/2018	72	4/14/2018	100	7/14/2018	191	10/13/2018	282	210	182	91	91		282				
314	7/13/2017	9/20/2017	69	10/18/2017	97	2/21/2018	223	4/20/2018	281	212	184	58	58		281				
315	8/24/2016	10/15/2016	52	11/19/2016	87	1/7/2017	136	5/22/2017	271	219	184	135	135		271				
316	10/28/2015							6/29/2016	245	245				245					
317	8/12/2016	12/13/2016	123	2/14/2017	186	3/11/2017	211	7/24/2017	346	223	160	135	135		346				
318	8/24/2017	12/1/2017	99	1/5/2018	134			2/5/2018	165	66	31		31		165				
319	9/9/2017	10/25/2017	46	11/22/2017	74	12/20/2017	102	3/30/2018	202	156	128	100	100		202				
320	3/18/2016							1/14/2017	302	302				302					
321	8/13/2018	10/8/2018	56	11/22/2018	101			1/5/2019	145	89	44		44		145				

322	3/15/2016							8/25/2016	163	163				163					
323	11/25/2016	1/11/2017	47	2/8/2017	75	3/8/2017	103	11/18/2017	358	311	283	255	255		358				
324	7/28/2017							1/2/2018	158	158				158					
?25	10/10/2016	12/1/2016	52	1/17/2017	99	2/23/2017	136	6/9/2017	242	190	143	106	106		242				
326	11/9/2018	1/2/2019	54	2/6/2019	89	3/13/2019	124	4/23/2019	165	111	76	41	41		165				
327	12/8/2017	1/31/2018	54	2/28/2018	82	3/28/2018	110	4/7/2018	120	66	38	10	10		120				
328	4/3/2018	5/23/2018	50	6/27/2018	85	8/1/2018	120	10/23/2018	203	153	118	83	83		203				
329	12/5/2018	1/18/2019	44	2/20/2019	77	4/10/2019	126	4/26/2019	142	98	65	16	16		142				
330	12/29/2018							6/18/2019	171	171				171					
331	9/8/2017	10/25/2017	47	12/14/2017	97	1/15/2018	129	5/6/2018	240	193	143	111	111		240				
332	5/29/2017	7/13/2017	45					2/13/2018	260	215			215		260				
333	5/27/2018	7/11/2018	45	8/18/2018	83	9/19/2018	115	12/10/2018	197	152	114	82	82		197				
334	12/14/2016							11/25/2017	346	346				346					
335	2/1/2017	3/23/2017	50	4/21/2017	79	6/12/2017	131	10/2/2017	243	193	164	112	112		243				
336	11/28/2017	1/27/2018	60	2/14/2018	78	3/14/2018	106	8/23/2018	268	208	190	162	162		268				
337	12/4/2017							5/20/2018	167	167				167					
338	1/22/2018	3/10/2018	47	4/12/2018	80	5/17/2018	115	8/20/2018	210	163	130	95	95		210				
339	8/20/2018	10/10/2018	51	11/14/2018	86	12/12/2018	114	1/25/2019	158	107	72	44	44		158				
340	7/21/2016							6/4/2017	318	318				318					
341	12/13/2017	4/18/2018	126					8/30/2018	260	134			134		260				
342	5/17/2017	7/5/2017	49	8/2/2017	77	8/30/2017	105	3/11/2018	298	249	221	193	193		298				
