Missed anti-D immune globulin administration to postpartum patients in 2 health systems: an unrecognized patient safety risk

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BACKGROUND: Maternal-fetal Rh-alloimmunization is a rare but potentially fatal event, most often caused by maternal exposure to D-antigen-presenting Rh-positive erythrocytes at the time of delivery. Prophylaxis with anti-D immune globulin is highly effective with a low side-effect profile and results in a dramatically decreased risk of alloimmunization. Postpartum anti-D immune globulin prophylaxis is recommended by national societies to reduce Rh-alloimmunization. We hypothesized that a small number of postpartum patients do not receive prophylaxis as indicated.

OBJECTIVE: We investigated patients in 2 separate health systems that did not receive indicated prophylaxis and devised a suite of Electronic Health Record interventions to prevent future errors.

STUDY DESIGN: We reviewed charts retrospectively from Electronic Health Record data of 2 urban academic health systems, the MetroHealth System and Oregon Health & Science University. We identified all Rh-negative postpartum patients and their infants delivering from 2014 to 2019. The primary outcome was the proportion of postpartum patients not receiving indicated anti-D immune globulin prophylaxis. Once cases of missed anti-D immune globulin prophylaxis were identified, we reviewed individual charts to determine the relevant clinical circumstances and potential causes for error.

RESULTS: Of 29,801 deliveries over 5 years (15,444 at MetroHealth System and 14,357 at Oregon Health & Science University), there were 3087 Rh-negative postpartum patients, of whom 7 were alloimmunized and ineligible for prophylaxis. Anti-D immune globulin was indicated for 2162 (70.0%) women as they delivered an Rh-positive infant. A total of 37 indicated patients did not receive postpartum anti-D immune globulin. Twenty patients were offered prophylaxis and declined. We missed a total of 17 opportunities, thus our institutions appropriately offered indicated anti-D prophylaxis to 99.2% of patients over a period of 5 years. Of the 17 true misses, anti-D immune globulin was ordered for some patients, whereas others did not have an anti-D immune globulin order placed. A toolkit in the Electronic Health Record consisting of decision-support hard stops, automated documentation, and longitudinal reporting was implemented at the MetroHealth System in the year after its inception. The Toolkit identified and helped prevent 4 potential misses, resulting in a 100% anti-D prophylaxis rate at the MetroHealth System.

CONCLUSION: Given the serious nature of Rh-alloimmunization, we believe missed prophylaxis should be a never event. Through examination of our current processes, we identified areas of improvement and developed a Postpartum Anti-D Immune Globulin Prophylaxis Electronic Health Record Toolkit, which showed improvement in administration rates. Such a toolkit has the potential to identify patients appropriately and avoid missed anti-D immune globulin prophylaxis events.

Key words: anti-D immunoglobulin, electronic health record toolkit, maternal-fetal alloimmunization, missed prophylaxis, never event, obstetrical informatics, obstetrical quality improvement, rhesus immunoglobulin prophylaxis

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**Introduction**

Maternal-fetal Rh-alloimmunization is a rare but potentially fatal event that occurs when an Rh-negative pregnant patient is exposed to Rh-positive fetal erythrocytes presenting the D-antigen. Exposure most commonly occurs at the time of delivery, resulting in subsequent sensitization. Repeated exposure to Rh-positive erythrocytes results in a rapid and overwhelming maternal anti-D antibody response. Maternal immunoglobulin G antibodies cross the uteroplacental interface where Rh-positive fetal erythrocytes are susceptible to destruction by anti-D antibodies. Fetal erythrocyte hemolysis may cause severe fetal anemia which, if untreated, leads to heart failure, hydrops fetalis, and intrauterine fetal demise.1

Delivery commonly results in maternal exposure to fetal blood and, in the era before the routine administration of anti-D prophylaxis, the risk of alloimmunization to those who delivered a D-positive infant was approximately 16%.2 Anti-D immune globulin (RHIG), a human plasma derivative, can prevent alloimmunization in Rh-negative patients who deliver Rh-positive infants. Despite an unclear mechanism, postpartum anti-D prophylaxis is highly effective and reduces the rate of alloimmunization to only 1% to 2%.3 With an additional prophylactic administration at 28 weeks' gestation, this rate can be lowered even further to 0.1%.4

