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MAJOR ARTICLE

Safety of Live-Attenuated Measles, Mumps, and Rubella Vaccine Administered Within 2 Years of Hematopoietic Cell Transplant

Michaël Desjardins,[1,2,3] Xhoi Mitre,[1,2] Amy C. Sherman,[1,2] Stephen R. Walsh,[2] Matthew P. Cheng,[1,2,4] Sanjat Kanjilal,[2,5] Vincent T. Ho,[1] Lindsey R. Baden,[1,2,a] and Nicolas C. Issa[1,2,a]

[1]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts, USA, [2]Division of Infectious Diseases, Brigham and Women's Hospital, Boston, Massachusetts, USA, [3]Division of Infectious Diseases, Centre Hospitalier de l'Université de Montréal, Montreal, Québec, Canada, [4]Division of Infectious Disease, McGill University Health Centre, Montreal, Québec, Canada, and [5]Department of Population Medicine, Harvard Pilgrim Healthcare Institute & Harvard Medical School, Boston, Massachusetts, USA

Background. Measles, mumps, and rubella (MMR) vaccine is a live-attenuated vaccine usually contraindicated within the first 2 years of hematopoietic cell transplant (HCT). The objective of this study was to assess the safety of MMR vaccine when administered within 2 years of HCT.

Methods. We conducted a retrospective review of patients who received MMR vaccination within 2 years of an autologous or allogeneic HCT, mostly in the context of the 2019 measles outbreak. Adverse reactions were collected for 42 days postvaccination, and all hospitalizations and deaths following vaccination were reviewed.

Results. A total of 129 patients (75 autologous and 54 allogeneic HCT) were vaccinated 300–729 days after HCT (median, 718 days), and 39 (30%) of these were vaccinated earlier than 23 months post-transplant. Ten adverse reactions in 7 patients (5%) were identified within 42 days of vaccination: 6 respiratory tract infections (3 with fever) and 1 rash. The rash was seen in a 37-year-old female who had an allogeneic HCT 542 days before vaccination. She presented with a centrifugal maculopapular rash, confirmed to be caused by the vaccine strain rubella virus. She fully recovered. No other vaccine-associated illness was identified in the cohort after a median follow-up of 676 days.

Conclusions. MMR vaccine appears to be well tolerated in select HCT recipients when given between 300 and 729 days after transplant. An uncomplicated case of vaccine-associated rubella illness was seen after vaccination. Assessment of potential risks and benefits of MMR vaccination given within 2 years of HCT remains important.

Keywords. hematopoietic cell transplant; measles; mumps; rubella; vaccine.

In 2019, the largest measles outbreak since 1992 occurred in the United States, with more than 1280 confirmed cases between January and December [1]. Immunocompromised individuals, particularly those with T-cell defects such as hematopoietic cell transplant (HCT) recipients, are at higher risk of progressive and severe measles infection [2–4]. Importantly, antibodies against measles, but also against mumps and rubella, wane in the years following HCT, and a significant proportion of seropositive patients will eventually become seronegative after transplantation [5–10]. Measles, mumps, and rubella (MMR) immunization remains the best strategy to protect patients post-HCT against these viral infections. However, like other live-attenuated vaccines, MMR is contraindicated in immunocompromised individuals [11].

After HCT, immune reconstitution occurs in different phases, with initial recovery of innate immunity and slower reconstitution of T-cell and B-cell immunity, which may take up to 1–2 years [12]. In general, live-attenuated vaccines are considered safe when administered 2 years after HCT. More specifically, the American and European guidelines on vaccination of HCT recipients recommend MMR vaccination starting 24 months after transplantation in patients without graft-vs-host disease (GVHD) and ongoing immune suppression [13, 14]. These recommendations are based on theoretical concerns of vaccine-associated illness if the vaccine is administered earlier and on published data supporting the safety of MMR given >2 years post-HCT [6]. In the midst of a measles outbreak, given the lack of any specific measles active antiviral therapy, the benefits of receiving the MMR vaccine <2 years post-HCT may outweigh the risks for select patients. However, safety data are lacking to support this approach.

