


# The development of a quality improvement project to improve infection prevention and management in patients with asplenia or hyposplenia

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**To cite:** O'Neill NE, Baker J, Ward R, *et al.* The development of a quality improvement project to improve infection prevention and management in patients with asplenia or hyposplenia. *BMJ Open Quality* 2020;**9**:e000770. doi:10.1136/bmjopen-2019-000770

Received 9 July 2019

Revised 13 December 2019

Accepted 30 December 2019

## ABSTRACT

Asplenia and hyposplenia (a/hyposplenia) are associated with increased morbidity and mortality from complications including infection. The recommended measures to reduce the risks associated with infection include patient education, vaccination and early initiation of antibiotic therapy for fever. Despite these recommendations, there is poor adherence to best practice management of patients with asplenia or hyposplenia (PWA/H). We present the development methodology and pilot data of a quality improvement project that explored whether a programme involving a novel medical alert card together with a patient and healthcare provider educational booklet increased vaccination rates and improved awareness and understanding of the infectious implications of a/hyposplenia. Our aim was to increase the proportion of those appropriately vaccinated and the proportion of patients with proper understanding of fever management by twofold in 18 months. Questionnaires were used locally as a root-cause-analysis to confirm the need for education and evaluate the effectiveness of the programme, as well as patient satisfaction. An interdisciplinary team developed a toolkit composed of a medical alert card and booklet. The toolkit was distributed to PWA/H who presented for a haematology clinic visit at a tertiary care centre. A separate set of questionnaires was then used to evaluate satisfaction and obtain feedback from patients and practitioners receiving the toolkit for the first time. Changes suggested by patients and practitioners with unanimous agreement among study investigators were made to the toolkit. The pilot study showed an increase in vaccination rates and awareness of vaccination status and appropriate fever management. The majority of the patients and practitioners found the information provided by the toolkit helpful. Given these promising single-centre findings, the intervention is being extended to another tertiary care centre with a large red blood cell disorders programme to evaluate its generalisability. The next step will be to expand the scope to paediatric PWA/H.

## PROBLEM

Patients with asplenia or hyposplenia (PWA/H)) are at risk of life-threatening infection. Overwhelming postsplenectomy infection (OPSI) occurs in 5% of patients<sup>1</sup> and has a mortality rate of 38%–70%.<sup>2–4</sup> Patients

with functional asplenia and hyposplenia (a/hyposplenia) who have not undergone a splenectomy can present with a life-threatening infection comparable to an OPSI.<sup>5</sup> There is specific guidance focused on the prevention and management of infection in this patient population.<sup>6–8</sup> Despite this, PWA/H are often managed inappropriately which leaves them exposed to unnecessary risk and speaks to a gap in knowledge translation.<sup>9</sup> Some work in this patient population has been previously done,<sup>10–11</sup> however, to our knowledge, the evaluation of a multimodal quality improvement intervention for both PWA/H and their healthcare providers has not previously been performed. We present the methodology employed in the development of this programme and the pilot data from a tertiary care centre that explored whether a medical alert card and patient/healthcare provider educational booklet increase vaccination rates and improve awareness and understanding of the infectious implications of a/hyposplenia in adults. Our aim was to double the proportion of those appropriately vaccinated and the proportion of patients with proper understanding of fever management, as this was thought to represent a clinically meaningful change by the study investigators. A secondary objective was to measure patient satisfaction for those who received and used the toolkit, as well as patient and practitioner satisfaction and feedback in those receiving the toolkit for the first time. Satisfaction data and feedback was collected with the aim to successfully extend the intervention to another tertiary care centre, home to the largest Canadian adult red blood cell (RBC) disorder programme in the country managing approximately 1000 PWA/H.

