

ADVOCACY



TMV's Lokmanya Tilak Law College's

QUARTERLY eMAGAZINE

Volume II

Issue 7 (October to December 2022)

CONTENTS

1. Analytical Study on Impact of bankruptcy on shareholders.....
2. Review on Fertility, Abortion Laws, Maternal Mortality Ratio.....
3. Critical Analysis Regulations Of Donation Of Organs In India.....

Student Editor
Sahil Jagtap
LLB 2nd Year

Faculty In-Charge
Asst. Prof. Vidhya Shetty

Articles invited for the next issue, interested candidates can mail your articles on advocacytmv@gmail.com

DISCLAIMER

Facts and opinions in articles published in the online e-Magazine “Advocacy” are solely the personal statements of respective authors. Authors are responsible for all contents in their article(s) including accuracy of the facts, statements, citing resources, and so on. Online e-Magazine “Advocacy” and editors disclaim any liability of violations of other parties’ rights, or any damage incurred as a consequence to use or apply any of the contents of e-magazine “Advocacy”. Material submitted to e-Magazine “Advocacy” must be original and not published or submitted for publication elsewhere. Author is responsible to get permission from previous publisher or copyright holder if an author is re-using any part of paper (i.e. figure or figures) published elsewhere, or that is copyrighted. The editors consider all material in good faith and that the e-Magazine “Advocacy” have full permission to publish every part of the submitted material including illustrations.

Impact of bankruptcy on shareholders

-By Rasika loya

Absarct: -

Like other businesses, companies that declare bankruptcy also have a capital structure. This indicates that both debt and equity are included in their capital structure. We have been discussing the interests of the debt holders—specifically, how they will be compensated in the case of liquidation or reorganization—constantly in the last several columns. Like other businesses, companies that declare bankruptcy also have a capital structure. This indicates that both debt and equity are included in their capital structure. We have been discussing the interests of the debt holders—specifically, how they will be compensated in the case of liquidation or reorganization—constantly in the last several columns.

Yet, we have fully disregarded the issue of shareholders up until this point. Because stockholders are not seen as benefactors of a bankrupt corporation, this is the case. Throughout the process, their wants and preferences are ignored. In this post, we'll detail just how the bankruptcy process impacts shareholders' interests.¹

Introduction:-

A person or business may file for bankruptcy if they are unable to pay their debts or other commitments. For those who are struggling to make ends meet, it offers a new beginning.

A petition is filed, either on behalf of the debtor, which is more often, or on behalf of creditors, which is less frequent, to start the bankruptcy process. All of the debtor's assets have been measured and assessed, and some or all of the debt may be repaid with the help of the assets.²

A shareholder is a person or entity that has invested money in a company in exchange for a "share" of ownership. This ownership is represented by ordinary shares or preferred shares issued by the company and held by the shareholders.³

If a company files for bankruptcy protection, it is possible that its stock will lose most (if not all) of its value and the company will be liquidated. This is bad news for shareholders. But here's a fact that may surprise some investors: Securities of bankrupt companies can, and often do, continue to trade because there is no federal law prohibiting trading in the stocks of

¹<https://www.managementstudyguide.com/impact-of-bankruptcy-on-shareholders.htm>

²<https://www.investopedia.com/terms/b/bankruptcy.asp>

³<https://www.bdc.ca/en/articles-tools/entrepreneur-toolkit/templates-business-guides/glossary/shareholder>

bankrupt companies. However, investors should be aware that trading shares of a bankrupt company is incredibly risky and could result in the loss of their entire investment.⁴

Chapter 11 bankruptcy :-

The definition of Chapter 11 bankruptcy is quite specific. In bankruptcy, there are two groups to consider: the debtor and his creditors. The company that files for bankruptcy is called the “debtor,” and any entity or person that has claims against that debtor is called a “creditor.” If a company has several subsidiaries, each legal entity must file a separate bankruptcy petition, creating a group of debtors with bankruptcy cases that are usually handled jointly by the bankruptcy court. However, each group of creditors of the debtor is treated separately.