In the context of the 2019 outbreak, hematologists and transplant infectious diseases specialists at Brigham and Women's Hospital/Dana Farber Cancer Institute (BWH/DFCI), Boston,

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[a]Co-senior authors.

Correspondence: Michaël Desjardins, MD, Division of Infectious Diseases, Brigham and Women's Hospital, 75 Francis St, PBB-A4, Boston, MA 02115 (mdesjardins2@bwh.harvard.edu).

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Massachusetts, considered offering MMR vaccination <2 years post-transplant on a case-by-case basis. In particular, it was recommended to offer MMR vaccine to clinically stable HCT recipients starting at 12 months after transplantation in the absence of immunosuppressive therapy or intravenous immunoglobulin administration within the preceding 2 months. The final decision was left to the discretion of the treating physicians. Measles serologies pre- and postvaccination were encouraged to assess vaccine immune status prevaccination and immune response postvaccination. The primary objective of this study was to assess the safety of MMR vaccine when administered within 2 years of HCT.

METHODS

Study Population

A retrospective review was conducted in all patients who received an autologous or allogeneic HCT at BWH/DFCI between 1/2017 and 12/2018 and subsequently received the MMR vaccine (MMR II, Merck & Co, INC, Whitehouse Station, NJ, USA) <2 years after transplant. A separate cohort of patients with multiple myeloma who received autologous HCT between 3/2009 and 1/2014 and were also found to be vaccinated <2 years after transplant while on therapy with thalidomide analogue and/or proteasome inhibitor were also included. This additional cohort was included to increase the number of auto-HCT recipients, particularly those on maintenance therapy for multiple myeloma. In this cohort, there was no specific guidance for early MMR vaccination. The decision to vaccinate was made by the treating physicians.

To ensure optimal postvaccination safety data collection, only patients who had proof of MMR vaccination in their DFCI electronic medical record (EMR) and still had active follow-up locally were included. MMR vaccine was administered as a single dose by subcutaneous route at a dosage of 0.5 mL. Each dose contained not less than 1000 tissue culture infectious doses (TCID50) of measles virus, 12 500 TCID50 of mumps virus, and 1000 TCID50 of rubella virus [15].

Data Collection

Patients' demographics, date and type of HCT, underlying hematologic disease, date of MMR vaccination, type of immunosuppressive or maintenance therapy, and lymphocyte count on the day of vaccination were collected from the EMR. Data on other major immunosuppressive therapies such as anti-CD20 (eg, rituximab), anti-CD52 (alemtuzumab), antithymocyte globulin, and immunotherapy such as chimeric antigen receptor (CAR) T-cell therapy received from the time of HCT until 1 month post–MMR vaccination were also collected. Reactions that could be linked to the vaccine [11, 16] were extracted from the chart, including skin rash, fever, upper respiratory tract infections, pneumonia/pneumonitis, arthralgia/arthritis, parotitis, orchitis, aseptic meningitis, encephalitis, or other neurological disease, from the time of vaccination through 42 days. Because MMR vaccine has rarely been associated with late neurologic adverse reactions in immunocompromised patients, such as measles inclusion body encephalitis [17], all hospitalizations and deaths following vaccination were reviewed. In addition, to ensure that no cases of vaccine-associated disease were missed through the chart review process, all positive cases of immunoglobulin M (IgM) or polymerase chain reaction (PCR) for measles, mumps, and rubella confirmed by the microbiology laboratory since 5/2015 were reviewed. Absolute numbers and proportions were used to describe the different elements of the safety assessment. Statistical analyses are descriptive.