Our pilot site was a tertiary academic hospital. Our target study population was the 100 PWA/H presenting to a haematology



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clinic at the pilot site. Although all PWA/H were eligible to participate, we anticipated the majority of our study population would include patients with relapsed or refractory immune thrombocytopenia (ITP) or thrombotic thrombocytopenic purpura (TTP) who had previously undergone splenectomy given the large patient populations with these conditions at the pilot site. The haematology clinics are staffed predominantly by haematologists and trainees with occasional nursing support. After many years of working in the haematology clinics, it became apparent that many patients' postsplenectomy management fell through the cracks in terms of both vaccination and education regarding the clinical significance of a/hyposplenia. We worried that a patient could die of overwhelming bacterial sepsis without the proper measures having been taken to reduce this risk. It was time for us to address the problem and make it feasible and sustainable for clinicians to 'do the right thing'.

## BACKGROUND

The terms asplenia and hyposplenia refer to absent or diminished splenic function, respectively. Functional a/hyposplenia can be caused by hepatic, gastrointestinal, autoimmune, neoplastic and haematological disorders.<sup>5</sup> Atraumatic indications for splenectomy include malignancy and haematological autoimmune disorders, such as ITP,<sup>12</sup> and other haematological conditions such as inherited RBC disorders (eg, sickle cell anaemia) and TTP.<sup>13</sup> Therefore, it is common for haematologists to manage PWA/H.

The spleen plays an important role in immune regulation and defence. Thus, individuals with a/hyposplenia are at risk of certain infections, including encapsulated bacteria such as *Streptococcus pneumoniae*, *Neisseria meningitidis* and *Haemophilus influenzae* type b.<sup>14</sup> As a result, a/hyposplenia are both associated with increased morbidity and mortality from complications of infection.<sup>15</sup>

Strategies to prevent and reduce the risks of infection in people with a/hyposplenia include vaccination, rapid access to antibiotics and education.<sup>6,8,9</sup> Since fever is often the initial manifestation of infection, PWA/H should be counselled to seek urgent medical care at fever onset.<sup>6</sup> Adult PWA/H should have access to preprescribed antibiotics which should be taken at fever onset if unable to seek medical attention within 2 hours.<sup>6,9</sup> Ideally, PWA/H should carry an alert card or bracelet and an up-to-date vaccination record.<sup>8,16</sup>

Poor communication and education regarding infection risk and preventative measures by healthcare providers for people with asplenia has been described.<sup>9,17</sup> The main barrier to appropriate care is lack of provider recognition of the infection correlative mortality risk associated with a/hyposplenia.<sup>3</sup> There is evidence to support the utility of an alert card and education programme that addresses this infection risk in this patient population.<sup>10,11,18</sup> The risk of infection can be significantly reduced by using systematic, long-term approaches to care of PWA/H.<sup>18</sup>

## MEASUREMENT

### Primary objective

Our aim was evaluated by comparing the results from a baseline preintervention questionnaire to the results from a similar postintervention questionnaire. We measured the self-reported vaccination status for pneumococcal, *Haemophilus influenzae* type b, meningococcal and influenza vaccines as a co-primary outcome measure. A patient was considered to be completely vaccinated if they were up-to-date with all of the four vaccines. Patient awareness of appropriate fever management was the other co-primary outcome measure defined by their understanding to present for urgent medical care at fever onset as indicated by the patient's response to an open-text question. An additional outcome measure was evaluated as the proportion of patients who reported they had been prescribed an antibiotic to use if more than 2 hours from medical attention at fever onset.

### Secondary objective

Using Likert Scale based responses, we evaluated the helpfulness of the toolkit as a co-secondary outcome measure. These questions were included in the postintervention questionnaire completed by patients exposed to the toolkit. Patients and practitioners from the sites receiving the toolkit for the first time completed a questionnaire involving Likert Scale based questions focused on utility and clarity of the information provided in the toolkit. Questions regarding clarity of the toolkit were specified to page and/or section (eg, clarity of the management algorithm) to evaluate the other co-secondary outcome measure. The perspective of patients and practitioners on the need for information on the asplenic/hyposplenic condition was an additional outcome measure. We provided an open-text portion of the questionnaire where we asked for qualitative feedback to allow for iterative improvement of the toolkit.