As RHIG is now the standard of care, given its clear benefits for future pregnancies and minimal risk, institutions should have highly reliable processes to routinely administer RHIG to indicated patients. However, institutions may not reach 100% compliance with this recommendation. Indeed, Badami et al reported that 41% of gravidas with new Rh-D sensitization had previously missed an opportunity for anti-D prophylaxis, despite clinician recognition of a sensitizing event.4 The true rate of missed postpartum anti-D prophylaxis opportunities is not known. We suspected that there is a small number of patients who did not receive prophylaxis as indicated at our institutions. Therefore, we aimed to establish the rate of indicated anti-D prophylaxis in our 2 institutions and examine the current workflows and related alerting mechanisms. Further, we sought to assess the utilization of a toolkit for the electronic health record (EHR) to prevent missed postpartum RHIG prophylaxis administration before hospital discharge.

**Materials and Methods**

**Setting**

The initial Plan-Do-Study-Act (PDSA) cycle was performed at both the MetroHealth System (MHS) in Cleveland, Ohio and at Oregon Health & Science University (OHSU) in Portland, Oregon for deliveries between 2014 and 2019.

The study was approved by the institutional review boards of both institutions. The second PDSA cycle was performed at MetroHealth for 1 year after the initial cycle, concluding in October 2020.

**Implementation**

Our teams used a series of PDSA cycles for continuous quality improvement in RHIG prophylaxis. This paper outlines the application of the PDSA model for 2 cycles, initially focusing on postpartum administration of RHIG, given that this is the most likely obstetrical event resulting in sensitization.

**Plan-Do-Study-Act Cycle 1a: gathering data and developing a toolkit at MetroHealth System (July 2019 –October 2019)**

**Plan**

Members of the MHS team identified that it was difficult for providers to confirm that postpartum patients had been given appropriate RHIG prophylaxis when indicated. Because of this challenge, we were concerned that our team may have missed opportunities for prophylaxis. After forming a performance improvement (PI) team, we determined that we wanted to initially focus on the postpartum setting, with the goal of 0 missed opportunities for prophylaxis.

**Do**

Using EHR data (Epic Systems Corporation, Verona, WI), we performed a retrospective chart review of postpartum patients hospitalized for delivery. We collected data from Epic’s Clarity database using Structured Query Language (SQL). Data validation of the SQL query was performed via manual chart check of a 1% random sample of all maternal Rh-negative patients. For each Rh-negative patient, our query identified the associated neonate(s), blood type(s), and antibody statuses of each gravida and neonate, delivery date and time, and RHIG administration date and time. From the query, postpartum patients who did not receive RHIG within 72 hours after delivery or before hospital discharge were identified as potential misses.
Study
Individual charts were then reviewed to determine whether potential misses identified by our query were true cases of missed prophylaxis. To validate true misses, the maternal and neonatal charts were reviewed independently by 2 investigators (K.B. and G.L.) to identify causes of the missed RHIG administration. Cases not deemed to be true misses included preexisting maternal alloimmunization, declining of RHIG after informed consent, and incomplete documentation of correct administration.

Next, we evaluated the workflows for the management of Rh-negative postpartum patients (Figure 1). The patient’s blood type is displayed in the banner at the top of the chart in the outpatient and inpatient Electronic Health Record (her). Once admitted to Labor and Delivery, the patient’s blood type is automatically pulled into the History & Physical (H&P) template. The providers document a management plan in the H&P. After delivery, if indicated, the provider orders the neonatal Rh evaluation from cord blood and orders RHIG in the postpartum order set for all Rh-negative postpartum patients. When the neonatal Rh-evaluation results become available in the EHR, the nurse’s actions depend on the infant’s blood type: if the blood type is Rh-positive, they administer maternal RHIG and document it in the patient’s Medication Administration Record (MAR); if the infant’s blood type is Rh-negative, the nurse cancels the RHIG order. When rounding the next day, the provider reviews the infant’s Rh evaluation result and the maternal MAR to determine whether the patient received RHIG as indicated. The provider manually documents whether RHIG was indicated and given in the maternal postpartum note. Once appropriate management is complete, the provider places a discharge order. Estimated time to look up and document maternal and fetal Rh-types along with RHIG administration was at least 27 seconds under ideal network conditions.

