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How do I ... implement diagnostic management teams in transfusion medicine?

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Abstract

Diagnostic management teams (DMTs) were conceptualized approximately twenty years ago in response to increasing subspecialization in medicine. DMTs are a collaboration between diagnostic experts and clinicians that aim to improve accurate and timely diagnosis and treatment of disease. Diagnostic experts provide their expertise in the increasingly complex realm of laboratory testing and interpretation of those test results to guide appropriate test utilization for individual patients. Not only can this approach improve patient care and safety, but DMTs also decrease healthcare costs by reducing unnecessary testing and potential diagnostic errors. Following the DMT construct and principles along with the 2015 National Academy of Medicine recommendations, our transfusion medicine (TM) service streamlined the workup and management of platelet refractory (PR) patients by developing and implementing a formal PR laboratory consult. The goals of this DMT and consult are to improve diagnostic management of PR patients and to decrease delays in providing these patients with appropriate and compatible platelet units. A comprehensive interpretation of test results is directly uploaded to the patient's electronic medical record (EMR), which is associated with a CPT code allowing for compensation for the PR evaluation. Herein we describe the development of and experience with the DMT since its implementation.

DIAGNOSTIC MANAGEMENT TEAM (DMT)

Over the last several decades, the field of medicine has advanced greatly leading to an exponential growth in knowledge that physicians are expected to manage and master. This has in turn led to a trend toward subspecialization. While specialization allows for physicians to hone their skills and develop expertise in particular areas of medicine, it has also led to a disconnect among the subspecialties. Subspecialties often operate within their own silos of information.¹ This trend is especially true for diagnostic specialties, such as pathology, and is further compounded by a lack of formal pathology training, including

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AUTHORSHIP

J.W. worked on data acquisition, analysis, and drafting of the manuscript. C.L.D., J.D.R., and H.C.S. developed and implemented the DMT into the transfusion practice as well as guided the project and final manuscript. S.M.K. worked on the design of the manuscript and drafting and revision of the manuscript. All authors approved of the final submitted manuscript.

CONFLICT OF INTEREST

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transfusion medicine, for trainees in U.S. medical schools.^{2,3} The separation of diagnostic specialties creates a black box in which clinicians often do not fully understand the myriad of laboratory tests available, when to use them, and how to interpret the results. Dovetailing with subspecialization in medicine is the growth of “defensive” medicine in which clinicians may order unnecessary testing in order to protect themselves from potential litigation. All of this can lead to diagnostic errors, delayed diagnoses, subpar management of disease, and increasing healthcare costs.

Little effort was made to address these issues until about two decades ago when the concept of DMTs was born. These teams bring together diagnostic experts, typically pathologists, and clinicians who are in direct contact with patients. Pathologists are able to provide expert advice on test selection and accurate test result interpretation. This direct communication between subspecialties allows for faster and more accurate diagnoses and thus expedites proper treatment for patients. DMTs have been successfully created and used in various areas including coagulation, leukemia and lymphoma, transfusion medicine, and microbiology.⁴ While it is difficult to quantify the improvement such DMTs have made in patient care and safety, it has been shown to greatly reduce healthcare costs by thousands to millions of dollars per year.⁴ These savings are not limited to the United States. The Italian Government is conducting a review of its healthcare spending and has similarly found that improvements in diagnostic services which cost little to implement save thousands to millions of euros as well.⁴⁻⁶

In 2015, the National Academy of Medicine published the “Improving Diagnosis in Health Care” report in which they issued several recommendations with the goal of improving diagnostic quality and safety.⁷ In order to achieve this goal, the recommendations emphasize and advocate for a shift in the diagnostic process from one based on the traditional physician-centric model to a patient-central model. This patient-central model uses a multidisciplinary team of healthcare professionals to arrive at the correct diagnosis and facilitate proper care for patients. Unlike prior recommendations and models, the 2015 recommendations expand the multidisciplinary teams to include diagnostic specialties such as radiology and pathology, encouraging collaboration between clinicians and diagnosticians. Such collaboration can improve diagnostic interpretation and, in turn, enhance patient care and safety.^{8,9} DMTs perfectly encompass the goals these recommendations are striving to achieve. At our institution, we saw the need for such a construct on the TM service, especially in regard to workup, diagnosis, and management of PR patients.