A questionnaire method has been used in similar patient populations to ascertain patient knowledge of infection and its prevention.<sup>10,17</sup> The questionnaires were a cost-effective method that would assess our outcome measures with minimal disruption of clinical flow. The questionnaires also provided anonymity, particularly important for questions regarding satisfaction.

### Baseline measurement

At the pilot site, 28 patients completed the baseline preintervention questionnaire. Ten (36%) patients claimed they were completely vaccinated. The proportion of patients who said they were vaccinated against pneumococci, *Haemophilus influenzae* type b, meningococci and influenza virus was 50%, 39%, 50% and 39%, respectively. At baseline, 5 of 20 (25%) patients were aware of appropriate fever management. None of the 28 patients said they had been prescribed an antibiotic to use if more than 2 hours away from medical attention at the time of fever onset.

## DESIGN

We conducted a prospective, multimodal, sequential quality improvement study in the haematology clinics at a tertiary care centre (pilot site), and secondarily in a large RBC disorders programme at another tertiary care centre (extension-study site). The study involved three phases within 18 months where we: (1) Designed a toolkit to enhance awareness and understanding of infectious management of PWA/H. (2) Implemented the toolkit and evaluated its effectiveness. (3) Evaluated patient and provider satisfaction with the toolkit and refined it accordingly. We allocated 3 months to phase I, and the remaining 15 months to phase II and phase III; with the distribution of the toolkit and preintervention questionnaire taking place in months 4 to 16 (ie, for 1 year). The project began by assembling a team to develop a toolkit consisting of a medical alert card and educational booklet for patients and their healthcare providers. We presumed the intervention would be feasible since a medical alert card and booklet for other conditions had previously been effectively incorporated in other haematology clinics at the pilot site. We chose a medical alert card and education intervention based on recommendations made in previous studies,<sup>8 16</sup> and the benefits shown in an existing programme.<sup>10 18</sup> In the haematology clinic, a preintervention questionnaire was administered to patients prior to the distribution of the toolkit. The postintervention questionnaire was administered at the patient's next visit to the clinic. We also intended to evaluate the long-term sustainability (eg, 1–2 years after baseline) of awareness and understanding of fever management and the infectious implications of a/hyposplenia. This did not occur as there was no specific study budget which led to a lack of dedicated research personnel available at these time points. To further assess satisfaction and obtain recommendations to improve the toolkit materials, a set of questionnaires was administered to patients and providers who were previously unfamiliar with the toolkit at the pilot site and the extension-study site. Unanimously agreed on recommendations were implemented and new versions of the toolkit materials were subsequently created.

## STRATEGY

### Phase I: development of the toolkit

The aim of phase I was to develop the toolkit materials to enhance vaccination rates and fever management among adult PWA/H.

The root-cause-analysis began with a librarian-assisted literature search and through that we found that the main reported barrier to appropriate care for PWA/H was lack of provider recognition of the infection associated mortality risk.<sup>3</sup> Furthermore, there was previous evidence to support the utility of an alert card and targeted education programme that addresses the infection risk in this patient population.<sup>10 11 18</sup> With this evidence we proceeded to develop a toolkit that would include a medical alert card and educational booklet. Thus, an interdisciplinary team

of stakeholders was engaged and provided strategies to enhance the medical management of PWA/H. A project team was assembled including adult and paediatric haematologists, an infectious diseases specialist, a nurse practitioner and research personnel. A toolkit consisting of a medical alert card and educational booklet for PWA/H was developed. The toolkit was targeted towards both patients and practitioners. The information included in the toolkit was based on published guidance on the care of patients with asplenia<sup>6 7</sup> and vaccination recommendations were adapted from the Canadian Immunisation Guide (section on immunisation of persons with asplenia or hyposplenia).<sup>19</sup>

The toolkit materials were reviewed by the patient education department for plain language. The toolkit was reviewed by the Antimicrobial Subcommittee at St. Michael's Hospital, to ensure that the information was consistent with the hospital's current policies and procedures.

### Phase II: evaluating effectiveness of the toolkit

The aim of phase II was to evaluate the effectiveness of the initial iteration of the toolkit at the pilot site. A secondary aim was to assess patient satisfaction with the toolkit.

