Perspective

Business on Hope: A Case Study on Private Cord Blood Stem Cell Banking

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Traditionally, medical practice has been recognized as one of the professional practices with high honors. The interaction between physicians and patients is to provide health care services without the profit orientation. In modernized economy and in today's world of business, the relationship between doctors and patients has been dramatically changed. This transformation is very obvious in the private sector. Health care providers sell their services. Patients have been approached as customers. Decisions to make an investment on new medical technologies or new services would accompany with careful consideration on cost-benefit ratio, on marketing and also on short and long term return of the investment. However, most of the medical services available in the past were focusing on the "real" and "tangible" products. This means that the patients or the customers would obtain diagnosis, treatment, palliation or prevention for the fees they paid. They can at least obtain and can feel some direct or indirect health benefits from the services. With the advancement of science and technology, there is recently a new model of business that sells only the hope for future use. Private cord blood stem cell banking is a good example for this business model. Actually, business on hope is not the brand new business model. Insurance is a well-known classical prototype of business on hope. However, when this kind of business model is applied for medical services, there should be some precautions and also intervention including an oversight system from the government sector to make sure that all the information delivered to the clients and family is accurate and unbiased. From the public policy perspective, this business of hope should be appropriately regulated to preserve consumer rights while promoting the advancement of science and technology through sustainable business development.

Keywords: *Stem cells, Cord blood banking, Business, Insurance, Hope*

J Med Assoc Thai 2008; 91 (4): 577-80
Full text. e-Journal: *http://www.medassocthai.org/journal*

Traditionally, medical practice has been recognized as one of the professional practices with high honors. The interaction between physicians and patients is to provide health care services without the profit orientation. In modernized economy and in today's world of business, the relationship between doctors and patients has been dramatically changed. This transformation is very obvious in the private sector. Health care providers sell their services. Patients have been approached as customers. Decisions to make an investment on new medical technologies or new services would be accompanied with careful consideration on cost-benefit ratio, marketing and also short and long term return of the investment. However, most of the medical services available in the past were the "tangible" products. This means that the patients or the customers would obtain diagnosis, treatment, palliation or prevention for the fees they paid. They could at least obtain some direct or indirect health benefits from the services. With the advancement of science and technology, there is recently a new model of business that sells only the hope not the concrete products.

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From the public policy perspective, this kind of business when being used for medical service would need a special form of regulation to make sure that the information provided is accurate and reliable.

Background

Umbilical cord blood stem cells are stem cells collected from the umbilical cord at birth that can produce all of the blood cells in the body (hematopoietic). Cord blood is currently used to treat patients who have undergone chemotherapy to destroy their bone marrow due to cancer or other blood-related disorders (from the NIH resource for stem cell research)(1).

Public cord blood banking

There is no question on the benefit of public cord blood banking to which pregnant women altruistically donate their umbilical cord blood for hemopoietic stem cell (HSC) transplantation similar to bone marrow stem cell donation. Like bone marrow donor registry, public cord blood banking also helps increasing the availability of donor HSCs. There is little argument against storing umbilical cord blood from siblings in families with a known genetic disease since the stored cord blood would have a "high probability" to be used for transplantation to treat genetic diseases in the future.

Private cord blood banking

Private or autologous cord blood strorage is the banking of cord blood with the intention to using in the future for that individual in the case of developing degenerative diseases or having injuries. This concept is based on the assumption that the cells stored at the time of birth would have the potential to be used for therapeutic purposes at the time needed in the future.

Some facts about private cord blood banking

1. Umbilical cord blood is very unlikely to be used. The chance of using it for autologous transplant is less than 1 in 20,000. (2-3) However, commercial providers usually quote a higher number of prearranged usage in at risk children.

2. For acute leukemia, the most likely indication for autologous cord blood transplantation, improvements in conventional therapy and allogenic transplantation hesitate the choice toward autologous transplantation. There are arguments against the use of autologous cells, including the presence of pre-leukemic mutations and the high rate of relapse. (4)

3. Cord blood collections often contain only enough HSCs to be used in children (not adults). From technical perspective, the expansion of stem cells from cord blood may be possible in the future but this may need to be clearly informed.