IDENTIFYING A FOCUS FOR DMT WITHIN THE TRANSFUSION MEDICINE SERVICE: PLATELET REFRACTORINESS (PR)

A patient is considered PR when the patient fails to achieve an adequate increase in platelet count following a platelet transfusion.^{10,11} One way to determine if a patient has an adequate increase is to calculate the corrected count increment (CCI).¹² At our institution, we use the CCI equation to determine if a response is adequate 1-hour after transfusion of an ABO

compatible platelet product.¹³ As we define a normal CCI to be greater than or equal to 7,500, increments of less than 7,500 meet the criteria for PR.¹⁴

There are two main categories of PR etiologies: non-immune and immune. Approximately 50% of cases are non-immune in nature, e.g., secondary to fever, infection, disseminated intravascular coagulation, medications, and bleeding.^{15,16} The remaining 50% are immune-mediated with 30–40% of cases attributed to human leukocyte antigen (HLA) alloantibodies and 2–10% of cases due to human platelet antigen (HPA) alloantibodies.¹⁷ HLA and HPA alloantibodies are formed from prior exposure to foreign HLA and HPA antigens during previous transfusions, pregnancy, and transplants.¹⁸

In order to properly diagnosis and manage PR, a series of steps must occur that involves the exchange of information between the laboratory, via the TM service, and the clinical team caring for the patient. First, it must be determined if the patient is truly PR using a method such as the aforementioned CCI. If the patient meets the definition of PR, the etiology must be identified. A thorough history, review of the medical record, and physical examination of the patient can help to identify non-immune etiologies. Once non-immune etiologies have been excluded, immune causes can be tested for with HLA and HPA antibody assays.¹⁹

A variety of testing platforms are available to detect HLA antibodies including lymphocyte immunofluorescent test, lymphocytotoxic test platelet immunofluorescence test, enzyme-linked immunosorbent assay (ELISA), and micro-bead based flow cytometry. ELISA and flow cytometry are the more sensitive and least time consuming of these methods.²⁰ For HPA antibodies, ELISA based methods and indirect platelet immunofluorescence testing are available.²¹ If HLA antibodies are detected, the patient's HLA type and HLA antibody specificity should be determined. HLA matched (HLAm) or HLA antigen negative platelet products can then be selected based on the compatibility of the donor/recipient HLA types or platelet products that do not express the cognate HLA antigens to the patient's specific alloantibodies, respectively. The latter approach provides a larger number of potentially compatible products.^{22,23} Alternatively, crossmatch-compatible (XM_c) platelets may also be effective for patients with both HLA and HPA antibodies. Platelet crossmatching can be performed using a solid-phase red cell adherence assay that identifies potential compatibility of a platelet unit without requiring knowledge of the HLA or HPA type or antibody specificity. However, this process can be very labor intensive, especially when looking for XM_c platelet units for patients who are heavily alloimmunized.^{24–26}

IMPETUS AND RATIONALE FOR DMT

Given the various steps and tests involved in diagnosing and managing PR patients, we recognized that our clinicians would frequently order a myriad of tests and not always in the appropriate order for proper PR work up. Some clinicians would informally consult the TM service for help with test/product selection, but often we were not notified of such patients at the start of the investigation. Once notified, TM physicians had to determine what testing still needed to be performed and what, if any, platelet products needed to be ordered. This ultimately led to unnecessary testing and delays in getting the appropriate platelet products to these patients. As such, our TM service decided to streamline the workup and

management of PR patients by developing and implementing a DMT and a formal PR laboratory consult in April 2018. This process was a large cooperative effort among the TM service, blood bank, hospital information technology, the hospital medical practice committee, the billing department, and the hematology service.