Adult PWA/H seen by a haematologist were identified by their haematologist and approached to participate during their appointment scheduled in accordance with standard of care. Eligible patients were asked to complete a questionnaire to determine baseline vaccination status and awareness and understanding as part of a further needs assessment. The questionnaire measured patients' awareness of their vaccination status and understanding of a/hyposplenia including appropriate fever management. Following the questionnaire, the toolkit was distributed to the PWA/H. A postintervention questionnaire was completed by the patient at their next clinic visit (typically more than 3 months from the original appointment) to reassess vaccination status, knowledge acquisition and its sustainability, and patient satisfaction. This phase of the study served to: (1) Confirm the need for education. (2) Evaluate the effectiveness of the toolkit. (3) Provide rationale for extension to a larger patient cohort at the extension-study site.

### Phase III: evaluating patient and practitioner satisfaction and feedback

The aim of phase III was to evaluate patient and practitioner satisfaction and obtain feedback from individuals receiving the toolkit for the first time. A questionnaire was designed with two parts: Part 1: Satisfaction and Part 2: Feedback. Two versions were created: one patient-specific and one practitioner-specific. The practitioner-specific questionnaire and toolkit was distributed via email to physicians affiliated with either site and who would likely encounter the toolkit materials in real clinical practice (ie, family and emergency physicians). The patient-specific questionnaires with the toolkits were distributed at both hospitals to PWA/H attending haematology clinics.

### Patient and practitioner satisfaction

Part 1 was designed to measure patient and practitioner satisfaction with the toolkit using a Likert Scale and an open-text format.

### Patient and practitioner feedback

Part 2 of the questionnaire was in open-text format to obtain open-ended feedback. Suggestions were summarised and project investigators individually voted to agree or disagree with each suggestion. Changes with unanimous agreement among study investigators were made to the toolkit. Changes that were not unanimously agreed on were discussed until study investigators came to an agreement.

## RESULTS

### Phase I: development of the toolkit

Within 3 months, a toolkit consisting of a medical alert card and educational booklet for PWA/H was developed to enhance vaccination rates and fever management. The medical alert card provided identifying information, vaccination records, action items at fever onset and vaccination schedules. The booklet, targeted to both patients and clinicians, provided information on a/hyposplenism, signs and symptoms of infection, vaccinations, and vaccination schedules. A section was dedicated to fever management including an algorithm adapted from literature<sup>6,7</sup> with information on blood cultures and administration of antibiotics.

### Phase II: effectiveness of the toolkit

Vaccination status and awareness and education of a/hyposplenism

The 28 PWA/H who received the toolkit completed a postintervention questionnaire at their next visit to the haematology clinic. As anticipated, the majority of patients who received the toolkit were patients with ITP or TTP given the large patient populations with these conditions at the site. The median duration between the completion of the preintervention and the postintervention questionnaire was 119 (19–428) days. Preintervention and postintervention vaccination rates are presented

in table 1. Preintervention, 36% of patients reported that they were completely vaccinated. Importantly, postintervention, 61% of patients reported that they were completely vaccinated and three (11%) patients were taking measures to become appropriately vaccinated. The number of patients aware of appropriate fever management increased from 7 (25%) to 18 (64%). Preintervention, none of the patients reported having a prescribed antibiotic if more than 2 hours away from medical care at fever onset. Postintervention, 18 (64%) patients were aware of having a prescribed antibiotic for this indication.

### Patient satisfaction

Of the 28 patients who obtained the toolkit, 27 completed the satisfaction questionnaire. The reported helpfulness of the medical alert card and booklet was 74% and 85%, respectively.

### Phase III: patient and practitioner satisfaction and feedback

Phase III began after the toolkit was distributed for 1 year at the pilot site and was completed within 1–2 months.

### Patient and practitioner satisfaction

Ten PWA/H, five from each site, who were receiving the toolkit for the first time completed the satisfaction questionnaire. All of the patients found the information in the toolkit helpful or very helpful. Eight (80%) patients found the booklet understandable. Eight of nine (89%) patients agreed that there is a need for information for patients (with one non-respondent).