Act
On the basis of the review of the workflow, we identified several opportunities for improvement. We therefore developed the Postpartum RHIG Prophylaxis Toolkit, consisting of:

1. An automated documentation phrase (ie, Epic SmartPhrase) embedded in the note-template used in postpartum rounds (Figure 2)
2. An interruptive, point-of-care decision support advisory (ie, Epic Best Practice Advisory [BPA]) with a required acknowledgment (Figures 3 and 4)

The RHIG toolkit unobtrusively integrates into current workflows.

The documentation phrase in the postpartum rounds automatically documents the maternal blood type, neonatal blood type, and whether RHIG was indicated and had been administered during the hospital stay. The BPA tool was created to evaluate the patient and interrupt both providers and nurses in opening charts of indicated patients without RHIG administration 72 hours postpartum, or when a discharge order was placed on the chart, whichever came first. The toolkit was developed with input from relevant stakeholders including obstetrical residents, nurses, midwives, attendings, leadership, clinical informatics, and decision support teams.

Plan-Do-Study-Act Cycle 1b: gathering data and developing a toolkit at Oregon Health & Science University (December 2020—Present)

Plan
While the MHS team was in the process of its first PDSA cycle, we discussed the project with colleagues at OHSU, who opted to perform a similar PI project in their own institution. They too formed a local PI team and set the goal of 0 missed opportunities for postpartum RHIG prophylaxis.

FIGURE 1
Diagram of the MetroHealth System postpartum RHIG prophylaxis workflow

Existing Workflow for Rh-Negative Patients
- Provider orders type and screen
- Blood type displays in EHR banner
- Blood type automatically pulls into H&P
- Provider documents management plan
- Provider orders neonatal Rh evaluation from cord blood
- Provider orders RHIG in postpartum order set
- Infant Rh-Positive
  - Nurse administers RHIG
  - Nurse documents in EHR
  - Physician documents completed plan in subsequent rounds note
- Infant Rh-Negative
  - Nurse cancels RHIG order
  - Physician documents completed plan in subsequent rounds note
- Discharge

New Workflow for Rh-Negative Patients
- Provider orders type and screen
- Blood type displays in EHR banner
- Blood type automatically pulls into H&P
- Provider documents management plan
- Provider orders neonatal Rh evaluation from cord blood
- Provider orders RHIG in postpartum order set
- Infant Rh-Positive
  - Nurse administers RHIG
  - Nurse cancels RHIG order
- Infant Rh-Negative
  - Nurse administers RHIG
  - Nurse cancels RHIG order
  - Automated documentation phrase included in all postpartum round notes
- Discharge

Ongoing Tracking and Reporting

The RHIG toolkit unobtrusively integrates into current workflows.

RHIG, anti-D immune globulin.

Brackney. Missed postpartum Rh-alloimmunization prophylaxis. Am J Obstet Gynecol Glob Rep 2021.
The OHSU team performed the same retrospective chart review of their Epic EHR, also using the Epic Clarity database and SQL. They performed data validation with manual chart check of a 1% random sample.

Study
Individual chart review was also performed at OHSU to identify potential cases of missed prophylaxis and confirm true cases of missed prophylaxis. To validate true misses, all potential cases were reviewed independently by 2 investigators (A.H. and M.R.). Because the MHS team had just evaluated its workflow for the management of Rh-negative postpartum patients, the OHSU team compared its workflow against that document. They found that they use very similar
workflows, likely because they use the same EHR.

**Act**

OHSU is currently evaluating the application of the Postpartum RHIG Prophylaxis Toolkit in their institution, consisting of the same automated documentation phrase in the postpartum note template, an interruptive point-of-care BPA, and report tracking.

**Plan-Do-Study-Act Cycle 2: disseminating information and applying toolkit at MetroHealth System (October 2019—October 2020)**

**Plan**

The MHS team presented its findings and the toolkit to the inpatient nursing and provider teams in various forums throughout the summer of 2019. We planned to monitor the uptake of the documentation tool, firing of the BPA hard stop, and track any future cases of missed RHIG.

**Do**

We began using the clinical documentation phrase and BPA hard stop on October 23, 2019.

