Hematopoietic Stem Cell Donor and Recipient Evaluation

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Donor selection and evaluation is crucial to hematopoietic stem cell transplantation. Evaluation of donor fundamentally assesses the risk of infectious disease transmission to the recipient and improves the quality of hematopoietic progenitors cell (HPC) product. It also minimizes the chances of adverse donor reactions during the donation process. Ideally, the donor evaluation should involve eliciting a detailed medical history, high-risk behavior, and psychosocial evaluation followed by a complete physical examination and a battery of investigation. Any abnormal finding would not necessarily lead to donor deferral but help the clinical team to closely access the risk versus benefit. It is mandatory to take informed written consent from all donors. Special considerations are taken in autologous patients and pediatric donors to obtain a good quality HPC product. A thorough review and evaluation of all vital organ function in the recipients should be completed to determine transplant eligibility. The disease status at the time of HSCT will help the physician determine the conditioning regimen to prescribe. Pre-transplant psychosocial risk factors are said to predict survival after HSCT. The hematopoietic cell transplant comorbidity index (HCT-CI) is a commonly used tool to score pre-transplant comorbidities that predict non-relapse mortality and survival. Patient and donor education is a vital part of care for HSCT patients, their families, and informal caregivers. Proper documentation of consents, procedures, and treatment plan should be done in compliance with regulatory guidelines. FACT-JACIE International Standards Accreditation covers clinical program related to cellular therapy. Accreditation requires trained, competent staff and a quality management plan, which includes policies and standard operating procedures for a cellular therapy program.

Abstract

Donor selection and evaluation is crucial to hematopoietic stem cell transplantation. Evaluation of donor fundamentally assesses the risk of infectious disease transmission to the recipient and improves the quality of hematopoietic progenitors cell (HPC) product. It also minimizes the chances of adverse donor reactions during the donation process. Ideally, the donor evaluation should involve eliciting a detailed medical history, high-risk behavior, and psychosocial evaluation followed by a complete physical examination and a battery of investigation. Any abnormal finding would not necessarily lead to donor deferral but help the clinical team to closely access the risk versus benefit. It is mandatory to take informed written consent from all donors. Special considerations are taken in autologous patients and pediatric donors to obtain a good quality HPC product. A thorough review and evaluation of all vital organ function in the recipients should be completed to determine transplant eligibility. The disease status at the time of HSCT will help the physician determine the conditioning regimen to prescribe. Pre-transplant psychosocial risk factors are said to predict survival after HSCT. The hematopoietic cell transplant comorbidity index (HCT-CI) is a commonly used tool to score pre-transplant comorbidities that predict non-relapse mortality and survival. Patient and donor education is a vital part of care for HSCT patients, their families, and informal caregivers. Proper documentation of consents, procedures, and treatment plan should be done in compliance with regulatory guidelines. FACT-JACIE International Standards Accreditation covers clinical program related to cellular therapy. Accreditation requires trained, competent staff and a quality management plan, which includes policies and standard operating procedures for a cellular therapy program.

Keywords

Hematopoietic stem cell transplantation · Evaluation · Medical history · Complete physical examination · Pediatric donors · Accreditation · Adverse reactions · Apheresis · Consents · Central line · Eligibility · Comorbidity index · Caregiver
Introduction

Hematopoietic stem cells (HSC) derived from bone marrow (BM) or peripheral blood (PB) provide for more than 68,146 allogeneic HSC transplants annually (Niederwieser et al. 2016). Normally, HSC reside in the bone marrow and could be collected by aspirating from the posterior iliac bones. In recent times, increasingly growth factors or chemotherapy is being used to mobilize HSC into the PB and subsequently collected from the blood by apheresis. 70% of the collected HSC grafts are obtained from related donors and 30% from unrelated donors to recipients. Donor selection and evaluation is crucial to hematopoietic stem cell transplantation. Donor selection is mainly based on the HLA matching, age of the donor, and relation and type of transplant. It ensures selection of the best available donor, minimizing the risk to the donor and the recipient during transplantation. Donor evaluation fundamentally assesses the risk of infectious disease transmission to the recipient and the quality of the hematopoietic progenitor cell product (HPC) and minimizes the chances of adverse donor reactions during the donation process. Ideally, the donor evaluation should involve eliciting a detailed medical history and high-risk behavior, followed by a complete physical examination and a battery of investigations (see Fig. 1). It is not only crucial to minimize the risk of transmissible infections in the recipients, but also to have an understanding of potential physical and psychological implications of donation on the donors. Therefore, it is advisable to perform the pre-donation evaluation within 30 days of planned donation (Aprili et al. 2013). Hematopoietic stem cell transplant (HSCT) is a potentially life-saving treatment for patients with hematologic malignancies and some non-malignant blood diseases. The treatment carries a high risk of morbidity and mortality. Non-relapse mortality (NRM) is associated with infection, or organ dysfunction. Additionally, allogeneic recipients carry the risk for graft-versus-host disease (GvHD). Recent studies have shown improvements in outcomes over the
past few decades explained mainly by the decreased risk of NRM (Tanaka et al. 2016). Improved supportive care has made this treatment accessible to many patients, who were earlier ineligible. Recipient selection becomes even more vital as we offer this treatment to a more diverse population of patients.

Medical History

It is important to assess the risk of transmission of at least the following infectious agents:

- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human immunodeficiency virus (HIV)
- Cytomegalovirus (CMV)
- West Nile virus
- Human T-cell lymphotropic virus 1/2 (HTLV)
- Syphilis
- Chagas

Since there are many more pathogens and emerging infections than available tests to detect them, a detailed medical history of any present or past infections becomes indispensable. The art of eliciting relevant medical history by a trained physician could also overcome the shortcoming of test that may be falsely negative. It is important to enquire about any history of disease exposure to hepatitis, toxoplasmosis, and tuberculosis. A HPC donor questionnaire (see Fig. 2) would systematically cover history pertaining to sexual behavior, drug abuse, and interventional procedure like surgeries, tattooing, dental treatment, etc. A positive answer would not necessarily lead to donor deferral but help the clinical team to closely access the risk versus benefit. Travel history and location of residence could help identify additional risk of malaria, severe acute respiratory distress (SARS), bovine spongiform encephalopathy (BSE), and tick-borne infections. Screening potential donors could yield clues to potential genetic and immune defects that are transmissible (Horowitz and Confer 2005). Family history of the donor may also suggest a possibility of inherited thrombotic states. For example, Factor V mutation and prothrombin (Aprili et al. 2013). In addition, NMDP and FACT-AABB have devised a model questionnaire in this regard for further reference.