Eleven physicians; three emergency and three family physicians from the extension-study site, and two emergency and three family physicians from the pilot site, completed the satisfaction questionnaire. Written feedback was obtained from an additional emergency physician practising at the pilot site. Ten (91%) physicians found the toolkit helpful or very helpful. Six (55%) physicians found the vaccination schedules easy to follow. Nine (100%) physicians agreed that there is a need for information on a/hyposplenism for healthcare providers (with two non-respondents).

The results of questionnaires evaluating patient and practitioner satisfaction were used to modify the toolkit. The vaccination schedules were removed from the booklet and back of the medical alert card since almost half of the physicians found the schedules only 'somewhat easy to follow' and since the specific vaccines recommended by the Canadian Immunisation Guide and public funding for these vaccines were subject to change over time. Therefore, to improve clarity and ensure that our toolkit was not providing guidance that could be out of date, a direct link to the Canadian Immunisation Guide for persons with a/hyposplenism<sup>19</sup> was provided in the educational booklet and on the back of the medical alert card. The current version of the medical alert card (figures 1 and 2) will be distributed at the extension-study site.

**Table 1** Preintervention and postintervention vaccination rates

	Preintervention, N (%)	Postintervention, N (%)	Change, N (%)
Pneumococcal vaccine	14 (50)	19 (68)	5 (18)
<i>Haemophilus influenzae</i> type b vaccine	11 (39)	18 (64)	7 (35)
Meningococcal vaccine	14 (50)	19 (68)	5 (18)
Influenza vaccine	11 (39)	16 (57)	5 (18)
Completely vaccinated	10 (36)	17 (61)	7 (35)

**MEDICAL ALERT**
**Person with Asplenia  
or Hyposplenia**

Patient name
Date of birth (YY/MMM/DD)
Emergency contact name
Emergency contact phone

Vaccination	Date of 1st Dose DD/MMM/YY	Date of 2nd Dose DD/MMM/YY	Date Reimmunization Due DD/MMM/YY
Meningococcal conjugate A,C,Y,W-135 (Menactra, Menveo, Nimenrix)			
Meningococcal polysaccharide A,C,Y,W-135 (Menomune)		Not applicable	Not applicable
Multicomponent meningococcal B (Bexsero)			Not applicable
Haemophilus influenzae type B conjugate (Act-HIB, Hiberix)		Not applicable	Not applicable
Pneumococcal conjugate 13-valent (Pneumar 13)		Not applicable	Not applicable
Pneumococcal polysaccharide 23-valent (Pneumovax 23)		Not applicable	

Vaccination	Reimmunization	Date Received	Date Received	Date Received	Date Received
Seasonal influenza (flu)	Administer every year				

**What to do if you have a fever**  
 If your temperature is 38.0°C (100.4°F) or higher, **immediately** go to the nearest Emergency Department for treatment.  
 If you cannot get to a hospital within 2 hours of when your fever started, take a single dose of  
 \_\_\_\_\_  
 (Name of prescribed antibiotic)  
 and go to the nearest Emergency Department. **Show this wallet card to the doctor taking care of you.**

Physician Name \_\_\_\_\_  
 Physician Signature \_\_\_\_\_ Date \_\_\_\_\_

**Figure 1** Front of the medical alert card.

### Patient and practitioner feedback

The results of the feedback questionnaire were used to modify the toolkit prior to future implementation at the extension-study site. Of the 10 patients who completed the questionnaire, 4 found that there was no important information missing from the toolkit. Two patients suggested to include information on how to prevent infection other than vaccinations (eg, hand washing). The suggestions provided by all 12 contacted physicians were summarised into 18 suggestions. Fourteen (78%) suggestions were incorporated as there was unanimous agreement among study investigators. No other changes were made after discussion occurred between study investigators on each suggestion that was not unanimous. In response to the physicians' requests, more detailed information regarding admission to hospital and patient follow-up was added to the flow chart for fever management. The flow chart was added to the back of the medical alert card to increase its accessibility to healthcare providers (figure 2).