**Study**

In the subsequent year, we tracked the number of BPA hard stop firings and spoke with the clinicians who interacted with the firings. We wanted to learn whether these were frustrating or interruptive to their workflow and found that they appreciated the reminders rather than being bothered by them. One of our PI team members personally assisted many of the clinicians so that they would routinely use the postpartum note template with our RHIG documentation phrases. We learned that the residents often passed down this information from one class to the next because they appreciated the time saved by avoiding the tedious search for maternal and neonatal Rh data. We also verbally asked for feedback from various clinicians using the documentation phrases to see if they needed any modification.

**Act**

We planned to share our findings within our institutions and beyond, so that others can benefit from our process and toolkit.

**Results**

At MHS, there were 15,444 deliveries from July 1, 2014 to July 1, 2019. In total, 1488 postpartum patients (9.6%) were Rh-negative. There were 1014 Rh-negative patients (68.1% of all Rh-negative patients) who delivered an Rh-positive or Rh-unknown infant. Two of the 1014 Rh-negative patients were previously alloimmunized, leaving 1012 of Rh-negative patients (68.0%) who had an indication for postpartum RHIG prophylaxis. A total of 12 patients (1.2%) did not receive indicated postpartum RHIG prophylaxis. Five (0.5%) of the patients with an indication for prophylaxis declined administration after implementation.

**FIGURE 4**

Sample Interruptive BPA for patients without indicated RHIG at discharge

Brackney. Missed postpartum Rh-alloimmunization prophylaxis. Am J Obstet Gynecol Glob Rep 2021.
appropriately documented counseling; none of them underwent postpartum sterilization. Seven (0.7%) of the postpartum patients with an indication for prophylaxis did not receive it as planned. Thus, the MHS institutional rate of indicated anti-D prophylaxis was 98.8%. When the 5 patients who declined prophylaxis after appropriately documented counseling were excluded, the rate reached 99.3%.

Review of the clinical scenarios surrounding the 7 missed postpartum RHIG opportunities at MHS demonstrated that 2 of the patients never had an order placed during their hospitalization: each of these patients had an initial lab report of Rh-negative infant blood type, which was later amended. Of the 5 patients who had an order placed but never received RHIG, one had limited English proficiency, and one was hearing-impaired. The other 3 patients had no identifiable risk factors.

At OHSU, there were 14,357 deliveries from January 2014 to December 2019. There were 1599 (11.1%) Rh-negative patients and 1150 of these (71.9%) delivered an Rh-positive or Rh-unknown infant. Five of the 1150 Rh-negative patients were previously alloimmunized, leaving 1145 (71.6%) of Rh-negative patients who had an indication for postpartum RHIG prophylaxis. There were 24 patients (2.1%) who did not receive indicated prophylaxis. Fifteen of these indicated patients declined prophylaxis: 12 patients because they underwent tubal ligation or hysterectomy, were planning vasectomy, or otherwise not planning future pregnancies; 1 declined because of needle phobia; and the other 2 declined for undocumented reasons. Three other patients underwent permanent sterilization without documented declination of RHIG, so they were considered misses. Therefore, in total, 10 (0.9%) of the postpartum patients with an indication for prophylaxis did not receive it as planned. Of these, providers placed RHIG orders for 2 patients, but RHIG was never administered. The other 5 patients never had RHIG ordered. Thus, the OHSU institutional rate of indicated anti-D prophylaxis was 97.9%. When the 15 patients who declined prophylaxis were excluded, the rate reached 99.1%.

Taken together, of a total of 29,801 postpartum patients at both institutions, there were 3087 (10.4%) Rh-negative patients and 1115 of these (71.9%) delivered an Rh-positive or Rh-unknown infant. Five of the 1115 Rh-negative patients were previously alloimmunized, leaving 1110 (71.6%) of Rh-negative patients who had an indication for postpartum RHIG prophylaxis. There were 24 patients (2.1%) who did not receive indicated prophylaxis. Fifteen of these indicated patients declined prophylaxis: 12 patients because they underwent tubal ligation or hysterectomy, were planning vasectomy, or otherwise not planning future pregnancies; 1 declined because of needle phobia; and the other 2 declined for undocumented reasons. Three other patients underwent permanent sterilization without documented declination of RHIG, so they were considered misses. Therefore, in total, 10 (0.9%) of the postpartum patients with an indication for prophylaxis did not receive it as planned. Of these, providers placed RHIG orders for 2 patients, but RHIG was never administered. The other 5 patients never had RHIG ordered. Thus, the OHSU institutional rate of indicated anti-D prophylaxis was 97.9%. When the 15 patients who declined prophylaxis were excluded, the rate reached 99.1%.