RESULTS

Baseline Characteristics

In HCT recipients with documented MMR vaccination after transplant, 34/150 (22.7%) in the 2009–2014 cohort and 95/147 (64.6%) in the 2017–2018 cohort were administered MMR vaccine <2 years after transplant. Of these 129 patients, there were 75 (58%) autologous HCT recipients and 54 (42%) allogeneic HCT recipients (Table 1). The median age at vaccination was 61 years, and 57% of the patients were male. The most frequent underlying hematologic disease was multiple myeloma for auto-HCT and acute myelogenous leukemia for allo-HCT. The median time from transplant to MMR vaccination (interquartile range [IQR]) was 718 (675–725) days, with 39 (30%) patients being vaccinated <23 months post-transplant (Figure 1). The earliest vaccination happened 300 days after transplant. At the time of vaccination, 55 patients (43%) were on immune therapy, 48 of whom were on maintenance therapy for multiple myeloma after auto-HCT. The most commonly used agents were thalidomide analogue, mainly lenalidomide, and proteasome inhibitor, mainly bortezomib. Eleven (20%) allo-HCT recipients had mild GVHD at vaccination, 3 of whom were on immunosuppressive therapy (prednisone 10–20 mg daily). Three other allo-HCT recipients were receiving immunosuppressive therapy for their underlying disease. In addition, 2 auto-HCT recipients received chimeric antigen receptor T-cell (CAR-T) therapy between HCT and vaccination (122 and 384 days before vaccination), and 1 allo-HCT recipient received rituximab 415 days before vaccination. Pre- and postvaccination measles serologies were not collected systematically.

Adverse Reactions Postvaccination

Early Reactions (<42 Days Postvaccination)

Within 42 days postvaccination, 10 adverse reactions for 7 patients were reported: 4 auto-HCT recipients (3 on maintenance therapy) and 3 allo-HCT recipients (1 with mild GVHD not receiving immunosuppressive therapy and 1 on maintenance ponatinib) (Table 2). There were 6 cases of respiratory tract infections presenting 14–35 days after vaccination, 5 in patients vaccinated between 23 and 24 months post-HCT. All cases were

Table 1. Baseline Characteristics of Patients who Received MMR Within 2 Years of HCT (n = 129)

Median age (IQR, range), y	61 (48–68, 20–77)
Male sex, No. (%)	74 (57)
Median time from transplant to MMR (IQR), d	
All cohort (n = 129)	718 (675–725)
Vaccinated <23 mo post-transplant (n = 39)	578 (407–665)
Type of HCT, No. (%)	
Autologous HCT	75 (58)
Allogeneic HCT	54 (42)
Measles serology	
Prevaccination, No. (%)	
Not available	124 (96)
Negative	2 (2)
Positive	3 (2)
Postvaccination, No. (%)	
Not available	124 (96)
Negative	2 (2)
Positive	3(2)
Autologous HCT (n = 75)	
Underlying hematologic disorder, No. (%)	
Multiple myeloma	51 (68)
Non-Hodgkin lymphoma	15 (20)
Hodgkin disease	9 (12)
Maintenance/immunosuppressive therapy at vaccination, No. (%)	49 (65)
Thalidomide analogue	36 (48)
Proteasome inhibitor	4 (5)
Thalidomide analogue + proteasome inhibitor	5 (7)
Dexamethasone (in combination therapy)	10 (13)
Other[a]	4 (5)
Other major immunosuppressive therapy from HCT to vaccination, No. (%)	2 (3)
Anti-CD20	0 (0)
Anti-CD52	0 (0)
Antithymocyte globulin	0 (0)
CAR-T therapy	2 (3)
IVIG at vaccination	3 (4)
Median lymphocyte count (IQR, range), K/μL	1.2 (0.9–1.6, 0.2–3.0)
Allogeneic HCT (n = 54)	
Underlying hematologic disorder, No. (%)	
Acute myelogenous leukemia	16 (30)
Myelodysplastic syndrome	10 (19)
Red cell disorder	7 (13)
Myeloproliferative disorder	6 (11)
Other	15 (28)
Type of allogeneic HCT, No. (%)	
Matched-related donor	6 (11)
Matched-unrelated donor	34 (63)
Mismatch donor	3 (6)
Haploidentical transplant	11 (20)
Conditioning regimen, No. (%)	
Myeloablative	20 (37)
Reduced intensity	34 (63)
Presence of GVHD at vaccination, No. (%)	
Mild	11 (20.4)
Moderate/severe	0 (0)
Immunosuppressive therapy at vaccination	6 (11)
Prednisone, No. (%)	3 (6)
Dose of prednisone, range, mg	10–20
Ruxolitinib, No. (%)	2 (3)
Other,[b] No. (%)	3 (6)
Other major immunosuppressive therapy from HCT to vaccination, No. (%)	1 (2)
Anti-CD20	1 (2)
Anti-CD52	0 (0)
Antithymocyte globulin	0 (0)
CAR-T therapy	0 (0)
Median lymphocyte count (IQR, range), K/μL	1.8 (1.1–2.3, 0.3–5.1)