343	9/2/2017	10/25/2017	53					4/5/2018	215	162			162		215				
344	7/22/2017							4/4/2018	256	256				256					
345	7/10/2016	9/13/2016	65	10/11/2016	93			10/22/2016	104	39	11		11		104				
346	3/30/2017							10/21/2017	205	205				205					
347	5/4/2016	6/26/2016	53	8/8/2016	96	9/7/2016	126	2/28/2017	300	247	204	174	174		300				
348	11/7/2017							5/9/2018	183	183				183					
349	9/17/2018							6/18/2019	274	274				274					
350	1/11/2018	2/28/2018	48	3/28/2018	76	4/25/2018	104	6/26/2018	166	118	90	62	62		166				
351	8/21/2017	10/7/2017	47	11/18/2017	89			11/26/2017	97	50	8		8		97				
352	5/16/2016							1/14/2017	243	243				243					
353	10/12/2018	2/2/2019	113					5/20/2019	220	107			107		220				
354	4/26/2017	6/14/2017	49	7/17/2017	82	8/28/2017	124	3/13/2018	321	272	239	197	197		321				
355	5/6/2016	6/29/2016	54	8/3/2016	89	9/7/2016	124	12/5/2016	213	159	124	89	89		213				
356	12/19/2017	1/31/2018	43	2/28/2018	71	3/28/2018	99	5/23/2018	155	112	84	56	56		155				
357	12/11/2017	1/28/2018	48	2/28/2018	79	3/28/2018	107	8/8/2018	240	192	161	133	133		240				
358	6/27/2018	8/20/2018	54	9/19/2018	84	10/24/2018	119	12/9/2018	165	111	81	46	46		165				
359	11/13/2018	12/27/2018	44	2/6/2019	85	3/6/2019	113	5/17/2019	185	141	100	72	72		185				
360	12/12/2017	1/29/2018	48	3/7/2018	85	4/11/2018	120	7/13/2018	213	165	128	93	93		213				
361	4/16/2017	5/31/2017	45	6/28/2017	73	7/26/2017	101	4/16/2018	365	320	292	264	264		365				
362	6/1/2017							3/20/2018	292	292				292					
363	12/26/2016							6/27/2017	183	183				183					
364	10/10/2016							5/30/2017	232	232				232					
365	3/12/2017							9/26/2017	198	198				198					
366	11/1/2016							6/27/2017	238	238				238					
367	6/12/2018							1/22/2019	224	224				224					
368	6/16/2017							3/21/2018	278	278				278					
369	8/11/2017	9/27/2017	47	10/25/2017	75	12/6/2017	117	6/16/2018	309	262	234	192	192		309				
370	8/9/2018							5/26/2019	290	290				290					
371	4/6/2016	5/18/2016	42	6/22/2016	77			3/30/2017	358	316	281		281		358				
372	7/2/2018	9/12/2018	72	11/10/2018	131	1/23/2019	205	2/17/2019	230	158	99	25	25		230				
373	7/4/2018	9/19/2018	77	10/17/2018	105	11/22/2018	141	1/2/2019	182	105	77	41	41		182				
374	5/4/2017							1/7/2018	248	248				248					
375	4/19/2016	6/18/2016	60	7/23/2016	95	8/20/2016	123	1/8/2017	264	204	169	141	141		264				