Psychosocial Evaluation

Psychosocial evaluation of all donors is advisable before donation. It helps to identify donor motivations. Related and unrelated donors may have different reasons to donate, but negative outcome of transplant may have an adverse impact on the donor’s mind. ELIPSY (ARTHIQS European Union 2014) suggested the assessment of the following aspects:

- Quality of life before and after donation
- Socioeconomic status
- Employment status
- Motivations for donation
- Psychological well-being before and after donation
- Experience of donation
- Pre-donation information about the procedure
- Impact of recipient outcome

Physical Examination

A complete physical examination, including assessment of venous access for apheresis collections, is undertaken by a trained physician, who is not associated directly with medical care of the recipient to avoid any bias (Bräuninger et al. 2014). A general physical examination is done to rule out any skin rash, ulcer, recent tattoo, jaundice, genital lesions, oral thrush, lymphadenopathy, or any organomegaly. For BM donors, other than the site of collection (posterior iliac spine), special attention is given to oral airways and spine, as the donors are subjected to intubation during anesthesia. The rationale behind donor physical examination is to identify signs of any behavioral or physical abnormality, such as intravenous drug abuse or any illness (Horowitz and Confer 2005).

Based on the medical history, a targeted systemic examination is done to evaluate clinical
Apheresis Program, HCT Division, Department of Clinical Haematology and HCT

**Allogenic Donor Screening Form-HPC, Apheresis and HPC, Marrow**

| Name of Donor | Age/Sex: |
|--------------|----------|
| Address:     | Mobile No. |
| Name of the Patient: | Relation to the patient: |

Screening of donors protects the patient (the recipient) from transmission of infectious diseases and protects the donor as well. Kindly answer the questions below carefully and honestly.

Please be assured that your responses shall be kept confidential at all times. A ‘YES’ answer may not necessarily exclude you from donating stem cells. Thank you.

| Donor Questionnaire                                                                 | Yes | No |
|-----------------------------------------------------------------------------------|-----|----|
| Are you feeling good today?                                                        |     |    |
| Do you have hypertension or diabetes?                                              |     |    |
| Do you have any skin disease, persisting diarrhoea or cough or burning urination? |     |    |

|                                                                                     |     |    |
| In the last one **week** have you                                                  |     |    |
| Had cold, cough, sore throat or any other infection?                               |     |    |
| Taken any medication?                                                              |     |    |

|                                                                                     |     |    |
| In the past **8 weeks** have you                                                   |     |    |
| Had any vaccination? If yes, which                                                 |     |    |

|                                                                                     |     |    |
| In the past **3 months** have you                                                  |     |    |
| Had malaria or dengue?                                                             |     |    |
| Have undergone any dental procedure or root canal treatment?                      |     |    |
| Had a tattoo or ear or body piercing?                                             |     |    |

|                                                                                     |     |    |
| In the past **6 months** have you                                                  |     |    |
| Had a Zika virus infection or had sexual contact with a Zika virus infected person? |     |    |
| Lived in or traveled to an area with an increased risk for Zika virus transmission? |     |    |
| Have you undergone any surgery or procedure that involved local/ spinal or general anesthesia? |     |    |

|                                                                                     |     |    |
| In the past **12 months** have you                                                |     |    |
| Had a blood transfusion?                                                           |     |    |
| Come into contact with someone else’s blood or had an accidental needle-stick?    |     |    |
| Had sexual contact with anyone else who takes money or drugs?                     |     |    |
| Had sexual contact with a male who has ever had sexual contact with another male? |     |    |

Fig. 2 (continued)
| Question                                                                 | Yes | No |
|--------------------------------------------------------------------------|-----|----|
| Lived or had sexual contact with a person who has hepatitis?             |     |    |
| Lived or had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus |     |    |
| Had a transplant or graft such as organ, bone marrow, stem cell, cornea, sclera, bone, skin or other tissue? |     |    |
| Had or been treated for syphilis or other sexually transmitted infections? |     |    |
| Been in juvenile detention, lockup, jail or prison for more than 72 hours? |     |    |
| Had a dog or animal bite?                                                |     |    |
| For women: have you had pregnancy, miscarriage or abortion or breast feeding? |     |    |
| **Have you EVER**                                                        |     |    |
| Had a positive test for the HIV/AIDS virus or hepatitis?                 |     |    |
| Been diagnosed with any neurological disease or mental health disorder?  |     |    |
| Had heart disease or kidney disease or cancer or stroke or epilepsy or severe allergy? |     |    |
| Had a bleeding condition or a blood disease?                            |     |    |
| Had any autoimmune disease like psoriasis, rheumatoid arthritis etc.?    |     |    |

Signature of the Donor: ______________________ Date: ______________________

Doctor’s comments:

Name & Signature of Doctor

Fig. 2  Sample donor questionnaire
risk factors. Review of neurological, respiratory, cardiovascular, gastrointestinal, and musculoskeletal systems, assisted with imaging (chest X-ray, abdominal ultrasonography, echocardiography), would help in identifying comorbidities and plan the donation appropriately (see Fig. 3). Since BM collections take place under anesthesia, it is imperative that the pre-anesthetic check-up is done. For PB stem cell collections, assessment for venous access is crucial. Usually for a healthy donor, peripheral venous access on cubital fossa is preferred for drawing blood. Care is taken not to use the vein before harvesting. Allogeneic donors with poor venous status and autologous donors are subjected to central line insertion through jugular/subclavian/femoral veins for the collection of peripheral stem cells. Similar to the criteria for non-cardiac surgery, a pre-donation risk score is assessed to ensure the donor’s physical fitness for PB stem cell or BM donation (Worel et al. 2015). In case of any abnormality, further testing and specialist consultant is desirable.