Abbreviations: CAR-T therapy, chimeric antigen receptor T-cell therapy; GVHD, graft-vs-host disease; HCT, hematopoietic cell transplant; IQR, interquartile range; MMR, measles, mumps, and rubella.

[a]Other therapies include rituximab (n = 1), daratumumab (n = 1), isatuximab (n = 1), brentuximab (n = 1).

[b]Other therapies include sirolimus (n = 1), tacrolimus (n = 1), methotrexate (n = 1).

medically attended. Three had associated fever, and 5 had chest x-rays performed, all of which were negative for pneumonia or pneumonitis. One patient tested negative for respiratory syncytial virus and influenza by PCR. In all cases, there was no clinical suspicion of a vaccine-related illness. No measles, mumps, or rubella testing was performed. Five patients received oral antibiotics empirically, and all fully recovered. No adverse reactions were seen in the 2 patients who received CAR-T therapy or between HCT and MMR vaccination.

There were 3 patients who were hospitalized within 42 days of vaccination. The first admission was for an elective nasal and palatal reconstruction surgery. The second was for the investigation of progressive kidney failure that had been evolving for months before MMR vaccination and was thought to be due to tacrolimus toxicity. Both hospitalizations were deemed not related to MMR vaccination. The third hospitalization was in a 37-year-old female, who had a history of acute lymphoblastic leukemia and had undergone a matched unrelated donor myeloablative allogeneic HCT 542 days before vaccination. On the day of vaccination, she was on maintenance ponatinib (tyrosine kinase inhibitor, BCR-ABL pathway), her total lymphocyte count was 1.7 K/mcL, and she reported feeling well. Twelve days after, she presented with a maculopapular rash that initially appeared on the face and progressed to the shoulders, arm, and chest (Figure 2). She denied any associated symptoms such as fever, conjunctivitis, cough, coryza, or arthralgia. She was briefly hospitalized out of an abundance of caution because of an initial suspicion that the rash could be measles. IgM serology for measles and rubella was negative. Extensive workup for other infectious diseases, including parvovirus B19, adenovirus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human immunodeficiency virus (HIV), herpes simplex virus (HSV), and varicella-zoster virus (VZV), was negative. A nasopharyngeal swab returned negative for measles PCR but positive for rubella PCR (MA State Public Health Laboratory, MA, USA), which was later confirmed to be the vaccine strain (genotype 1a). The patient fully recovered without complications.