376	11/3/2017	12/19/2017	46	1/30/2018	88	3/3/2018	120	6/5/2018	214	168	126	94	94		214				
377	10/19/2018	12/12/2018	54	3/13/2019	145	4/10/2019	173	5/19/2019	212	158	67	39	39		212				
378	2/15/2018	4/4/2018	48	5/2/2018	76	6/6/2018	111	8/23/2018	189	141	113	78	78		189				
379	5/26/2017							5/3/2018	342	342				342					
380	4/19/2017							10/5/2017	169	169				169					
381	10/25/2016							9/18/2017	328	328				328					
382	11/4/2018	12/19/2018	45	1/23/2019	80	2/27/2019	115	6/5/2019	213	168	133	98	98		213				
383	8/19/2017							6/19/2018	304	304				304					
384	6/28/2016							4/5/2017	281	281				281					
385	7/27/2017							1/16/2018	173	173				173					
386	1/11/2019	4/3/2019	82					4/11/2019	90	8			8		90				
387	5/13/2018	6/27/2018	45	8/1/2018	80	9/5/2018	115	11/9/2018	180	135	100	65	65		180				
388	4/15/2018	6/5/2018	51					12/8/2018	237	186			186		237				
389	10/7/2017							10/3/2018	361	361				361					
390	2/4/2018	4/19/2018	74	5/24/2018	109	6/28/2018	144	7/26/2018	172	98	63	28	28		172				
391	3/20/2017	5/13/2017	54	7/12/2017	114			10/8/2017	202	148	88		88		202				
392	2/27/2018							2/1/2019	339	339				339					
393	9/7/2018							2/16/2019	162	162				162					
394	11/19/2017							11/4/2018	350	350				350					
395	10/15/2018	12/5/2018	51	1/2/2019	79	2/18/2019	126	6/14/2019	242	191	163	116	116		242				
396	11/16/2017							5/29/2018	194	194				194					
397	4/16/2018	6/6/2018	51	7/4/2018	79	8/8/2018	114	4/13/2019	362	311	283	248	248		362				
398	6/24/2017	8/14/2017	51	9/26/2017	94	10/30/2017	128	3/19/2018	268	217	174	140	140		268				
399	6/21/2016							11/29/2016	161	161				161					
400	8/6/2018	9/21/2018	46	10/20/2018	75	11/24/2018	110	6/13/2019	311	265	236	201	201		311				
401	3/29/2018	5/17/2018	49	7/2/2018	95			7/30/2018	123	74	28		28		123				
402	8/4/2018							3/31/2019	239	239				239					
403	8/13/2018	9/28/2018	46					4/18/2019	248	202			202		248				
404	6/2/2017							4/14/2018	316	316				316					
405	8/10/2017							5/13/2018	276	276				276					
406	12/6/2017							7/30/2018	236	236				236					
407	11/8/2017							5/27/2018	200	200				200					
408	5/31/2018	7/18/2018	48	8/24/2018	85	9/26/2018	118	4/17/2019	321	273	236	203	203		321				
409	11/29/2016							9/6/2017	281	281				281					
410	5/10/2017	7/3/2017	54	8/5/2017	87	9/5/2017	118	1/3/2018	238	184	151	120	120		238				
411	6/23/2018	8/5/2018	43	9/15/2018	84	10/14/2018	113	2/28/2019	250	207	166	137	137		250				
412	8/16/2017	10/11/2017	56	11/16/2017	92	12/20/2017	126	3/12/2018	208	152	116	82	82		208				
413	1/11/2017							12/2/2017	325	325				325					
414	1/26/2016							9/28/2016	246	246				246					
415	3/24/2018	5/17/2018	54	6/20/2018	88	7/26/2018	124	12/23/2018	274	220	186	150	150		274				
416	10/13/2016							2/24/2017	134	134				134					
417	8/17/2018	10/3/2018	47	11/7/2018	82	12/15/2018	120	12/18/2018	123	76	41	3	3		123				
418	11/17/2017							6/6/2018	201	201				201					
419	3/9/2018	5/7/2018	59	6/4/2018	87	7/2/2018	115	11/13/2018	249	190	162	134	134		249				
420	9/28/2017	11/17/2017	50	12/21/2017	84	2/6/2018	131	5/20/2018	234	184	150	103	103		234				
421	9/29/2017	12/13/2017	75					4/24/2018	207	132			132		207				
422	9/6/2018	10/27/2018	51	11/24/2018	79	12/24/2018	109	2/20/2019	167	116	88	58	58		167				
42*	10/6/2016	11/23/2016	48	12/28/2016	83	1/25/2017	111	6/9/2017	246	198	163	135	135		246				
424	2/28/2017	4/12/2017	43	5/24/2017	85			7/3/2017	125	82	40		40		125				
425	1/2/2016	2/17/2016	46	3/28/2016	86	5/6/2016	125	11/6/2016	309	263	223	184	184		309				
426	7/3/2017							4/19/2018	290	290				290					
427	8/31/2016	11/16/2016	77	12/21/2016	112	1/18/2017	140	7/30/2017	333	256	221	193	193		333				
428	12/23/2016							8/23/2017	243	243				243					
429	3/11/2017	5/6/2017	56	6/3/2017	84	7/1/2017	112	2/10/2018	336	280	252	224	224		336				