Implementation of the toolkit in The MetroHealth System

The new EHR toolkit was implemented at MHS on October 23, 2019. In the first 12 months after implementation, the interruptive BPA fired 9 times. One alert identified a patient who was already alloimmunized, one identified a patient who declined prophylaxis, and 3 identified patients who had received RHIG without complete documentation. We believe that the other 4 firings averted missed postpartum prophylaxis because in each situation, the discharge order was placed before RHIG administration. Although the rare event of missed prophylaxis was not expected to demonstrate a statistically significant change within our study period, we do believe that our work is clinically significant. Since the application of these tools in our clinical practice, we have observed no missed postpartum RHIG administrations. The toolkit was developed at MHS and is freely available via the corresponding author to all institutions that use Epic. The toolkit has been shared with OHSU and is under evaluation for implementation. OHSU’s goal in this study was limited to PDSA cycle 1, which identified the missed RHIG administration rate in the postpartum
The patient population of our 2 hospital systems.

The use of the nonmandatory, automatic documentation phrase by residents and staff in their postpartum notes was evaluated via an SQL query of Epic’s Clarity database. Although there is no metric available in our study to measure the effectiveness of automatic documentation phrases in reducing missed RHIG administration, the use of the phrase does decrease documentation burden on the end-user. During the first 2 months after go-live, uptake of the automated documentation phrase was low. Use of the automated documentation phrase was found in 13 postpartum notes for 7 different Rh-negative postpartum patients. A total of 47 Rh-negative patients gave birth during this initial survey window. The automated documentation phrase was used in the postpartum notes of 15% of the Rh-negative patients and almost 2 times per patient during the initial survey window.

Our usual workflow for notifying staff about new features in the EHR involves sending a department-wide message in the form of an “Epic Tip” within the EHR, describing the new feature and how it can be experienced by the end-user. We suspect that these tips are often glossed over or completely ignored. However, we did see significant uptake immediately after a personalized email was sent out to the staff by our division director highlighting the time efficiency of adding the automated documentation phrase to note templates.

During months 2 to 4 after go-live, the use of the automated documentation phrase was found in 45 postpartum notes for 20 different Rh-negative postpartum patients. There was a total of 36 Rh-negative patients who gave birth during this second survey window. The automated documentation phrase was used in the postpartum notes of 56% of the Rh-negative patients and just over 2 times per patient during the second survey window. In the first year after go-live, 72% of Rh-negative patients had at least 1 note in their chart using the automated documentation phrase. In total, 462 notes contained the automated documentation phrase. Most of the uptake throughout the year was by PGY-1 and PGY-2 residents who are often responsible for most of the postpartum rounding at MHS. We expect that as new generations of residents join the program, their seniors will pass on the use of this automated documentation tool and uptake will increase accordingly.

Monitoring future outcomes and any progress made possible by these tools was simplified for our end-users. Each firing of the hard stop BPA is reviewable via Slicer Dicer (Epic’s self-service visual cohort querying tool) that all approved staff have access to. The SQL scripts were added to our reporting portfolio and can be run by select users in the obstetrics department without need for support from our technical teams or business intelligence teams.

**Comment**

**Principal findings**

About 10% of delivered patients at our US centers were Rh-negative. Approximately two-thirds of those gravidas had Rh-positive neonates who could be impacted by errors of omission in RHIG administration. Our institutions appropriately offered indicated anti-D prophylaxis to 99.2% of patients over a period of 5 years. Extrapolating these findings, 8 in 1000 Rh-negative postpartum patients who deliver an Rh-positive infant would be expected to miss appropriate anti-D prophylaxis. Implementation of our toolkit at MHS improved our anti-D prophylaxis rate to 100% in the subsequent year.

**Results in the context of what is known**

Because Rh-alloimmunization can have devastating results in future pregnancies, we believe that hospitals should work toward the goal of never failing to provide RHIG prophylaxis when it is indicated. Many quality efforts are aimed at commonly occurring problems or those rare events that may have severe consequences. To our knowledge, there are no previously published rates of missed postpartum RHIG prophylaxis.