**Laboratory Investigations**

Complete blood counts and peripheral smear examination of the donor give several clues to any underlying disease in the donor. Mild anemia (<2 g/dL below lower limit of normal) is acceptable for HPC donation. High-performance liquid chromatography (HPLC) is done to identify donors with hemoglobinopathies. Persons with thalassemia trait or α-thalassemia or β-thalassemia minor are considered suitable for HPC donation (Worel et al. 2015). Growth factors are avoided in donors with sickle cell disease and sickle cell β-thalassemia as it may cause severe sickle cell crises (Worel et al. 2015). Hence, PB stem cell collections are not recommended in these complex sickle hemoglobinopathies. Donors with thrombocytosis are deferred from HPC donation due to the increased risk of venous thromboembolism. Donors with platelet disorders having excessive bleeding or bruising are also deferred (see Fig. 4). If peripheral blood smear examination reveals red cell abnormalities like predominant spherocytes or elliptocytes or parasites, donor is not advised to donate HPC until further evaluation and treatment. Blood tests are done to screen for infectious disease markers based on country-specific regulatory guidelines and may at least include:

- HIV (anti-HIV1 and 2)
- HBV (HBsAg)
- HCV (anti-HCV)
- Syphilis (VDRL, TPHA)
- CMV (anti-CMV IgM, IgG)
- HTLV (anti-HTLV1/2 IgG)
- Chagas
- Malaria
- Toxoplasmosis (anti-toxoplasma IgG, IgM)
- ABO/Rh blood grouping
- Antibody screening
- Compatibility testing with the recipient’s blood samples.

In females of reproductive age group, β-HCG is also done to exclude the possibility of pregnancy, as growth factor mobilization may have undesired adverse effects on pregnancy (including the risk of spontaneous abortion).

**Adverse Donor Reactions**

HPC collections from donor (allogeneic) or from the patient (autologous) are not without adverse effects. Even though, HPC donation is a safe procedure, it may cause adverse reactions. Hence, it is desired to assess all donors for increased risk of adverse reactions. BM donation has higher incidence of anemia, hemorrhage, hypotension, and longer stays in the hospital. The reported adverse events with BM donation are 56% and with apheresis collection are 46%. However, there is no definite evidence to suggest any method safer than the other (Siddiq et al. 2009). The estimated apheresis procedure-related mortality is 3 per 10,000 procedures (Kenyon and Babic 2018). The most common apheresis procedure-associated morbidity is related to citrate toxicity, which may manifest with features of hypocalcaemia. Hence pre-procedure serum calcium levels in the donor would guide calcium supplementation.
## HCT DONOR WORK-UPSHEET

| Name of Donor | Age/Sex: |
|---------------|----------|
| MR No.        | Date of Birth: |
| Email ID:     | Mobile No. |
| Name of the Patient | Relation to the patient: |

### Significant Medical History (any co-morbidities):

### Medications (if Any):

### PHYSICAL EXAMINATION:

| Ht (cms): | Wt (Kgs): | BSA: | PR (bpm): | BP (mmHg): | Temp(˚F): |
|-----------|-----------|------|----------|-----------|-----------|
| Cubital veins: | | | | SpO2: | RR (cpm): |
| RS: | | | | PA: | Iliac region (in BM Donors): |

### LABORATORY TESTS:

#### Haematology:

1. Hb (g/dl):.......................... 2. Platelet Count (/mm³):.......................... 3. TC/DC (/mm³):.......................... 4. Peripheral blood smear & Retic count (as reported by Lab Consultant):..........................

#### Coagulation:

5. Prothrombin Time: ......... 6. Partial Thromboplastin Time: ......... 7. INR: .........

#### HLA studies:

HLA match: ..........................

#### Biochemistry:

1. Liver Function Tests
   - Bilirubin (mg/dl): Total- .......................... Conjugated- ..........................
   - Total Protein (g/dl):.......................... Albumin (g/dl):..........................
   - SGOT(U/l):.......................... SGPT(U/l):.......................... ALK PHOS (U/l):..........................
2. Creatinine (mg/dl):.......................... Urea:..........................
3. Serum Electrolytes: Na:.............. K:.............. Calcium: .......................... Mg: .......................... Phosphorus: ..........................

Only in donors of thalassemia patients:

4. HPLC: ..........................
5. S. Ferritin: ..........................

Fig. 3 (continued)
Hypovolemia in donors could be anticipated in anemia, low birth weight, and cardiovascular compromise (Kenyon and Babic 2018). Therefore, the pre-donation assessment would help the medical team to prepare appropriately and promptly manage the potential adverse reaction (Horowitz and Confer 2005). For peripheral HPC collections in desired numbers, growth factors are used subcutaneously, and sometimes, additional stem cell mobilizers like plerixafor may be administered.

It is imperative to rule out the following conditions in the donors, which could precipitate serious complications on growth factor (G-CSF) administration (Aprili et al. 2013):

**Microbiology**

1. HBsAg ……...2. HIV-1 & 2 Abs…………………………3. HBC Ab………………… 4. HCV…………………………
5. Anti Hbs Ab : ………….. 6. CMV IgM…………………………7. CMV IgG…………………………8. VDRL:…………………………

**Transfusion Medicine**: 

1. Blood Group: …………..Rh (.……….. ) . 2. Antibody Screen: Positive/ Negative 3. Compatibility testing:………..

4. Anti-A/ Anti-B titers (In ABO mismatch only):

**CARDIOLOGY**

1. ECG:……………………………
2. 2-D echo (if >40 years):……………… Cardiologist opinion: Fit/ Not fit

**RADIOLOGY:** Chest X-ray ( >40 years or if required):…………………………

**beta-hCG testing** (for all females in reproductive age):

**Stress Cytogenetic test** (For suspected Fanconi’s Anemia):

**Study specific testing or Co-morbidity Evaluation with concerned Specialist (if any):**

PAC (BM Donors/ requiring deep sedation)-

**HCT Scoring for Co-morbidities:**

**Donor Eligible/ Non-eligible for HPC Donation** (Note if any precautions required)

Any exceptions:

| Name of Donor Physician | Name of Apheresis Consultant | Name of Clinical Consultant |
|-------------------------|-----------------------------|----------------------------|
| Signature:              | Signature:                  | Signature:                  |
| Date:                   | Date:                       | Date:                       |

**Fig. 3** Pre-transplant donor work-up
Inflammatory disorders (e.g., iritis, episcleritis)
- Autoimmune disorder (e.g., rheumatoid arthritis, multiple sclerosis)
- Predisposing factors or history of arterial/deep vein thrombosis
- Liver disease
- Splenomegaly

The adverse effects of HPC donations are transient and well tolerated by healthy donors, yet it is important to inform all donors of potential risks (ARTHIQs European Union 2014). The European BMT society surveyed more around 262 transplant centers and reported serious adverse events (in Table 1) that may occur (Joerg et al. 2009).