4. Non-hematologic uses of cord blood stem cells remain questionable since it is unclear whether non-hemopoietic stem cells are present in sufficient numbers for use against most of the degenerative conditions.

5. If there is future requirement for autologous stem cells, failure to have autologous cord blood stem cells stored is unlikely to be hopeless. HSCs could still be collected from bone marrow or peripheral blood, and stem cells are able to be isolated from other accessible sources (e.g., deciduous teeth).

Ethical and economic concerns

"Once in a lifetime opportunity" to "save the key components to future medical treatment", freezing "a spare immune system" or "the invaluable gift for the whole family" are the key terms often being used to persuade parents to store cord blood. The companies may also use their definition describing cord blood stem cells as "something that may conceivably save your baby's life". Also, there are usually lengthy lists of diseases potentially amenable to stem cell therapy in the future, including Parkinson's disease, diabetes, cancer, and heart diseases. This would undoubtedly raise hopes and make private cord blood storage very promising. If we would apply the concept of standard informed consent in medical research to this kind of marketing strategy, the information provided should be accurate and unbiased. Then, who should be responsible and accountable for the accuracy of this information? The company should have the right to provide information to persuade their customers but the customers should also have the right to obtain update and unbiased information.

Moreover, cord blood collection imposes a considerable burden on the obstetrician or midwife. In addition to informed consent, parental blood collection, the associated packaging, and paperwork must be done. This may distract health care providers from their primary task of caring for the mother and baby at a vulnerable time. Is it ethically sound to take the risk in this scenario when its future usefulness is not clear but the risk is understandable?

From the public health perspective, since the majority of cord blood transplants have used cells donated from another person and there is a global shortage of public cord blood stem cells, the increase in private cord blood storage may make less cord blood stem cells available for public use. This would make the shortage situation worse.

What's the experts' opinion internationally?(2)

The concept of cord blood banking in "low risk" or "no risk" families has been widely discussed and debated. After significant concerns from the American Academy of Pediatrics and American College of Obstetricians and Gynecologists, the Royal College of Obstetricians and Gynecologists (UK) concluded in 2001 that routine, directed commercial cord blood banking could not be justified scientifically, was logistically difficult, and therefore could not be recommended solely from a scientific standpoint. In 2002, the French National Consultative Ethics Committee for Health and Life Sciences made a similar suggestion. In Italy, private banking has been banned. A European Union (EU) report emphasized serious ethical concerns about commercial cord blood banking and questioned their validity on selling a medical service of "no real" application.

An example of problem cases in China: Call for the appropriate oversight system(5)

According to Reuters' news, there was a case in China that the parents would sue the cord blood banking company suspected of concealing the fact that their children's umbilical cord blood, believed to be a likely cure for future blood diseases, was tainted. In a case like this, who should be responsible for overseeing and regulating the contract between the parents and companies? Who should be responsible for monitoring the process of cord blood stem cell collection and banking process? How to make sure that practices of the companies are up to the acceptable standards?

What should be the appropriate solutions?

When the business on hope, as in the case of private cord blood banking, has been examined through the market lens, there is a supply available through advancement in technology and there is a "huge" demand on private cord blood banking for future use. Then, the result is simple. Currently, private cord blood banking is a big business worldwide and seems to be expanding rapidly.

With some facts and ethical concerns discussed earlier, the business on hope like private stem cell banking should not be treated as an ordinary business model like others that sellers and buyers will interact freely and products would be sold in the free market regulated only by demand and supply. Since this is part of the medical service and the parents seems to be in the vulnerable period to make a decision and would like to do everything that is beneficial to their beloved child even for the future. So, the free market option would put vulnerable parents at risk for buying and spending without a careful decision.

The banning of private cord blood banking seems to be impossible and also inappropriate because there is currently a "huge" demand in the market already. If it has been banned, this will drive the business into the international market that the service is available or drive it into the "black" market that would make the control and regulation even more difficult.