IDENTIFYING PROBLEMS IN THE CURRENT MANAGEMENT OF PR PATIENTS

Before implementing a DMT, we first examined the current workup and management of PR patients by performing a retrospective review of requests for HLA and XMC platelet products over the previous 9 months. This review highlighted the need for a standardized system and targeted specific areas for improvement. For example, approximately 60% of the time a CCI was not performed to assess for platelet refractoriness prior to the primary team ordering special platelet products. Another area in which inconsistencies in ordering patterns existed was in antibody testing. At our institution there are two platelet antibody testing platforms: an ELISA based indirect platelet antibody screen (LIFECODES PakPlus) in the Special Coagulation laboratory, which tests for HPA and HLA Class I antibodies, and a FlowPRA screen (One Lambda) used in our HLA laboratory that exclusively detects HLA antibodies. Our review found that the ordering of such screening tests was inconsistent for PR evaluation, highlighting the uncertainty among clinicians of the appropriate tests to order. Further evaluation of the data revealed that sometimes both screening tests were ordered and that some cases were discordant (e.g., negative ELISA, positive FlowPRA). If we were going to develop a diagnostic algorithm to guide our DMT, we first needed to ensure we understood the limitations of the tests for PR evaluation.

To this end, we retrospectively reviewed seven years' worth of data comparing the ELISA results to the FlowPRA in the detection of HLA antibodies. Only ELISA indirect platelet antibody screens that had an accompanying flow cytometry screen were included. We found that of the 348 ELISAs performed during that period, 63 (18%) had corresponding FlowPRA cytometry screens. The FlowPRA was concordant (positive ELISA, positive flow) with the ELISA in all cases, however the ELISA was discordant (negative ELISA, positive flow) to the FlowPRA in 13 cases. Though the ELISA had 100% specificity, the sensitivity was only 68% in comparison to the FlowPRA. Notably, the ELISA would miss high levels of HLA (99% PRA) that were detected on the FlowPRA, possibly due to the hook effect on the ELISA.²⁷ As the FlowPRA was shown to be a more sensitive screen, we decided our algorithm would incorporate both the ELISA and FlowPRA to detect HPA antibodies and improve detection of HLA antibodies, respectively.

An HLA antibody specificity test (LABScreen® Single Antigen Bead [SAB] assay, One Lambda), which defines the targets of the HLA antibodies, is another necessary assay for the evaluation of PR. Our retrospective review found that this test was also ordered inconsistently during the evaluation of PR patients. At times this test was not ordered despite positive FlowPRA results while at other times it was unnecessarily ordered when the FlowPRA results were negative (i.e., in the absence of HLA antibodies). To solve this problem a new test order was created, the HLA Platelet Refractory Screen, which includes

an initial FlowPRA antibody screen with reflex to HLA SAB testing when the antibody screen is positive. This order obviated the need to, and confusion associated with, ordering HLA antibody specificity testing as well as prevented unnecessarily ordering of HLA SAB testing when the FlowPRA screen was negative.

THE PLATELET REFRACTORY DIAGNOSTIC ALGORITHM

Once the baseline functionality of the original process was established and we thoroughly targeted areas that needed improvement, an algorithmic approach to testing, diagnosing and transfusing these patients was developed (Fig. 1). When a clinical team is concerned that a patient may be PR, they place the order “TM Evaluation of PR Patient” via the computerized physician order entry (CPOE). This generates an order set which authorizes the TM service to order and interpret appropriate tests as part of the evaluation (Fig. 2). The order set also sends an automatic notification to the TM service pager. Once the TM service is notified, they request the clinical team to perform a 1-hour CCI using ABO compatible platelets, if not already done, and the resident on the TM service performs a chart review to identify potential causes for PR. When the CCI is above 7,500, no further tests are ordered and the patient continues to receive ABO compatible platelets. When the CCI is less than 7,500, platelet XM testing is initiated, which is performed at an out-of-state reference blood center. Because this testing can take several days, we decided it was best to perform this step before completing the remaining testing in order to prevent delays in receiving XMc platelets, should they be needed. It should be noted that the percentage of tested platelets found to be XMc can also indicate the presence of anti-platelet antibodies not detected by other tests; these results can be obtained from the reference laboratory, and are incorporated into the algorithm. Concurrent to the ordering of XMc platelets, the ELISA indirect antibody screen and FlowPRA screen are ordered simultaneously.