### Counseling and Consent

At the time of donor evaluation, an informed written consent on infectious disease testing, mobilization, the process of donation (PB stem cell apheresis or BM aspiration), and storing donor data should be secured. During

### Table 1 Possible severe adverse effects in donors after mobilizing agents and stem cell donations

| System                      | Adverse effects                                      |
|-----------------------------|-------------------------------------------------------|
| Cardiovascular system       | Cardiac arrest                                        |
|                             | Myocardial infarction                                 |
|                             | Supraventricular arrhythmia                            |
|                             | Severe hypertension                                   |
| Thromboembolic              | Deep vein thrombosis                                  |
|                             | Pulmonary embolism                                    |
|                             | Stroke                                                |
| Pulmonary                   | Transfusion-related lung injury                       |
|                             | Pulmonary edema                                       |
| Hemorrhage                  | Subdural hematoma                                     |
| Non-specific                | Seizures                                              |
|                             | Splenic rupture                                       |

---

**Fig. 4** Conditions in which HPC donation is not recommended
counseling, patient/donor and their family members are oriented to the apheresis room and the cell separator. To ensure safety of the product and the recipient, the donor is encouraged to maintain good personal hygiene to prevent infection. Besides ensuring donor confidentiality, the risks and benefits of donation are clearly explained to the donor. The consent forms and educational material on HPC collection should be clearly written in a language understood by the donor. Thus, the informed consent is an integral part of donor evaluation. In unrelated donations, the patient and donor identity is concealed for a period of time, as mandated by country-specific regulations or registry’s policy. The donor is sensitized to the consequences for the recipient, in case the donor refuses to donate after the initiation of recipient’s conditioning regimen. In BM collections, consent for anesthesia should be additionally taken. Consent for central line insertion is taken in PB stem cell donors with poor venous access (German Standards for Unrelated Blood Stem Cell Donations 2014). In case the donor is less than 18 years of age, consent is required to be obtained from the parents or legal guardian. It is desirable to involve donor advocates for differently abled and pediatric donors, who fail to understand the donation process and are unable to give consent. Donor should be informed regarding his availability and additional donation in case of platelet requirement, graft rejection, and immune cell collection.

**Donor Deferral**

42.7% of all deferrals are made on the basis of medical history. Autoimmune diseases, history of previously treated malignancy, and other chronic medical conditions (Bräuninger et al. 2014) (as in Fig. 4) are potential causes for deferral. The principle of HPC donor deferral is based on parameters related to donor and recipient safety (see Fig. 5). Pre-transplant donor work-up and testing is crucial to produce quality HPC product and ensure a safe donation. Unrelated donor eligibility is based on strict criteria that accept an unrestrictedly healthy donor. The eligibility of related donors is significantly variable between centers. Physicians tend to accept family donors, who may not qualify as unrelated donors because of their age (beyond 18–60 years) and comorbidities. For example, related donors with past HBV or HCV infections may donate, in absence of suitable alternatives. It has been seen that mobilized peripheral stem cell collection, females, and increasing age are associated with higher deferral rates.

**Donor Follow-Up**

All donors should be followed up post-donation by the donation center. The donor’s complete blood counts and serum electrolytes (German Standards for Unrelated Blood Stem Cell Donations 2014) are advised post-donation.

![Fig. 5 Principle of donor deferrals with examples](image)
Bone marrow donors are followed up for 12 months for adverse effects of donation and hematological recovery (Aprili et al. 2013). In case of PB stem cell donors, follow-up for 10 years is advisable to rule out malignancies post-growth colony-stimulating factors (G-CSF) exposure during mobilization (Aprili et al. 2013). Centers have spaced out follow-up visits as per their institutional policy. However, it is seen that the interval between follow-ups increases with time post-donation. Some centers advise 6 months, 1, 2, 5, and 10 years after donation (German Standards for Unrelated Blood Stem Cell Donations 2014). Besides the donor, the post-donation health issues could have potential bearing on the recipient’s health (WMDA 2017). It is imperative to have a robust follow-up program to ensure minimum dropouts.

**Documentation**

It is essential for some qualified medical personnel to clearly record donor eligibility in the patient’s medical records before the initiation of donor’s mobilization and patient’s preparative chemotherapy (Kenyon and Babic 2018; Pierelli et al. 2012; JACIE).

**Issues Related to Pediatric Donor**

Children may safely donate HPC without any major adverse effects (Horowitz and Confer 2005). However, pediatric donation has several ethical and legal ramifications. Since there is no medical benefit from donating HPC, it is considered undesirable to subject a child to any medical risk related to anesthesia or bone and nerve injury due to HPC donation. The donor may have psychological benefit from helping a sibling family member. Therefore, the American Academy of Pediatrics (AAP) has proposed guiding criteria to accept a pediatric HPC donor in non-research transplants:

(i) Absence of a HLA-matched adult-related donor. In case of multiple HLA-matched minor donors, the eldest donor is preferred.

(ii) Donation is for a sibling or closely related family member with whom the donor shares a healthy relationship.

(iii) The donation is potentially beneficial to the donor and the recipient. A disastrous outcome in the recipient may adversely affect the donor’s psychological and emotional well-being.

(iv) Parents’ consent and donors’ assent to be recorded.

In light of the above criteria, it is unacceptable to subject a minor to the risk of HPC donation for an unrelated recipient (Riezzo et al. 2017). Since the adverse effects of BM and PB stem cell donation are different, the donor’s wishes are to be taken into account. BM donors are likely to receive a blood transfusion; therefore an autologous red cell collection could be planned prior to HPC donation. In pediatric apheresis 66 % of subjects require central line insertions, and the risk of adverse reactions is 5.6%. The most common adverse effect in pediatric donors during PB stem cell collection is pain, due to central venous access (Hequet 2015). Another alternative vascular device management for children could be ultrasound-guided arterial line under expert clinical hands. One must weigh the pros and cons of this novel approach before establishing the arterial access. The other challenges of apheresis in children below 20 kg include poor venous access and small blood volume. It is required to prime the apheresis system with autologous red cells or allogenic red cells which are irradiated, leukodepleted, and cross-matched.