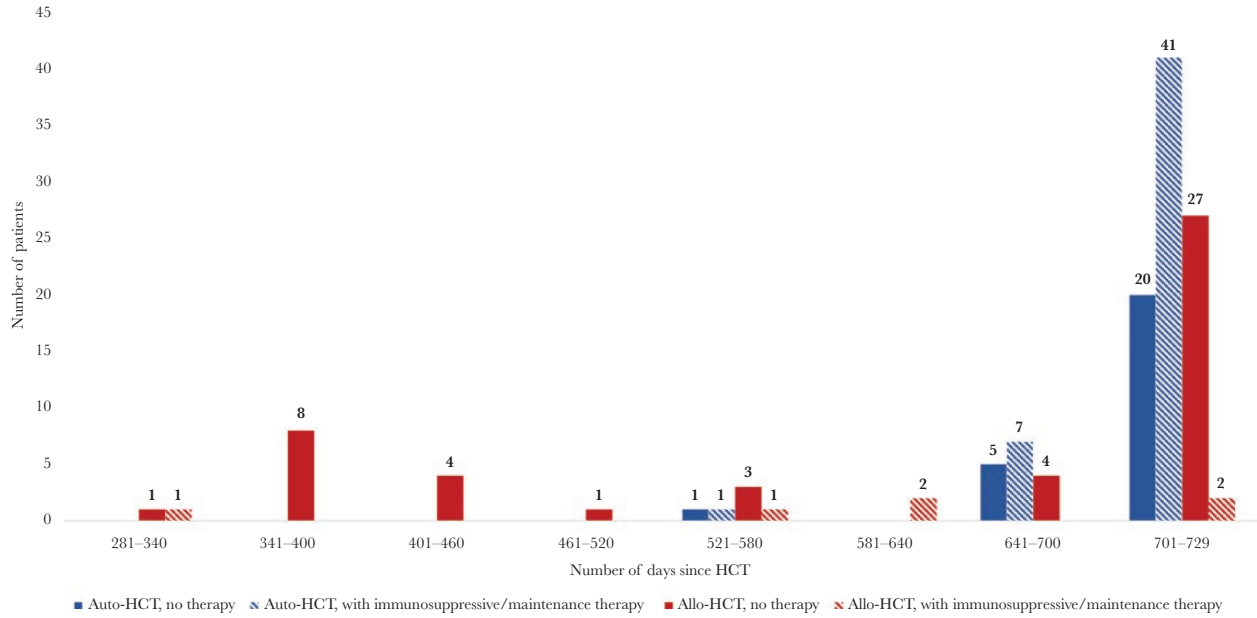

Figure 1. Number of patients vaccinated <2 years post-HCT, by number of days post-HCT, type of HCT, and concomitant use of immunosuppressive or maintenance therapy. Abbreviation: HCT, hematopoietic cell transplant.

Late Reactions (>42 Days Postvaccination)

To assess for late reactions, the medical records of the 129 patients were reviewed for a median of 676 days postvaccination. There was a total of 46 hospitalizations for 14 patients and 11 deaths during the follow-up period; 10 were related to complications of the underlying hematologic disease, and 1 was a sudden cardiac arrest 304 days after vaccination. None of the deaths were due to neurologic disease or considered to be related to the MMR vaccination. In addition, after reviewing all positive IgM and PCR results for measles, mumps, and rubella from the microbiology laboratory database since 5/2015, no case of wild-type or vaccine-associated infection other than the case described above was found in the cohort.

Table 2. Adverse Reactions Postvaccination

	Total Cohort (n = 129)
Adverse reactions within 42 d postvaccination, No. (%)	
Patients with adverse reaction	7 (5)
Rash	1 (1)
Respiratory tract infection	6 (4)
No treatment	1 (1)
Antibiotic treatment	5 (4)
Fever	3 (2)
Arthralgia/arthritis	0 (0)
Parotiditis	0 (0)
Orchitis	0 (0)
Pneumonitis	0 (0)
Encephalitis	0 (0)
Aseptic meningitis	0 (0)
All hospitalizations	3 (2)
Hospitalization for potential complication of MMR	1(1)
Death	0 (0)
Hospitalization and death >42 d postvaccination, No. (%)	
Patients hospitalized	14 (11)
All hospitalizations	46
Deaths	11 (9)
Hospitalization or death due to potential complication of MMR, No. (%)	0 (0)
Median duration of follow-up (IQR, range), d	676 (511–1922, 111–3693)

Abbreviations: IQR, interquartile range; MMR, measles, mumps, and rubella.

DISCUSSION

We hereby present the safety data analysis from HCT recipients who received MMR vaccination within 2 years of transplant. Many of these patients were vaccinated in the context of the 2019 measles outbreak.