### LESSONS AND LIMITATIONS

We successfully increased vaccination rates and awareness of proper fever management. The incorporation of feedback from key stakeholders critically improved the toolkit and will facilitate extension of the study to other sites.

#### Information for Healthcare Providers: Vaccinations

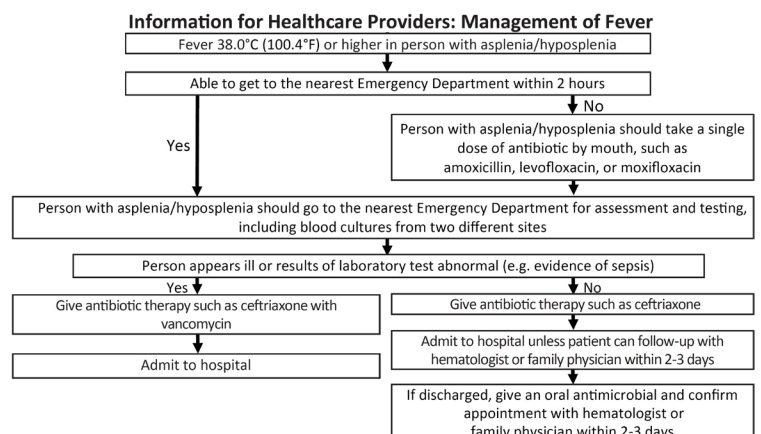
See the Canadian Immunization Guide for the most current recommendations at:

Website: <http://bit.ly/CanadianImmunizationGuide>

Please contact the on-call infectious disease physician and/or on-call hematologist at your institution for any questions and additional guidance.

A limitation of this project was that it relied on self-reported vaccination status if there was insufficient clinical documentation of a participant's vaccination status. Unless the patient had received the vaccine at the pilot site (eg, perioperatively for splenectomy performed at the pilot site), the patient's vaccination status could not be obtained by their haematologist through their hospital electronic medical record. Although a limitation, the poor documentation of vaccination status further highlighted the need for a readily available medical alert card that accurately describes patient vaccination status. The haematology clinics at the pilot site were not regularly equipped to provide vaccinations. Therefore the patient faced a barrier of receiving timely vaccinations. This emphasised the benefit of equipping the haematology clinics to provide vaccinations to PWA/H. We do not expect these to be limitations in the extension study since the haematology team provides vaccinations routinely to their patient population.

Another limitation of this project was that the postintervention questionnaire was not distributed at a consistent interval after receiving the toolkit. This is due to the different follow-up requirements of each individual patient. Unfortunately, up-to-date vaccination records were not always available at the time the postintervention



**Figure 2** Back of the medical alert card.



questionnaire was administered, especially in patients who were followed frequently by their haematologist. The incomplete availability of vaccination records likely attenuated the effect of our intervention. Also, the postintervention outcomes were measured at only one time point, usually within 4 months of receiving the toolkit. Long-term sustainability of the awareness and understanding of the implications of a/hyposplenia could therefore not be measured.

We learnt to establish a clear duration required between the completion of the preintervention and postintervention questionnaires and to extend the study duration to allow for sustainability to be measured. At the extension-study site, the postintervention questionnaire will be administered to participants at a clinic visit 3–9 months and 12–24 months from baseline which is in line with their routinely booked clinic visits which appear to be more standardised for clinical reasons than at the pilot site.

Another limitation is the potential lack of generalisability. The intervention was implemented mainly to an ITP and TTP adult patient population. In order to evaluate the generalisability of the intervention we will extend the intervention to additional (eg, sickle cell disease population) and larger patient populations at the extension-study site.

## CONCLUSION

This quality improvement project addressed an important knowledge and care gap for PWA/H and their healthcare providers. Our aim was met as we increased self-reported appropriate vaccination status exactly by twofold in 18 months, from 36% to 72%, if we consider the 61% of patients completely vaccinated and 11% taking the necessary steps to become appropriately vaccinated. Also, the proportion of patients aware of appropriate fever management increased greater than twofold from 25% to 65%. We also met our secondary objective by obtaining patient and practitioner satisfaction and feedback to facilitate extension of the intervention to another centre.