**Regulatory Issues**

Regulations governing manufacturing of cellular therapy products vary country- and region-wise. In the United States (US), several bodies like the American Association of Blood Banks (AABB), the American Society for Blood and Marrow Transplant (ASBMT), the International Society for Cellular Therapy (ISCT), and the National Marrow Donor Program (NMDP) provide guidelines for various aspects of cellular therapy. However, on
May 25, 2005, the US Food and Drug Administration (FDA) implemented new rules for manufacturing and administration of human-derived products, with the aim to reduce the transmission of infectious diseases. Similarly, the directives on tissues and cells (2004/23/EC) cover the European Union by law, and in the United Kingdom (UK), the Human Tissue Act 2004 is applicable to all tissue establishments. The purpose of regulations is to ensure compliance to good manufacturing practices (GMP). The GMP system covers standards for product collection, labelling, processing, handling, transport, and documentation. The Medicines and Healthcare Products Regulatory Agency (MHRA) is mandated to conduct inspections throughout UK to ensure quality and safety of human tissues and cells for patient treatment (JPAC). FACT-JACIE International Standards Accreditation covers clinical program related to cellular therapy. Accreditation requires trained, competent staff and a quality management plan that includes policies and standard operating procedures for a cellular therapy program (Kenyon and Babic 2018).

### Special Considerations in Autologous HSC Donations

In several disorders, including hematological malignancies, like multiple myeloma and lymphoma, autologous hematopoietic stem cell transplant is the treatment of choice. Autologous stem cell donors/patients may not necessarily fit the donor eligibility criteria; hence donor evaluation is of paramount importance. It would help identify risk factors and appropriately plan the donation. Since most autologous donors/patients mobilize HSC poorly in PB, the quality of HSC product in terms of stem cell count (CD34+ cells) could be sub-optimal. Therefore, it is required to identify poor mobilizer patients (see below) and plan alternative mobilization protocols.

- Advanced age (>60 years)
- Low platelet counts
- Low peripheral blood CD34+ count
- Extensive or refractory disease
- Additional comorbidities and reduced performance status
- Short period of time between chemotherapy and mobilization
- Prior treatment with lenalidomide
- Tumor infiltration of bone marrow
- Prior chemotherapy
- Prior radiotherapy

In addition to G-CSF, a small-molecule CXCR4 antagonist, plerixafor, is used to improve CD34+ cell counts in patients, prior to HSC harvest by apheresis. The patient is sensitized to the adverse effects of plerixafor, which includes diarrhea, nausea, and injection site reactions (EBMT NG 2009).

### Hematopoietic Stem Cell Transplant Recipient Evaluation

Hematopoietic stem cell transplant (HSCT) is a potentially life-saving treatment for patients with hematologic malignancies and some non-malignant blood diseases. The treatment carries a high risk of morbidity and mortality. Non-relapse mortality (NRM) is associated with infection, or organ dysfunction. Additionally, allogeneic recipients carry the risk for graft-versus-host disease (GvHD). Recent studies have shown improvements in outcomes over the past few decades explained mainly by the decreased risk of NRM (Tanaka et al. 2016).

The canvas has become more attractive and extensive with the arrival of haploidentical hematopoietic stem cell transplant. The options for haploidentical HSCT include T-depleted and T-repleted (post-transplant cyclophosphamide). A careful pre-transplant evaluation, preparation of patient, appropriate conditioning regimen and better peri-transplant supportive care has improved patient outcomes. Recipient selection becomes even more vital as we offer this treatment to a more diverse population of patients.

The whole concept of patient and donor evaluation before transplant becomes very critical as few of these evaluations will surface some important but modifiable risk factors which will have overall survival advantage if dealt comprehensively.
Physiologic/Organ Evaluation

Evaluating organ function is a key component to transplant recipient selection. A thorough review and evaluation of all vital organ function should be completed to determine transplant eligibility. An ideal transplant candidate should be in good physical, physiological, and psychological condition at the time of transplant. Although age is a consideration, physiologic age based on comorbidities, rather than only the chronological age, should play a part in the evaluation. In the next few paragraphs, we have discussed salient issues of transplant recipient in accordance with organ or system involved and have summed up the significant points in Table 2.

Pulmonary Evaluation

Transplant recipients are at a high risk for pulmonary complications. Complications may be caused by the conditioning regimen, which may include total body irradiation (TBI) and/or chemotherapy drugs with known pulmonary toxicity risk (busulfan, carmustine). Other causes may include infection, pulmonary GvHD, alveolar hemorrhage, or transfusion-related acute lung injury. Pulmonary function tests (PFTs) prior to HSCT can help identify patients at risk for developing post-transplant pulmonary complications (Hamadani et al. 2010). In general, a patient with a diffusion capacity of carbon monoxide (DLCO) greater than 60% of predicted is felt to be a suitable candidate for HSCT. If the DLCO is below 60%, further pulmonary investigation is warranted. Kids after age of 5 years are usually cooperative with PFTs, and it should be performed regularly (Jeremy and Wesley 2014). Patients with hyper-reactive airway disease are more likely to have obstructive pulmonary disease post-HSCT particularly if busulfan or total body irradiation has been used in conditioning. A recent chest X-ray without evidence of infection or other abnormalities is also a requirement prior to beginning the conditioning regimen. Patients who currently smoke should be encouraged to discontinue tobacco use prior to beginning the conditioning regimen. Research shows that current smoking appears to adversely affect the number of hospitalized days post-HSCT and overall survival (Ehlers et al. 2011).

| Table 2 | Transplant recipient evaluation |
|---------|---------------------------------|
| 1.      | History and physical examination |
| 2.      | Confirmation of pathology       |
| 3.      | Assessment of disease status – scans, bone marrow biopsy |
| 4.      | HLA typing (Class I and II high resolution), ABO typing, DNA extract (chimerism testing) |
| 5.      | Donor search                     |
| 6.      | Karnofsky performance status     |
| 7.      | Echocardiogram                   |
| 8.      | Electrocardiogram                |
| 9.      | Pulmonary function study with DLCO |
| 10.     | Chest X-ray                      |
| 11.     | Pregnancy test                   |
| 12.     | Hematology labs, coagulation labs |
| 13.     | Renal chemistries, urinalysis    |
| 14.     | Hepatic chemistries, vitamin D (25 OH vitamin D) |
| 15.     | Glucose-6-phosphate dehydrogenase (G6PD) |
| 16.     | Infections disease markers       |
| 17.     | Lumbar puncture for high-risk disease |
| 18.     | Dental evaluation                |
| 19.     | Fertility evaluation and preservation |
| 20.     | Dietary evaluation               |