Few studies have reported the safety of early MMR vaccine after HCT. During an outbreak in Brazil in 1997, 61 autologous or allogeneic HCT recipients aged 6–55 years (median, 25 years) were safely vaccinated between 9 and 18 months after transplant, with 53% still receiving immunosuppressive drugs [18]. Shaw et al. showed that MMR vaccine was safely administered to 79 children starting 1 year after HCT [19]. A recent systematic review described a total of 152 HCT recipients who received MMR vaccine earlier than 2 years post-transplant [20]. No cases of vaccine strain–associated illness have been reported in this population. Recent guidelines developed by the American Society for Transplantation and Cellular Therapy (ASTCT) were published in August 2019, after the diffusion of the local guidance at BWH/DFCI. The ASTCT recommends

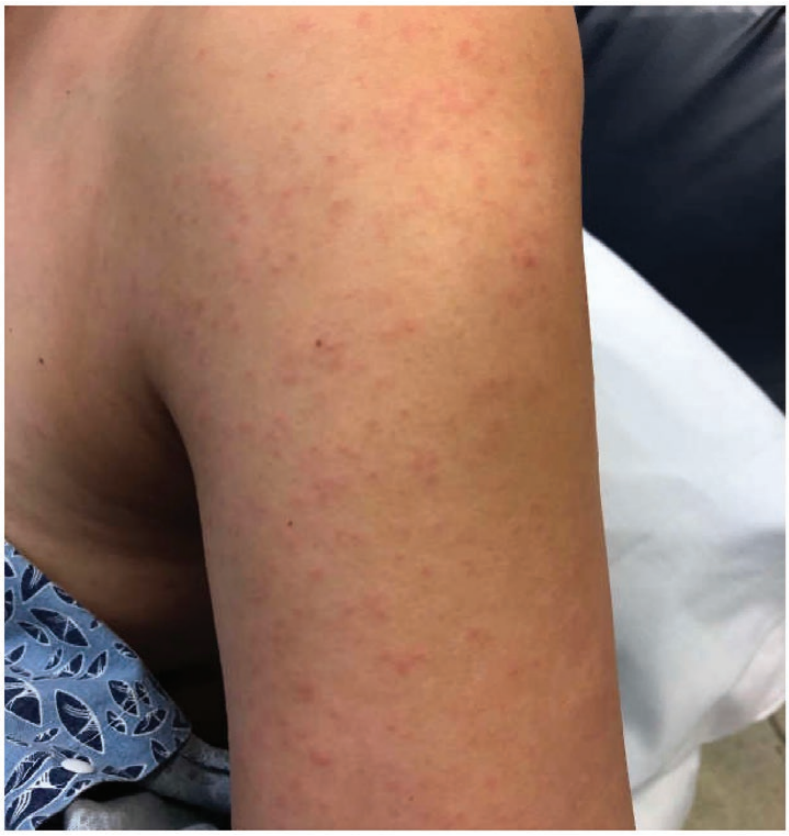

Figure 2. Vaccine strain rubella–associated maculopapular rash appearing 12 days post–MMR vaccine, given 542 days after allo-HCT. Abbreviations: HCT, hematopoietic cell transplant; MMR, measles, mumps, and rubella.

considering MMR vaccination during measles outbreaks in the community starting more than a year post-HCT in patients meeting specific criteria (including total lymphocyte count, IgG and IgA levels, immunosuppressive therapies), mostly based on experts' opinions [21]. Many patients included in our study would not been considered for vaccination according to these criteria. For example, a significant proportion of patients in our study had a total lymphocyte count <1 K/mcL. The ASTCT only allows early MMR vaccine for those with counts >1 K/mcL.

In our cohort of autologous and allogeneic HCT recipients, MMR vaccine was safe and well tolerated, with a low rate of adverse reactions. A significant proportion (43%) of the patients were receiving maintenance or immunosuppressive therapy at the time of vaccination, mostly multiple myeloma patients on maintenance therapy. A previous study demonstrated the safety of MMR vaccination in patients with multiple myeloma on maintenance lenalidomide or bortezomib after autologous HCT, but the majority were vaccinated >2 years post-transplant [22].