As part of the algorithm, 2–3 XMc platelets are ordered routinely when the CCI < 7,500. After these units are transfused, the TM service follows platelet count increments and reassesses the need for such products. If both antibody screens are negative, and at least 90% of tested platelets were XMc, the patient receives ABO compatible platelets for future transfusions. However, if fewer than 90% are compatible, we take it as an indication of anti-platelet antibodies in the recipient (despite the results of the ELISA and FlowPRA screens) and continue to obtain XMc platelets for future transfusions. If the patient is found to have HPA antibodies via the ELISA screen, the patient will get XMc platelets. This is regardless of whether or not they have HLA antibodies as well, since XMc platelets should account for all antibodies. If the patient is found to have HLA antibodies only, however, the reflex HLA SAB test is ordered as well as the HLA type, if not already available for the patient. Based on the results of these tests, HLA⁺ or antigen-negative platelet products are requested for the patient. When all tests are completed, the TM service issues a comprehensive report detailing the interpretation of the tests and a customized transfusion plan for the patient (see Fig. 3). These reports are entered in the patient’s EMR. All reports are associated with the clinical pathology consultation current procedural terminology (CPT) code 80502 to ensure compensation of the TM service for their evaluation.

PRIOR TO DMT IMPLEMENTATION: EDUCATING SHAREHOLDERS

After the TM service developed and reached consensus on the PR diagnostic algorithm, we approached our clinical colleagues to get their feedback and provide education on how the consult process would work. Given that platelet refractoriness mostly affects hematology patients either undergoing evaluation/induction for stem cell transplant or awaiting engraftment after transplant, we focused our attention on the Hematology department. First, we wanted to ensure that this was a service that they would find beneficial both to patients and their practice as physicians. Second, we wanted their feedback on the algorithm to verify it supplied them with the information they needed and was not too cumbersome to their work flow. Third, we used this time to provide education not only on the process of ordering the consult but the constituent steps of the algorithm, explaining the rationale for each sequential process. Once we had approval from Hematology, we approached hospital administration for approval of our consult and reflex testing therein. In specific, the TM service presented the PR DMT to the hospital's Medical Practice Committee (MPC), which is composed of hospital administration as well as representation from all the major medical specialties. The presentation gave us an opportunity to answer questions concerning the DMT and diagnostic algorithm, and more importantly, to demonstrate the laboratory's commitment to patient care. The DMT was unanimously approved by all the members of the MPC and the DMT was implemented subsequently in April 2018.

EXPERIENCE THUS FAR

We compared our retrospective data of requests for XM_c or HLA_m platelet products prior to the launch of the DMT (described earlier) to PR consult orders placed in the 9 months following implementation of the DMT. Specifically, we wanted to determine if there were improvements in the time it took to complete a 1-hour CCI, ELISA screen, FlowPRA screen, HLA SAB, and for the blood bank to obtain the first XM_c or HLA_m platelet unit for the patient after the TM service was notified.²⁸

There were 12 and 23 patients evaluated for PR preand post-DMT, respectively. The first step the TM service takes in evaluating possible PR patients is asking the clinical team to obtain the 1-hour post-transfusion platelet count. The time to complete the CCI did not appreciably change after the launch of the DMT. The vast majority of CCIs are completed within 1 day. There are, however, a small number of patients that took more than 2 days for a CCI to be performed. We recognized that this step in the algorithm is beyond the control of the TM service and may not be performed until the next day's platelet transfusion. We also had a few cases where the request for drawing a 1-hour platelet count was lost between shift/staff change.

After implementation of the DMT, 100% of patients with a CCI below 7,500 received testing in the appropriate order, including an ELISA and FlowPRA screens, and reflex SAB testing, if indicated. Whereas prior to the DMT, only 92% and 75% of patients had an ELISA and FlowPRA screen, respectively, and only 40% of those with a positive FlowPRA had a SAB assay subsequently performed (Fig. 4A). The time to complete the ELISA screen remained unchanged at a median of 2 days pre- and post-DMT. This test is only offered Monday–

Friday 8:00 AM to 5:00 PM in our Special Coagulation laboratory, so tests ordered late on Friday will not be done until Monday, making the turnaround time 3 days and potentially skewing the data. Conversely, FlowPRA and SAB tests are performed 24 hours a day, 7 days a week. The turnaround time for these tests decreased from a median of 4 days to a median of 2 days following implementation of the DMT. There was also a decrease by 1 day in the median time for patients to receive XM_c platelet units (Fig. 4B). The DMT prevented unnecessary testing in six patients who did not fit the criteria for immune-mediated PR by using a much less expensive 1-hour post-transfusion platelet count, thereby saving our laboratory money and resources.

