Abstract  Umbilical cord blood is an established source of stem cells useful for hematopoietic reconstitution. The first clinical transplantation in France by Eliane Gluckman in 1988 using HLA matched umbilical cord blood from a sibling on a 6-year-old boy with Fanconi’s anemia is an example of a successful transplantation. So far, more than 8,000 patients worldwide have been treated for malignant and inherent blood disorders [1, 2]. Our cord blood repository (CBR) was established as the part of the Life Sciences initiative, almost 7 years ago. The cord blood program consisted of developing a good network of obstetricians and social workers, develop manpower in various aspects of the banking activity, develop methods of process and analysis and above all, increase the level of awareness among the medical, paramedical fraternity and the general public on the cord blood program. The present paper gives a detailed account of our experience as we set up the repository.

Keywords  Cord blood unit · Human leukocyte antigen · Total nucleated cell count · Cryopreservation · Repository

Introduction

India is a country unified by its differences. As the second most populous nation on the globe, India has 28 states, 7 union territories, 22 national languages with more than 2,000 total ethnic groups where 6 of them are major as shown in Table 1 [3].

The present requirements of hematopoietic stem cells for our subcontinent are not met by the banks in the rest of the world as these banks cater to different population and ethnicities. The implementation and operation of an unrelated umbilical cord blood bank is analogous to the establishment of a new blood banking program.

Worldwide, the growth of autologous and related hematopoietic stem cell transplantation (HSCT) appears exponential; however, growth in the allogenic setting is relatively lesser due to lack of availability of suitable human leukocyte antigen (HLA) compatible grafts for patients [4]. The hardship faced by Asian patients in general, and Indians in particular, while awaiting a suitable bone marrow match turned them towards ‘cord blood’ as a ray of hope.

The healthcare provision for minority ethnic groups of India and Asia spread across the globe and the large, young population of ethnically and genetically diverse individuals in our country, is a very important consideration in the set up of this initiative.

Our public cord blood banking facility, licensed by the Indian FDA, is now operational for a little over 7 years. We have about 3,500 voluntary samples stored with us in the public cord blood banking facility, available for clinical use. We have gradually extended this banking service to families.
as well, to store cells for their own future use. We narrate our experience on this initiative.

**Aims and objectives**

Our objective was to establish various components of the cord blood program in order to produce cord blood derived stem cell products of requisite quality that would address clinical needs.

The establishment of this program consisted of laying down a quality management system that includes quality assurance, a robust donor education and recruitment, cord blood collection, transport, processing, cryopreservation, donor data management and HLA search request processing. It was not in our scope to set up our own transplant center as part of this program. This paper also includes challenges, opportunities and the progress made by us so far.

**Observations**

**General awareness**

Though the clinical applications on the use of cord blood was gaining momentum in the other countries, the level of awareness among the masses, the medical and paramedical professionals on the potential uses of cord blood was relatively low in this country, at the start of the program.

The collection of umbilical cord blood is a multi-step procedure that begins with donor recruitment. We required an informed consent from donor mothers well before delivery. There were several levels of resistance to accept the fact that cord blood, which is normally a bio waste, can be put to fruitful use. To bring about a paradigm shift in the understanding of this new subject, we had to learn it ourselves initially and generate interest among the medics and paramedics. This had to be done on a continuous basis. Sadly, it was not easy to convince the clinicians and paramedics as there were no success stories on the use of cord blood in this country then. Most clinicians of the earlier generation were happy practicing traditional medicine, rather than wanting to move to newer tools that are less tried and tested. In the Indian context, the senior physicians were extremely skeptical on the use of cord blood. In sharp contrast, the younger generation of physicians, were more open, receptive, and willing to learn by being participative. Interestingly, the internet access to information and overseas training programs taken up some of the doctors, added value to the program.

**Establishment of collection centers**

India has a high birth rate; childbirths are conducted by large corporate hospitals, public hospitals, private nursing homes, not for profit foundations, etc. It may be interesting to note that even today, some mothers deliver at home in rural India. With such complex healthcare delivery systems, we were looking out for birthing centers that will meet our quality requirements so as to enroll them as our collection facility. We found extreme resistance to enrollment, although many of them appeared cooperative and interested. We were keen on signing up with birthing centers catering to certain specific communities to ensure adequate ethnic representation. Antenatal practices at the hospitals and the track record of the clinicians and their capability to handle high-risk pregnancies and above all, their level of interest in the cord blood program were our important parameters. We signed up only with those collection centers that were keen on this program and rejected those that perceived it as an additional burden on the existing manpower and financial resources. It has taken us tremendous efforts to reach out to them on a continuous basis, keep them motivated, and send our counselors to talk to the mothers including putting up information to the doctors through our information booklets. Finally, we have been able to develop and maintain smooth working relationships with obstetricians, nurses, delivery suite personnel and hospital administrators at each of our participating collection centers. Further, these centers had to consent for being audited by the regulatory agencies at short notice.

These activities even now require immense efforts in terms of organizing numerous meetings and adequate communication and ongoing supportive efforts to maintain proper collection of cord blood in an area, which is not routinely designed or designated for such work.

**Consenting**

The cord blood consenting process was an experience worth mentioning. Trained staff or the physician himself administered consenting. The issues faced varied depending upon the birthing centers and the socio financial status of the customer base they catered to. We came across mothers with varying levels of literacy, education, and motivation. With a little orientation talk from our trained staff, most mothers were willing to see the importance of the program and participated and consented instantly. Apart from the mother, in certain communities in India, there were other decision-making members who mattered. Provisional consenting

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Percentage population</th>
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<tbody>
<tr>
<td>Hindu</td>
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<tr>
<td>Muslim</td>
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<td>Buddhist</td>
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<tr>
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<tr>
<td>Others</td>
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<tr>
<td>Religion not stated</td>
<td>3.1</td>
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</tbody>
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Table 1  Ethnic representation of the grafts at the CBR.