We describe the first case of postvaccination rubella illness in an HCT recipient. This patient presented 12 days after vaccine with a centrifugal rash without other rubella symptoms. The nasopharyngeal swab confirmed the presence of the vaccine strain of rubella. Rash is known to occur after MMR vaccine, usually reported in 2% of vaccinees, but is usually thought to be due to the measles component [23]. Of note, vaccine strain rubella shedding has previously been demonstrated in healthy individuals receiving MMR vaccine. For example, in one study the virus was isolated in children with acute respiratory tract infections who had received MMR 12–26 days before [24]. Vaccine strain rubella has also been detected in the breast milk of 68% of breastfeeding women up to 34 days postvaccination [25]. However, vaccine strain–related illness has rarely been described. A recent report described 2 immunocompetent patients developing vaccine-associated rubella, who presented a rash 13 days after vaccine [26]. Similar to the case reported herein, both had uncomplicated courses. Among the HCT recipient population, a 12-year-old died 60 days post-transplant of fulminant hepatic failure with disseminated vaccine strain rubella, despite receiving his last MMR vaccine 8 years before [27]. The authors concluded that transmission from a newly vaccinated person was the only possibility to explain this infection. However, horizontal transmission from vaccine strain rubella has not been described elsewhere [26].

This report has several limitations. First, because this was a retrospective cohort analysis, mild adverse reactions or adverse reactions not reported in the medical charts may have been missed. Second, the median time from transplant to vaccination

was 718 days, approaching the 2-year mark post-HCT. However, 30% of the patients in our cohort received the vaccine <23 months after transplant (median, 578 days), providing valuable safety data on earlier vaccination. In addition, as most of the available safety data come from children and young adults, our results provide additional information regarding MMR safety in an older cohort of HCT recipients. Third, as the decision to offer MMR vaccine was left to the treating physicians, the healthiest patients may have been offered vaccination, potentially biasing our findings. Finally, no data on immunogenicity were available because the clinicians did not consistently order pre- and postvaccination serologies.

In conclusion, MMR vaccine administered ≥300 days post-HCT appears to be well tolerated in carefully selected individuals. No attributable severe outcomes or deaths were described. A single mild and uncomplicated case of vaccine-associated rubella illness was seen after vaccination. Providers should be aware of the potential risk of vaccine-associated illness in those receiving MMR <2 years after transplant, so they can promptly identify the syndrome and perform the appropriate workup. In the setting of a measles outbreak, assessment of potential risks and benefits of MMR vaccination given within 2 years of HCT remains important.

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Patient consent. The study was approved by the Mass General Brigham Human Research Committee. This study does not include factors necessitating patient consent.

Potential conflicts of interest. S.R.W. has received funding from NIH/NIAID as well as the Bill and Melinda Gates Foundation unrelated to this work and has conducted clinical trials funded by Janssen, Sanofi Pasteur, and Regeneron, also unrelated to this work. M.P.C. reports grants from McGill Interdisciplinary Initiative in Infection and Immunity, grants from Canadian Institutes of Health Research during the conduct of the study, personal fees from GEn1E Lifesciences (as a member of the scientific advisory board), and personal fees from nplex biosciences (as a member of the scientific advisory board), outside the submitted work. He is the co-founder of Kanvas Biosciences and owns equity in the company. He has 2 patents pending ("Methods for Detecting Tissue Damage, Graft Versus Host Disease, and Infections Using Cell-Free DNA Profiling" and "Methods for Assessing the Severity and Progression of SARS-CoV-2 Infections Using Cell-Free DNA"). L.R.B. is involved in HIV and COVID vaccine clinical trials conducted in collaboration with the NIH, HIV Vaccine Trials Network (HVTN), COVID Vaccine Prevention Network (CoVPN), International AIDS Vaccine Initiative (IAVI), Crucell/Janssen, Moderna, Military HIV Research Program (MHRP), Gates Foundation, and the Ragon Institute. N.C.I. received research grants from Merck, Astellas, GSK, and AiCuris. The remaining authors declare no relevant conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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