LESSONS LEARNED

Overall, the PR DMT has improved test utilization for these patients and has decreased the turnaround time to acquiring XM_c platelets, demonstrating the power of implementing such a robust, multidisciplinary process. We continue to monitor the PR DMT process and have identified a few key areas where further improvement is needed. Divergence from the algorithm has occurred in several cases and is likely due to inadequate education of the pathology residents about PR and the process for diagnosing and managing these patients. In academic settings such as our institution, various team members, particularly trainees, on both the clinical and laboratory sides are continually rotating through different services. Such shifting makes consistent and repeated education critical to the success of the DMT, particularly in the first several months of its existence. As noted above, we continue to have difficulty with obtaining a 1-hour CCI in a timely fashion. We are currently working on a process to improve CCI turnaround time by sending a purple top tube with the next platelet unit and instructions regarding the timing of the post-transfusion draw. Hopefully this will mitigate the issue of lost communication between shift/staff change. We also realized the need to build a formal order in the EMR to draw samples to send for platelet XM testing, as TM residents noted that they were spending a significant amount of time coordinating this process with the patients' nurses. Ultimately, the DMT process has already greatly improved the evaluation of PR patients and will only continue to do so with further fine tuning.

SUMMARY

As the field of medicine becomes increasingly sub-specialized, the need for collaborative work between various medical care teams is paramount. This need for collaboration merges with the shift in healthcare from a traditional physician-centric model to a patient-central model. In order to properly diagnose and manage patients efficiently and safely, a multidisciplinary team including both clinical and diagnostic specialties is necessary. Our TM service has demonstrated that streamlining the workup of PR patients with a formal DMT consult can lead to better test utilization and better care for these patients. Since the launch of this DMT, we have been able to expedite the diagnosis of PR, reduce delays in obtaining the appropriate platelet products, and decrease unnecessary testing. We hope our DMT consult can serve as a model for additional DMTs within our own institution and perhaps even inspire and serve as a template for other institutions and services outside of TM.

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Fig. 1.

Algorithm used by the DMT to evaluate patients with a clinical concern for PR.

Fig. 2.

Order set the clinical team selects to request a PR consult.

Transfusion Medicine Service Consultation
Reason for Consultation: Platelet Refractory
Patient name: [REDACTED]

Requesting Provider: [REDACTED]

MRN: [REDACTED]
ICD10: D69.59
CPT: 80502

We were requested to consult on this patient because of the clinical impression of platelet refractoriness. We have thoroughly reviewed the patient's clinical history, in order to identify potential non-immunologic reasons for platelet refractoriness. The patient is known to have AML. In addition, we confirmed the patient's platelet order to receive ABO-compatible platelet transfusions, followed by a 1-hour platelet count to allow calculation of the corrected count increment (CCI).

The CCI was 3000, showing the patient was platelet refractory.

The patient has not received crossmatch-compatible platelets. We ordered an indirect platelet antibody screen and an HLA antibody screen. The indirect platelet antibody and HLA antibody screens were both negative.

Given these results, we did not order any additional testing to identify the specificity of the patient's HLA antibodies (and to identify the patient's HLA type if not already determined) as this was not indicated.

Thus, we do NOT recommend HLA-matched/HLA-compatible platelets for future transfusions. The thrombocytopenia is likely due to the patient's underlying disease for which he is also receiving chemotherapy. We recommend ABO compatible platelet transfusions for any future platelet needs.

Fig. 3.

Example of the report entered into the patient's EMR after completion of the evaluation explaining the assays performed, interpretation of the results, and recommendations moving forward.

Fig. 4.

Comparison of pre- and post-DMT time percentage of patient in which antibody testing was performed (A), and time to complete the ELISA screen, HLA testing, and obtain compatible XM platelet units (B).