Cardiac Evaluation

Transplant recipients have been found to be at a generally low risk for cardiac complications; however, several risk factors should be considered during pre-transplant evaluation. Use of cyclophosphamide, history of anthracycline use, and underlying heart disease are important considerations. A thalassemia patient undergoing HSCT should be monitored carefully for arrhythmias. Many medications used to support patients through HSCT are known to prolong the QT interval. A 12-lead electrocardiogram is the standard care at baseline and should be followed serially with the use of known offending agents. In addition to a 12-lead electrocardiogram, an echocardiogram to assess baseline left ventricular ejection fraction (LVEF) should be completed. Generally,
a LVEF $>55\%$ is considered acceptable. If the LVEF is below 55%, a more extensive evaluation by a cardiologist should be included.

### Hepatic Evaluation

Hepatic function should be assessed as part of the pre-transplant evaluation in all patients, but special attention should be given in patients who have received multiple transfusions (e.g., thalassemia, myelodysplasia, leukemia, marrow failures) and cancer patients who have received 6-thioguanine, 6-mercaptopurine, vinca alkaloids, cyclophosphamide, carmustine, dacarbazine, etc. as their chemotherapy. An elevation in bilirubin, serum transaminases, and alkaline phosphatase is a risk factor for sinusoid obstructive syndrome (SOS) following HSCT. Additionally, evaluation of serum protein and albumin may be indicative of malnutrition. If liver enzymes are elevated, a more thorough evaluation is indicated. This should be done by an experienced hepatologist. Evaluation may include a liver biopsy to assess for irreversible liver damage. Abnormal liver function studies related to iron overload are not uncommon in patients with hematologic malignancies. Retrospective studies reveal that high serum ferritin levels in myelodysplastic syndrome (MDS) and acute leukemia patients have poor outcomes (Koreth and Antin 2010). Patients with a previous history of multiple red blood cell transfusions should have a baseline ferritin assessed. Elevated liver iron concentrations obtained by a liver biopsy are also direct measures of iron overload after HSCT (Koreth and Antin 2010). Patients who are noted to be malnourished or who suffer from cancer cachexia, obesity, or anorexia should be referred to a registered dietician with expertise in caring for cancer patients. If disease permits us time, a sincere attempt should be made to rehabilitate them before HSCT. Obesity alone is not considered a contraindication for HSTC. Vogl et al. conducted a retrospective study evaluating progression-free survival (PFS), overall survival (OS), and non-relapse mortality (NRM) in 1087 transplant recipients in 2011. They specifically looked at patients with multiple myeloma receiving melphalan and total body irradiation (TBI) conditioning followed by autologous HSCT. There was no overall effect of body mass index (BMI) on any of the variables noted. Although obese and severely obese patients had a superior PFS and OS compared with normal and overweight patients, the significance of this finding was unclear (Vogl et al. 2011). More research is needed to assess the impact of BMI on conditioning chemotherapy dosing and transplant outcomes.

A glucose-6-phosphate dehydrogenase (G6PD) level should be checked at baseline for all transplant recipients. A patient who is G6PD-deficient may be at a higher risk for acute hemolysis when exposed to oxidative stress, infection, or certain medications.

### Renal Evaluation

Hematopoietic stem cell transplant patients are exposed to a number of nephrotoxins as part of the conditioning regimen and supportive care following transplant. These drugs may include chemotherapy, immunosuppressive, antibiotics, and antiviral medications. Baseline serum creatinine level of $<1.5 \text{ mg/100 mL}$ and a calculated creatinine clearance above 60 mL/min are general inclusion criteria for HSCT. Patients with a baseline low glomerular filtration rate are at higher risk for developing post-HSCT chronic kidney insufficiency (Hamadani et al. 2010). In patients with abnormal renal function (including proteinuria), a thorough evaluation should be done to determine the cause, followed by early intervention when required (Hingorani et al. 2008). Care should be taken to optimize renal function prior to proceeding to HSCT (Hingorani et al. 2008).

### Infectious Disease Evaluation

A through history should be obtained from hematopoietic stem cell recipients to identify present and past infections. A list of commonly tested infectious disease markers is shown in Table 3. A physical examination, cancer treatment history,
review of infectious complications during previous treatment, and a previous history of immunosuppression are important aspects to assess. A dental history and assessment of previous structural abnormalities should be completed. Any recent exposure or recent illness may delay the start of the HSCT. Any symptom of an upper respiratory infection (URI) should be tested promptly for a community-acquired respiratory virus. A URI can turn into pneumonia in the immunocompromised HSCT patient. In a prospective study, among symptomatic patients, those with respiratory viruses detected had increased overall mortality compared with patients without viruses detected (Campbell et al. 2015). When possible, any identified infection prior to transplant should be fully treated. In some cases, treatment may continue throughout the HSCT.

Certain endemic pathogens should be assessed for latent or active infection. A history may reveal a risk of tuberculosis (TB) by exposure. In case of any history of exposure to tuberculosis, tuberculin skin test (TST) or interferon-gamma release assay (IGRA) should be completed. In immunosuppressed patients these tests may have False positive results. Other endemic pathogens should be tested in patients who live or have traveled to endemic areas (Tomblyn et al. 2009):

- Strongyloides stercoralis
- Coccidioides species
- Histoplasma capsulatum
- Trypanosoma cruzi
- Malarial parasite

Cytomegalovirus (CMV) is one of the most common infections seen in HSCT patients. Determining if the HSCT recipient has had prior exposure to CMV is an important part of the recipient assessment. A CMV antibody titer is positive in those exposed to CMV. The CMV status of the recipient may play a role in the donor selection. The recent approval of letermovir as a prophylaxis for CMV reactivation should be considered for those recipients who are CMV positive by antibody.

All patients undergoing HSCT should be screened for HIV. Although HIV is not an absolute contraindication for HSCT, those who are positive should undergo viral load and absolute CD4 count testing. Due to the success of antiretroviral therapy over the past decade, an increasing number of HIV-positive patients have been successfully transplanted (Hamadani et al. 2010). Medication compliance with antiretroviral therapy must be confirmed prior to moving forward with HSCT.