430	8/10/2018	9/26/2018	47	10/31/2018	82	11/28/2018	110	12/20/2018	132	85	50	22	22		132				
431	7/26/2017	12/21/2017	148	1/25/2018	183	2/21/2018	210	7/1/2018	340	192	157	130	130		340				
432	6/22/2016							1/20/2017	212	212				212					
433	3/1/2017							8/2/2017	154	154				154					
434	11/26/2017	1/17/2018	52	2/28/2018	94	3/21/2018	115	6/19/2018	205	153	111	90	90		205				
435	10/13/2017	12/8/2017	56	1/12/2018	91	2/21/2018	131	2/27/2018	137	81	46	6	6		137				
436	12/30/2017	3/8/2018	68	4/4/2018	95	5/5/2018	126	8/27/2018	240	172	145	114	114		240				
437	4/22/2017							12/29/2017	251	251				251					
438	7/18/2016	9/28/2016	72	10/26/2016	100	11/23/2016	128	3/31/2017	256	184	156	128	128		256				
439	3/4/2016	4/17/2016	44	6/23/2016	111	8/4/2016	153	1/1/2017	303	259	192	150	150		303				
440	11/11/2017							2/20/2018	101	101				101					
441	4/18/2016							3/21/2017	337	337				337					
442	7/11/2017							3/31/2018	263	263				263					
443	11/25/2017	1/17/2018	53	2/28/2018	95	3/28/2018	123	9/11/2018	290	237	195	167	167		290				
444	12/27/2017	2/18/2018	53	3/19/2018	82	4/19/2018	113	7/7/2018	192	139	110	79	79		192				
445	8/2/2017							3/25/2018	235	235				235					
446	11/23/2016	12/28/2016	35	1/28/2017	66	3/1/2017	98	7/8/2017	227	192	161	129	129		227				
447	8/25/2018	10/10/2018	46	11/21/2018	88	12/26/2018	123	4/15/2019	233	187	145	110	110		233				
448	7/23/2017							10/29/2017	98	98				98					
449	7/3/2017							2/18/2018	230	230				230					
450	5/18/2018							2/28/2019	286	286				286					
451	9/27/2018	11/16/2018	50	12/19/2018	83	2/6/2019	132	5/30/2019	245	195	162	113	113		245				
452	7/9/2016	9/21/2016	74	11/9/2016	123	12/21/2016	165	5/15/2017	310	236	187	145	145		310				
453	1/14/2018							6/5/2018	142	142				142					
454	11/21/2017	1/17/2018	57	2/21/2018	92	3/21/2018	120	4/26/2018	156	99	64	36	36		156				
455	7/25/2018	9/20/2018	57	10/25/2018	92	12/5/2018	133	5/22/2019	301	244	209	168	168		301				
456	8/25/2017							5/5/2018	253	253				253					
457	6/28/2017							3/12/2018	257	257				257					
458	3/18/2018	5/2/2018	45	6/13/2018	87	7/11/2018	115	10/9/2018	205	160	118	90	90		205				
459	7/31/2016							1/27/2017	180	180				180					
460	5/16/2016	9/7/2016	114					12/8/2016	206	92			92		206				
461	11/9/2017	2/21/2018	104	3/21/2018	132			4/4/2018	146	42	14		14		146				
462	1/15/2018	3/6/2018	50	4/4/2018	79	5/2/2018	107	6/30/2018	166	116	87	59	59		166				
463	8/8/2017	10/4/2017	57	11/8/2017	92			2/28/2018	204	147	112		112		204				
464	7/5/2018							5/31/2019	330	330				330					
465	2/15/2019	4/2/2019	46					4/15/2019	59	13			13		59				
466	7/29/2017							1/20/2018	175	175				175					
467	4/1/2018	5/16/2018	45	7/11/2018	101			8/1/2018	122	77	21		21		122				
468	4/7/2018							1/17/2019	285	285				285					
469	9/5/2016	11/15/2016	71	12/14/2016	100	1/16/2017	133	5/5/2017	242	171	142	109	109		242				
470	10/15/2016	11/22/2016	38	12/21/2016	67	1/26/2017	103	3/7/2017	143	105	76	40	40		143				
471	8/31/2017							5/20/2018	262	262				262					
472	12/8/2017	2/14/2018	68	3/21/2018	103	5/2/2018	145	7/12/2018	216	148	113	71	71		216				
473	9/10/2016							7/12/2017	305	305				305					
474	9/25/2017							4/6/2018	193	193				193					
475	10/23/2017	12/13/2017	51	2/14/2018	114	4/18/2018	177	7/2/2018	252	201	138	75	75		252				
476	8/10/2017							5/10/2018	273	273				273					
477	6/15/2018	8/16/2018	62	9/19/2018	96	10/25/2018	132	6/4/2019	354	292	258	222	222		354				
478	6/17/2016							10/19/2016	124	124				124					
479	11/6/2017	1/10/2018	65	2/21/2018	107	3/21/2018	135	6/19/2018	225	160	118	90	90		225				
480	9/5/2018							2/20/2019	168	168				168					
481	11/11/2018	1/2/2019	52	2/6/2019	87	3/13/2019	122	4/3/2019	143	91	56	21	21		143				
482	9/17/2016							1/17/2017	122	122				122					
483	1/12/2018							8/1/2018	201	201				201					