The results of the baseline patient understanding and awareness of the condition of a/hyposplenia is comparable to the results of two previous cohort studies.<sup>3 10</sup> Also, similar to previous work, a programme involving a medical alert card was found to improve uptake of recommendations.<sup>10</sup>

The infectious implications of a/hyposplenia have previously been described in the literature, as have the recommendations for infection prevention and the lack of adherence to this guidance. Readily available tools to facilitate the awareness and understanding of these prevention strategies are lacking. This study not only reports on the lack of understanding and awareness, but it also measures the improvement of these outcomes associated with the intervention.

The increase in reported vaccination rates and the awareness of vaccination status and appropriate fever

management provided a signal of effectiveness and rationale to continue to distribute the toolkit to PWA/H at the pilot site. Any PWA/H who present to a haematology clinic at the pilot site will receive a toolkit. Therefore we have the potential for an additional 70 patients to be positively impacted by the intervention. We will also implement an extension study to an RBC disorders programme at another tertiary care centre to evaluate its generalisability and effectiveness in a larger patient cohort. This programme manages approximately 1000 PWA/H including those with sickle cell disease and thalassaemia. Patients identified as a PWA/H will be given a tablet device to complete the web-based preintervention questionnaire in the waiting room. During the patient's appointment the haematologist or nurse practitioner will distribute the toolkit and provide education on living with asplenia/hyposplenia, and provide vaccinations, if applicable. The postintervention questionnaires will be completed during a clinic appointment 3–9 months and 12–24 months from baseline. If enhanced vaccination rates and sustained awareness and understanding among PWA/H regarding the importance of vaccination and appropriate fever management are demonstrated, we plan to offer this intervention widely to adult PWA/H and healthcare providers, at no cost.

Thereafter, we plan to expand the scope of our toolkit to paediatric patients. Paediatric PWA/H should benefit from similar strategies,<sup>20</sup> however, there are significant differences in the paediatric age group that must be addressed such as: use of prophylactic antibiotics, age-related vaccination schedules and family centred care.<sup>20</sup> The existing toolkit will be substantially modified for the paediatric population and evaluated through implementation in the haematology/oncology department at a quaternary care paediatric hospital. The ultimate hope is that this intervention will reduce the risk of infection, its associated morbidity and mortality, as well as empower patients to facilitate their safe medical care.

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**Acknowledgements** The authors thank Dr Martina Trinkaus, Dr Katerina Pavenski, Amy Skitch, Jessica Petrucci, Avery Longmore and Nicole Veloce for their assistance with patient recruitment and data collection. The authors also thank patients and practitioners for their participation in the study. The authors also thank the Antimicrobial Subcommittee and Patient and Family Education at St. Michael's Hospital for reviewing the toolkit.

**Contributors** NEO, JB, RW, CJ, LT, MS: contributed to the study design; contributed to the toolkit design; reviewed data collection tools; revised the paper

critically for important intellectual content; provided final approval of the paper; and agreed to be accountable for all aspects of the work. NEO, JB, RW, CJ, LT, MS, the Antimicrobial Subcommittee and Patient and Family Education at St. Michael's Hospital reviewed the toolkit. NEO, RW, CJ and MS contributed to patient recruitment and data acquisition. NEO and MS designed data collection tools, analysed and interpreted the data, and drafted the paper.

**Funding** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests** MS reports peer-reviewed grants for unrelated studies from Association of Hemophilia Clinic Directors of Canada Shire and Hemostasis and Thrombosis Research Society; unrestricted grants for unrelated studies from Octapharma, Amgen, Shire and Roche; personal fees from Novartis advisory board, Octapharma advisory board and Bayer advisory board. All other authors have nothing to disclose.

**Patient consent for publication** Not required.

**Ethics approval** This initiative was formally reviewed by institutional authorities and deemed to neither require Research Ethics Board approval nor written informed consent from participants.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article.

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