Epstein-Barr virus (EBV) serologies can identify patients at risk for post-HSCT lymphoproliferative disorder. Post-transplant lymphoproliferative disorder is most commonly reported in those HSCT patients who receive a T-depleted allogeneic graft or cells from an EBV seronegative donor.

The presence of the herpes simplex virus (HSV) and varicella zoster virus (VZV) serologies denotes prior exposure to the viruses. A previous exposure to herpes simplex virus (HSV) and/ or varicella zoster virus (VZV) should alert the Healthcare team about the possibility of a viral reactivation during transplant healthcare team should not be capitalized.

Patients undergoing HSCT should be screened for hepatitis B (HBV) and hepatitis C (HCV). Although a positive screen for HBV or HCV is not an absolute contraindication for HSCT, it does pose more risk for toxicity than those who are negative. Viral reactivation can lead to liver

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**Table 3  Infectious disease markers tested**

| No. | Marker                                      |
|-----|---------------------------------------------|
| 1.  | Hepatitis B surface antigen (HBsAg)        |
| 2.  | Hepatitis B surface antibody (anti-HBs)    |
| 3.  | Hepatitis B core antibody (anti-HBc)       |
| 4.  | Hepatitis C virus antibody (HCV antibody)  |
| 5.  | HIV1 and 2 antibody                         |
| 6.  | HTLV I/II                                   |
| 7.  | Red cell antibody screen                    |
| 8.  | Cytomegalovirus antibody (CMV IgG, IgM)    |
| 9.  | Blood type (ABO/Rh)                        |
| 10. | Syphilis (RPR)                              |
| 11. | Herpes simplex antibody (HSV)              |
| 12. | Varicella zoster antibody (VZV)            |
| 13. | Toxoplasma antibody (Toxo IgG)             |
| 14. | West Nile virus (WNV PCR)                  |
| 15. | Epstein-Barr virus antibody (EBV Ab)       |

*Required to be checked by Foundation for the Accreditation of Cellular Therapy (FACT)
failure, SOS, or cirrhosis. The HSCT team should be made aware if the patient is positive, so appropriate prophylactic and preemptive therapy can be considered during the course of treatment.

**Dental Evaluation**

A dental evaluation prior to HSCT is important to assess the recipient for any potential sites of infection that may materialize when the patient is immunosuppressed during treatment. Any dental surgery (pulpotomy or root canal treatment), extractions, or cavity fillings should take place prior to the transplant to minimize the risk of sepsis during transplant. There is much controversy regarding treatment of teeth with chronic periodontal pathology (Boguslawska-Kapala et al. 2017). At a minimum, a dental evaluation is required prior to HSCT.

**Disease Assessment**

In addition to the physical assessment to determine HSCT eligibility, disease status is a key determination of fitness for treatment. Patient selection has a large impact on results obtained. The disease status at the time of HSCT will help the physician determine the conditioning regimen to prescribe. Often a myeloablative conditioning regimen is preferred over reduced intensity conditioning for young, healthy patients and those who are not in complete remission. Patients who do not have chemosensitive disease are very unlikely to get any benefit from HSCT, and such a potentially toxic and expensive treatment should not be offered as a suggestive treatment.

**Psychosocial Assessment**

A psychosocial assessment by a mental health professional is a key part of the evaluation. Recent findings suggest that pre-transplant psychosocial risk factors predict survival after HSCT (Harashima et al. 2019). There is not a standard psychosocial assessment tool in use across HSCT programs. Most professionals would agree that a suitable caregiver and ability to be compliant with care are key supports needed for a successful outcome.

Several studies have reported psychosocial variables such as social support, depression, anxiety, coping skills, and smoking as predictors of post-HSCT survival; however, results have been contradictory. A recent large multicenter study analyzing data from the Center for International Blood and Marrow Transplant Research (CIBMTR) was able to address these limitations of prior small studies and confirmed an association between pre-transplant depression and poorer OS (El-Jawahri et al. 2017). Another study examined the relationship between pre-transplant pain and post-transplant quality of life (O'Sullivan et al. 2018). The study concluded that beyond pre-transplant pain, the patient’s self-efficacy for managing such pain and chronic disease is important in understanding quality of life after transplant. There is also evidence that psychosocial interventions may be useful in helping patients with effective coping mechanisms.

One commonly used tool to assess psychosocial fitness for transplant is the Psychosocial Assessment of Candidates for Transplant (PACT) scale. The PACT scored captures variables in four domains: social support, psychological health, lifestyle factors, and patient understanding of the HSCT process. The overall impression of the patient suitability is assigned a final score ranging from 0 (poor candidate) to 4 (excellent candidate). The PACT score can serve as a useful tool screening adult patients for psychosocial risk factors prior to HSCT (Hong et al. 2016).

It should always be remembered that if our patient is a minor (age <14 years) and parents are primary decision-makers or caregivers, we should offer the parents a psychological evaluation. If psychological deficits are identified at initial screening by a licensed Clinical social worker, it is advised that a psychiatric professional evaluates the patient before the transplant. A thorough medication review and assessment of potential barrier for safety should also be assessed by the HSCT team.
Hematopoietic Cell Transplantation (HCT)-Specific Comorbidity Index

Traditional factors such as age, type, and stage of underlying disease are insufficient to predict transplantation tolerance and post-transplant survival (Xhaard et al. 2008). Several retrospective studies are being conducted to review outcomes of acute myeloid leukemia patients undergoing induction therapy. In these patients, a pretreatment higher comorbidity burden is associated with increased early mortality and decreased survival (Wass et al. 2016). The hematopoietic cell transplant comorbidity index (HCT-CI) is a commonly used tool to score pre-transplant comorbidities that predict non-relapse mortality and survival (Sorror et al. 2005). The index contains 17 different categories of comorbidities represented by 16 categories as shown below. Patients are assigned points based on the comorbidities. Using the HCT-CI has enabled physicians to better counsel their patients on recommended treatment options. Based on the HCT-CI, a patient may be better suited for a reduced-intensity conditioning (RIC) regimen with less projected organ toxicity than a high-dose chemotherapy conditioning (HDC) regimen.

Prior to the development of the HCT-CI, age was felt to be the primary determinant of patient eligibility for HSCT. Researchers are using a composite comorbidity/age index to provide more information that could guide future research regarding suitability of groups of patients to different intensities of conditioning regimens (Sorror et al. 2014).