484	4/24/2017	7/12/2017	79	8/9/2017	107	9/13/2017	142	10/17/2017	176	97	69	34	34		176				
485	3/27/2018							9/21/2018	178	178				178					
486	5/3/2018	6/20/2018	48	7/23/2018	81	8/23/2018	112	9/19/2018	139	91	58	27	27		139				
487	2/2/2017							8/28/2017	207	207				207					
488	4/27/2018							4/22/2019	360	360				360					
489	4/3/2017							1/19/2018	291	291				291					
490	6/19/2017							9/7/2017	80	80				80					
491	8/14/2017							5/2/2018	261	261				261					
492	2/3/2017							12/14/2017	314	314				314					
493	10/8/2017							6/4/2018	239	239				239					
494	8/12/2017							6/17/2018	309	309				309					
495	12/10/2017	1/24/2018	45	2/28/2018	80	4/4/2018	115	5/31/2018	172	127	92	57	57		172				
496	2/7/2017							9/23/2017	228	228				228					
497	3/26/2018	6/6/2018	72	7/4/2018	100	8/1/2018	128	1/22/2019	302	230	202	174	174		302				
498	4/19/2018	6/28/2018	70	7/26/2018	98	8/23/2018	126	11/21/2018	216	146	118	90	90		216				
499	5/7/2018							4/3/2019	331	331				331					
500	3/8/2018	5/10/2018	63	6/14/2018	98	7/12/2018	126	12/2/2018	269	206	171	143	143		269				
501	8/9/2018							3/24/2019	227	227				227					
502	3/19/2018	5/7/2018	49	6/8/2018	81	7/8/2018	111	7/24/2018	127	78	46	16	16		127				
503	7/1/2016							2/26/2017	240	240				240					
504	8/5/2016							11/22/2016	109	109				109					
505	7/3/2017							10/31/2017	120	120				120					
506	2/27/2018	5/10/2018	72	6/14/2018	107	7/12/2018	135	11/22/2018	268	196	161	133	133		268				
507	10/7/2017							5/10/2018	215	215				215					
508	5/8/2018	7/4/2018	57	8/1/2018	85	10/3/2018	148	1/6/2019	243	186	158	95	95		243				
509	3/13/2017	5/5/2017	53	6/9/2017	88	7/10/2017	119	2/24/2018	348	295	260	229	229		348				
510	10/13/2016							4/22/2017	191	191				191					
511	4/3/2017							2/10/2018	313	313				313					
512	10/26/2017	2/14/2018	111					7/15/2018	262	151			151		262				
513	11/27/2018	1/23/2019	57	3/6/2019	99	4/3/2019	127	6/14/2019	199	142	100	72	72		199				
514	1/29/2018	3/14/2018	44	4/11/2018	72	5/16/2018	107	6/26/2018	148	104	76	41	41		148				
515	11/26/2017	2/1/2018	67	3/8/2018	102	5/10/2018	165	5/12/2018	167	100	65	2	2		167				
516	8/5/2016							4/14/2017	252	252				252					
517	1/29/2018	3/21/2018	51	4/25/2018	86			9/7/2018	221	170	135		135		221				
518	2/2/2018	4/4/2018	61	5/23/2018	110			8/13/2018	192	131	82		82		192				
519	6/6/2018	7/28/2018	52	8/25/2018	80	9/28/2018	114	3/28/2019	295	243	215	181	181		295				
520	11/16/2017	1/10/2018	55	2/14/2018	90			4/23/2018	158	103	68		68		158				
521	7/26/2017	9/13/2017	49	10/12/2017	78	11/13/2017	110	12/10/2017	137	88	59	27	27		137				
522	6/20/2018	8/3/2018	44					11/13/2018	146	102			102		146				
523	5/15/2018							4/22/2019	342	342				342					
524	11/6/2018							5/12/2019	187	187				187					
525	2/16/2017	4/20/2017	63	5/18/2017	91	7/20/2017	154	11/22/2017	279	216	188	125	125		279				
526	2/17/2017							10/29/2017	254	254				254					
527	8/30/2018	11/5/2018	67	12/5/2018	97	1/16/2019	139	2/9/2019	163	96	66	24	24		163				
528	10/6/2017							4/11/2018	187	187				187					
529	3/17/2017	5/8/2017	52	6/9/2017	84	7/10/2017	115	1/5/2018	294	242	210	179	179		294				
530	12/4/2015							10/16/2016	317	317				317					
531	7/11/2017	9/7/2017	58	10/5/2017	86	11/2/2017	114	12/16/2017	158	100	72	44	44		158				
532	3/17/2018	5/5/2018	49	6/6/2018	81	7/18/2018	123	9/22/2018	189	140	108	66	66		189				
533	8/12/2018							3/2/2019	202	202				202					
534	8/1/2017	9/21/2017	51	10/26/2017	86	12/7/2017	128	1/14/2018	166	115	80	38	38		166				
535	2/7/2017	4/13/2017	65	5/14/2017	96	7/24/2017	167	12/9/2017	305	240	209	138	138		305				
536	7/10/2017	8/23/2017	44	9/27/2017	79	10/25/2017	107	12/21/2017	164	120	85	57	57		164				
537	11/16/2016							10/24/2017	342	342				342					