This would come to the final solution that this kind of business should be available with appropriate oversight and monitoring system. Parents should have their rights to make a decision to collect their cord blood stem cells or not. If the cord blood stem cells are collected, they should be able to freely decide to donate it for public use or store it for future private use. The "key" and "critical" point to make business on hope fair and transparent is all the necessary information required to make a decision must be available, up to date and accurate. There should be an oversight system to monitor all the processes involved to make sure that the practice meets the standard and is reliable. If the potential of cord blood stem cells for future autologous use is reasonable and cost-effective for universal storage, then the government should make the effort to make this service affordable and available.

Conclusion

With the advancement of science and technology, there is currently an emerging business model on hope. When this business model is applied into the medical practice, the parents as a customer should be protected from obtaining biased and inaccurate information. The procedures and practice should also be oversight and regulated for quality and safety. The clear policy and regulation would help to make this kind of business to perform better and have sustainable growth.

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ธุรกิจบนความหวัง: กรณีศึกษาจากธนาคารเซลล์ต้นกำเนิดจากสายสะดือเพื่อการใช้ส่วนตัว

สรภพ เกียรติพงษ์สาร

โดยทั่วไปการประกอบวิชาชีพเวชกรรมได้รับการยกย่องและยอมรับว่าเป็นหนึ่งในวิชาชีพที่มีเกียรติสูง ความสัมพันธ์ระหว่างแพทย์และผู้ป่วยเป็นการให้บริการและความช่วยเหลือ โดยมิได้มุ่งเน้นที่ผลประโยชน์ ในสังคมสมัยใหม่และในโลกของธุรกิจความสัมพันธ์ดังกล่าวนี้เปลี่ยนไปอย่างมาก โดยเฉพาะในภาคเอกชน ผู้ให้บริการทางการแพทย์ “ขาย” การให้บริการและดูแลผู้ป่วยเสมือนเป็นลูกค้า การตัดสินใจลงทุนในเทคโนโลยี หรือ การบริการทางการแพทย์ในรูปแบบใหม่ มักควบคู่ไปกับการพิจารณาถึงความคุ้มทุน การประเมินตลาด และการคาดการณ์ผลตอบแทนทั้งในระยะสั้นและระยะยาว ในอดีตการให้บริการทางการแพทย์ส่วนใหญ่เป็นการให้บริการในลักษณะที่ผู้ป่วยสามารถสัมผัสและจับต้องได้ ผู้ป่วยได้รับการวินิจฉัย การรักษา การประคับประคองอาการ หรือ การป้องกันโรคจากค่าธรรมเนียมที่ได้จ่ายไป และได้รับประโยชน์ทางตรงหรือทางอ้อมจากการบริการนั้น ทั้งนี้ด้วยความก้าวหน้าทางวิทยาศาสตร์และเทคโนโลยี ในปัจจุบันจึงมีธุรกิจในรูปแบบใหม่ที่ขายความหวังเพื่อการรักษาโรคในอนาคต การจัดเก็บเซลล์ต้นกำเนิดเพื่อการใช้ส่วนตัวเป็นตัวอย่างที่เห็นได้ชัดเจนสำหรับแนวคิดนี้ แนวคิดของการดำเนินธุรกิจบนความหวังนั้นมิใช่แนวคิดใหม่โดยสิ้นเชิง หากมีการทำประกันเป็นตัวอย่างที่รู้จักกันมานาน แต่เมื่อนำแนวคิดการทำธุรกิจบนความหวังมาใช้กับการให้บริการทางการแพทย์ ควรจะเพิ่มความระมัดระวังและมีมาตรการในการกำกับดูแลจากภาครัฐเพื่อให้การให้ข้อมูลเป็นไปอย่างถูกต้องปราศจากการชี้นำ สำหรับมุมมองนโยบายสาธารณะการดำเนินธุรกิจบนความหวังควรจะได้รับการกำกับดูแลที่เหมาะสม ทั้งเพื่อเป็นการรักษาสิทธิของผู้บริโภคและจะเป็นการสนับสนุนความก้าวหน้าของวิทยาศาสตร์และเทคโนโลยีผ่านการลงทุนทางธุรกิจที่ยั่งยืน