Hematopoietic cell transplantation comorbidity index:

1. Hematopoietic cell transplant date
2. Arrhythmia (score = 1)
   (a) Atrial fibrillations
   (b) Atrial flutter
   (c) Supraventricular tachycardia
   (d) Sick sinus syndrome
   (e) Heart block
   (f) Ventricular arrhythmia
   (g) Others, specify
3. Cardiovascular comorbidity (score = 1)
   (a) Coronary artery disease
   (b) Congestive heart failure
   (c) Ejection fraction/shortening fraction
4. Inflammatory bowel disease (score = 1)
   (a) Crohn’s disease
   (b) Ulcerative colitis
5. Diabetes (score = 1)
   (a) Diabetes
   (b) Steroid-induced hyperglycemia
6. Cerebrovascular disease (score = 1)
   (a) Transient ischemic attack
   (b) Subarachnoid hemorrhage
   (c) Cerebral thrombosis
   (d) Cerebral embolism
   (e) Cerebral hemorrhage
7. Psychiatric disturbances (score = 1)
   (a) Depression
   (b) Anxiety
   (c) Others, specify
8. Hepatic comorbidity (score = 1–3)
   (a) Bilirubin evaluated two separate times between days 24 and 10 prior to transplant
   (b) Aspartate transaminase (AST) evaluated two separate times between days 24 and 10 prior to transplant
   (c) Alanine transaminase (ALT) evaluated two separate times between days 24 and 10 prior to transplant
   (d) Hepatitis B
   (e) Hepatitis C
   (f) Liver cirrhosis
9. Obesity (score = 1)
   (a) Height
   (b) Body mass index for age percentile
10. Infection (score = 1)
    (a) Documented infection
    (b) Fever of unknown origin
    (c) Pulmonary nodules suspicious for fungal pneumonia
    (d) PPD positive requiring TB prophylaxis
    (e) Others, specify
11. Rheumatologic comorbidity (score = 2)
    (a) Systemic lupus erythematosus
    (b) Rheumatoid arthritis
    (c) Polymyositis
    (d) Mixed connective tissue disease
    (e) Polymyalgia rheumatica
    (f) Others, specify
12. Peptic ulcer (score = 2)
(a) Gastric ulcer
(b) Duodenal ulcer

13. Renal comorbidity (score = 2)
   (a) Creatinine levels evaluated two separate times between days 24 and 10 prior to transplant
   (b) Patient on dialysis
   (c) Prior renal transplant

14. Pulmonary comorbidities
   (a) Diffusion capacity of carbon monoxide (DLCO) and forced expiratory volume (FEV₁)
      (i) 66–80% score 2
      (ii) ≤65% score 3

15. Prior solid tumor (score = 3)

16. Heart valve disease (score = 3)

17. Age (score = 1)
   (a) Age 40 or older

Patient Education

Patient education is cornerstone in the care for HSCT patients, their families, and informal caregivers. Assessing readiness for learning can guide the education plan. The informal caregiver is an integral part of the HSCT team. Information should be offered in a variety of ways to accommodate all learning styles. Written, didactic, and video education materials are essential pieces of the education process. Diverse cultures and educational background are considerations in offering effective education to patients and their informal caregivers.

Often patients and their informal caregivers are overwhelmed by the amount of information they are given over a short period of time. Memory for medical information is vital for good adherence to treatment. Ley’s model on effective communication in medical practice stresses the importance of memory next to factors such as the understanding of information and satisfaction with the treatment (Kessels 2003). Repetition and teach-back strategies are necessary to ensure that the patient and the informal caregiver understand the content. In addition to education on the treatment, medications, and potential side effects, teaching content should include specific symptoms for patients to monitor and a clear reporting mechanism should the symptom occur (Grant et al. 2005).

There are many resources available to enhance program-specific education. The National Marrow Donor Program (NMDP) has an extensive patient education platform to share with patients, families, and informal caregivers. Many of their resources are available in multiple languages. The informal caregiver is critical in contributing to a successful recovery after HSCT. A list of responsibilities of the informal caregiver is in Table 4. The informal caregiver is usually a family member or friend of the patient. Although they are committed to caring for the patient, they struggle with the burdens that come with the responsibility. Many informal caregivers report anxiety, depression, fatigue, and a decline in physical health. Healthcare providers who care for HSCT patients should also be vigilant in assessing the informal caregiver for signs of distress and poor health.

Team Members

A general list of HSCT healthcare team members is in Table 5. Each HSCT center will create a team that best fits their needs. In addition to committed team members, a sound sustainable infrastructure is necessary to manage these complex patients across the care continuum. Other members of the medical staff will be needed in consultation for HSCT patients. These include but not limited to palliative care, pulmonary medicine, infectious diseases, cardiology, gastroenterology, dermatology, neurology, radiation oncology, interventional radiology and endocrinology.
Registered Nurse Practice Implications

Hematopoietic stem cell transplant patients are one of the most complex populations for a nurse to care for. The registered nurse (RN) needs to pay careful attention to information gained during the patient evaluation to effectively care for the patient and the caregiver. Knowledge of infectious disease and prior medication exposure can alert the RN to the risk of complications. Understanding how the patient tolerated previous therapies can be important in early intervention of symptoms. An up-to-date knowledge of HSCT principles and standard practices will aid the RN in providing excellent care to the patient.

Conclusion

Donation of HSC is a voluntary and altruistic act. It is imperative to simultaneously ensure donor safety and recipient well-being for a successful hematopoietic transplant program. A thorough donor evaluation helps in early identification and mitigation of adverse donor reactions. It is desirable for medical personnel to explain all the mild and severe adverse effects of donation at the time of taking consent. Special needs should be addressed in autologous and pediatric donors. Therefore selection of the best available donor, complete donor evaluation, and appropriate donor preparation are crucial for retrieving a good-quality HPC product. A good yield of HSC facilitates successful engraftment of donor cells in the recipient. The evaluation of HSCT candidate is a complex and invasive process for potential patients. Physical testing, blood work, and psychosocial and disease status assessment provide important information for patients and providers to make an informed decision on the role of HSCT. Even though a patient may pass all of the evaluation criteria with ease, the outcomes are still not predictable for all patients. Excellent care based on evidence-based research will give every transplant patient the best option for a positive outcome.

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