538	5/30/2018							11/8/2018	162	162				162					
539	12/28/2017							3/24/2018	86	86				86					
540	5/20/2017	8/21/2017	93					10/27/2017	160	67			67		160				
541	10/26/2017	12/13/2017	48					12/18/2017	53	5			5		53				
542	8/24/2017							2/20/2018	180	180				180					
543	3/10/2019							4/27/2019	48	48				48					
544	2/15/2016	4/12/2016	57	5/18/2016	93	6/14/2016	120	1/11/2017	331	274	238	211	211		331				
545	4/29/2017							2/7/2018	284	284				284					
546	7/17/2017							1/27/2018	194	194				194					
547	2/9/2018	4/4/2018	54	5/2/2018	82	6/6/2018	117	6/20/2018	131	77	49	14	14		131				
548	1/20/2018	3/14/2018	53	5/19/2018	119	6/16/2018	147	8/16/2018	208	155	89	61	61		208				
549	1/16/2018							3/1/2018	44	44				44					
550	9/16/2018	12/10/2018	85	1/5/2019	111			1/6/2019	112	27	1		1		112				
551	6/20/2017							3/14/2018	267	267				267					
552	1/12/2018							3/21/2018	68	68				68					
553	10/14/2017							3/31/2018	168	168				168					
554	12/3/2017	1/24/2018	52	2/28/2018	87			3/10/2018	97	45	10		10		97				
555	4/8/2017							12/19/2017	255	255				255					
556	7/17/2018							1/11/2019	178	178				178					
557	3/18/2017	10/23/2017	219					1/22/2018	310	91			91		310				
558	10/5/2018	12/12/2018	68	1/12/2019	99			1/29/2019	116	48	17		17		116				
559	10/8/2017	11/24/2017	47	12/28/2017	81	1/25/2018	109	3/14/2018	157	110	76	48	48		157				
560	9/4/2016	10/13/2016	39	12/10/2016	97			12/12/2016	99	60	2		2		99				
561	1/2/2017	2/23/2017	52					3/27/2017	84	32			32		84				
562	8/1/2017	9/19/2017	49	10/18/2017	78			12/5/2017	126	77	48		48		126				
563	4/3/2018	5/28/2018	55	6/28/2018	86	8/2/2018	121	9/17/2018	167	112	81	46	46		167				
564	5/15/2018	7/7/2018	53	8/18/2018	95			10/16/2018	154	101	59		59		154				
565	10/7/2018	12/6/2018	60	1/9/2019	94	2/14/2019	130	5/10/2019	215	155	121	85	85		215				
566	7/6/2018	8/22/2018	47	9/24/2018	80	10/24/2018	110	3/20/2019	257	210	177	147	147		257				
567	5/16/2018	7/11/2018	56	8/8/2018	84			10/19/2018	156	100	72		72		156				
568	10/3/2017							5/3/2018	212	212				212					
569	4/5/2018	6/13/2018	69	7/11/2018	97	8/8/2018	125	9/13/2018	161	92	64	36	36		161				
570	2/10/2017	3/26/2017	44	4/29/2017	78	5/30/2017	109	9/26/2017	228	184	150	119	119		228				
571	2/16/2017							9/15/2017	211	211				211					
572	1/7/2019	3/20/2019	72	4/17/2019	100	5/15/2019	128	6/18/2019	162	90	62	34	34		162				
573	7/7/2016	9/3/2016	58	10/4/2016	89			10/13/2016	98	40	9		9		98				
574	4/27/2018							10/13/2018	169	169				169					
575	11/7/2015							6/9/2016	215	215				215					
576	2/8/2017	4/5/2017	56	5/6/2017	87	6/3/2017	115	1/4/2018	330	274	243	215	215		330				
577	11/24/2018	3/8/2019	104	4/12/2019	139	6/14/2019	202	7/3/2019	221	117	82	19	19		221				
578	2/20/2018	4/26/2018	65	5/24/2018	93	6/21/2018	121	7/18/2018	148	83	55	27	27		148				
579	10/8/2016	12/3/2016	56	2/3/2017	118	3/15/2017	158	5/20/2017	224	168	106	66	66		224				
580	6/23/2016	9/3/2016	72	10/1/2016	100	11/5/2016	135	11/6/2016	136	64	36	1	1		136				
581	12/11/2018							2/13/2019	64	64				64					
582	10/22/2016							1/19/2017	89	89				89					
583	5/26/2017							5/20/2018	359	359				359					
584	5/2/2017	6/19/2017	48	7/20/2017	79	8/25/2017	115	12/29/2017	241	193	162	126	126		241				
585	9/24/2017							5/4/2018	222	222				222					
586	9/11/2018	11/7/2018	57	12/9/2018	89	1/2/2019	113	2/14/2019	156	99	67	43	43		156				
587	7/4/2018	8/21/2018	48	9/26/2018	84			10/15/2018	103	55	19		19		103				
588	12/22/2018	2/6/2019	46	3/13/2019	81			6/5/2019	165	119	84		84		165				
589	6/6/2017	9/27/2017	113					2/10/2018	249	136			136		249				