Anti-D prophylaxis has minimal risk, and is without evidence of serious adverse events, cases of infectious disease, changes in laboratory safety values, or vital signs attributed to its administration. Current preparation methods are highly effective in removing viral particles, such as hepatitis A and C, parvovirus B12, and HIV. Thus, the American College of Obstetricians and Gynecologists (ACOG) recommends prophylaxis with RHIG for all postpartum Rh D-negative patients delivering Rh D-positive babies. In addition, unsensitized Rh D-negative gravidas are advised to receive prophylaxis at 28 weeks’ gestation and earlier if there are potentially sensitizing events in the pregnancy, such as invasive diagnostic procedures, external cephalic version, ectopic pregnancy, abortion, antenatal bleeding, or delivery of an Rh-unknown infant.

**Clinical implications**

With the processes in place for RHIG administration, our overall rate of missed cases was remarkably low. In addition, the error rate was very consistent across the 2 institutions, with similar administration protocols and electronic medical records. This rate could serve as a reference rate of indicated RHIG prophylaxis against which other institutions could compare their rates, though we urge all hospitals to aim for a goal rate of 100%.

It is interesting to note that many of the OHSU patients who declined RHIG underwent concomitant sterilization, whereas this was not the case at MHS. ACOG specifically recommends RHIG for patients undergoing postpartum sterilization because of the risk of alloimmunization that could limit the identification of compatible red cell units if the patient requires transfusion later in life. This recommendation, however, is controversial because it may not be cost-effective.

Although the baseline rate of misses was low, we recognize there are opportunities for improvement. Analogous to Reason’s Swiss cheese model, these
errors are rare but clinically significant holes in our system.⁷ Electronic support can prove useful in these high-risk but uncommon scenarios.

We found that it was burdensome for physicians to go to the neonate’s lab results, the patient’s MAR, and the postpartum note, and sought to consolidate this specific portion of the workflow. We also wanted to create a safety net that would catch any potential errors made by providers and nurses. With the implementation of our toolkit, we had no additional cases of missed RHIG administration.

We believe that the combination of clinical vigilance, automatic documentation phrases, BPA tools, and tracking systems is a strategy that will be simple to replicate in most electronic medical record platforms and could assist other institutions to identify and improve their missed RHIG prophylaxis rates as well. In addition, the toolkit decreases documentation burden by automating Rh and RHIG administration status in rounding notes. Furthermore, it avoids creating unnecessary work related to “alert fatigue” because the hard stop BPA triggers rarely (in our case only 9 times in the entire year) and adheres to the Five Rights of clinical decision support.¹⁰ Specifically, the advisory triggers and presents the right information (the maternal and fetal Rh status along with RHIG administration status), to the right person (physician or nurse at point of care), in the right intervention format (a hard stop BPA), through the right channel (via EHR interface), and at the right time in workflow (when attempting an early discharge for a patient that has not received indicated RHIG prophylaxis or when accessing the chart for such a patient after 72 hours have passed from delivery). These tools within the EHR can help us reach our goal of 100% administration of RHIG when it is clinically indicated. The implementation costs are minimal.

Research implications
It would be helpful for other institutions, especially those outside academic medicine, to compare rates of indicated RHIG prophylaxis, to determine whether this is truly a standard rate from which to compare.

In the future, we plan to apply the PDSA model to other clinical opportunities for anti-D prophylaxis (eg, the 28-week prenatal visit, encounters for first trimester bleeding) with additional cycles.

Strengths and limitations
The primary weakness in this reference rate is that it only evaluates postpartum administration, and does not investigate other potential missed opportunities throughout gestation. In addition, our study evaluated 2 academic institutions using the same EHR with nearly the same clinical processes at baseline. The rate may be different in other clinical settings, protocols, and populations. Lastly, although the authors believe the concepts of our toolkit can be applied to any contemporary EHR, it was only tested on Epic, which is used by both institutions included in this study.

Conclusions
We believe that our study can serve as a baseline for comparison of rates of indicated anti-D prophylaxis, and that our electronic support tools can be used by other institutions to similarly eliminate missed opportunities for prophylaxis, thereby reducing overall rates of Rh-alloimmunization.

Supplementary materials
Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.xagr.2021.100038.

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