													Count (N)	212	377		Difference	-17.89	
													Mean	223.25	205.36		SE	5.915	
													Standard Deviation	74.12	65.8		95%CI	-29.508 to -6.272	
													Mean Difference	17.89			Test Statistic t	-3.024	
													Significance level (p=)	0.0026			DF	587	
																	Significance level	p=0.0026	

Prashant Bhushan

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From: **NEJM Letter** <onbehalfof@manuscriptcentral.com>
Date: Thu, 20 May 2021, 11:36 pm
Subject: New England Journal of Medicine 20-33556
To: <jacob@puliyel.com>

Dear Dr. Puliyel:

Thank you for your email. We have been in contact with Dr. Kang regarding your letter, and the correspondence remains under consideration. You will be informed of the final editorial decision via email.

Sincerely,

Lauren Lindenfelser
Manager of Editorial Administration

New England Journal of Medicine
10 Shattuck Street
Boston, MA 02115
(617) 734-9800
Fax: (617) 739-9864
http://www.nejm.org

From: Jacob Puliyel <jacob@puliyel.com>
Sent: Tuesday, May 4, 2021 3:13 PM
To: Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine - 20-33556

Dear Sir
I am yet to receive a response from the Editor.
If no action is being taken by the NEJM in all these months,
I wonder if the matter should be investigated by some independent third party like Retraction Watch.

Please advise me when I should expect a response from the Editor
or otherwise what I should do to get this matter investigated.

Sincerely

Jacob Puliyel

Prashant Bhushan
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