A debtor begins bankruptcy proceedings by filing a bankruptcy petition with the Bankruptcy Court, a specialized federal court that handles a large number of both consumer and business bankruptcies each year. Once a company has followed the formal procedures of its articles of incorporation (such as a board resolution or shareholder vote) to take this extraordinary action, the company can file for bankruptcy by filling out a short form and paying a relatively small fee. Insolvency means that the total amount of debts is greater than the total amount of assets (or usually the failure to pay debts when they are due), no claim.

The date of application is important. Chapter 11 bankruptcy proceedings focus on preemptive creditors, that is, holders of debts, claims, and other obligations that arose before the date of the bankruptcy filing. With rare exceptions, debtors are not allowed to make advances to creditors outside of the bankruptcy process. On the other hand, creditors are given special protection to encourage customers and suppliers to continue doing business with the debtor during bankruptcy.⁵

Chapter 7 Bankruptcy:-

Bankruptcy is a big deal, so you need to understand it clearly. Title 11, Chapter 7 of the US Bankruptcy Code governs the process of liquidating assets. A bankruptcy trustee is appointed to liquidate assets released for creditors; after the income is used up, the remaining debt is paid. There are eligibility requirements to file Chapter 7, such as the debtor must not have been a Chapter 7 bankrupt in the previous eight years and the applicant must pass a means test. This process is also called “straight” or “liquid” bankruptcy.⁶

⁴<https://www.finra.org/investors/insights/what-corporate-bankruptcy-means-shareholders#:~:text=When%20a%20company%20files%20for,That's%20bad%20news%20for%20shareholders>

⁵<https://www.toptal.com/finance/bankruptcy/chapter-11-bankruptcy-what-is-it>

⁶<https://www.investopedia.com/terms/c/chapter7.asp>

Chapter 7 bankruptcy discharges most unsecured debts, meaning unsecured debts such as medical bills, credit card debts, and personal loans. However, some forms of debt, such as back taxes, judgments, child support and alimony, and student loans, are generally not eligible. Chapter 7 bankruptcy leaves a serious mark on your credit report for 10 years. During this time, it will probably be more difficult for you to get a loan. Regardless, you will likely see your credit recover after filing.⁷

Case studies:-

1. Lehman brothers case of bankrupt:-

Lehman Brothers was founded in 1850 by three brothers who immigrated to the United States from Germany and initially did business in South America. But soon they switched to the cotton business and moved their operations to New York. Lehman remained a commodities house until the early 20th century, when its focus shifted to public offerings and laid the foundation for a financial services institution that would become one of the world's top investment banks.

By 2008, after a brief merger with American Express, Lehman reinvented itself as an independent wealth management firm with more than 28,000 employees and more than \$600 billion in assets. But there were problems along the way: Its World Trade Center offices were destroyed in the Sept. 11 attacks, and it paid heavy penalties to regulators over how the bank's investment arm influenced the results of its research analysts.

These episodes became insignificant in 2008. Lehman was heavily involved in subprime lending, which led to unsustainable economic growth. But these were, by definition, riskier loans for consumers with low incomes and poor credit histories. Although Lehman suffered a \$50 million loss in 2007 due to the foreclosure of its subprime mortgage lender, Lehman remained open. In securitizing huge mortgages for resale, the company sold the best mortgages and kept the worst, which proved disastrous. Massive losses were reported and Lehman Brothers shares lost three-quarters of their value – and then fell again as the takeover rumors continued. A mass exodus of customers followed, credit institutions sharply discounted the company's assets, and the US federal government refused to take steps to prevent the company's collapse. Lehman Brothers was forced to file for bankruptcy in September 2008. Its failure had a lasting negative impact on global markets and became the 2007-2008 stock market crash. A symbol of the chaos of the financial crisis.⁸

⁷<https://www.nerdwallet.com/article/finance/chapter-7-bankruptcy>

⁸<https://www.britannica.com/event/bankruptcy-of-Lehman-Brothers>

2.Essar Steel case :-

The Essar Steel Case is a landmark judgment in Insolvency and Bankruptcy law that ended the supremacy of creditors in the committee of creditors in claim allocation cases. This is one of the oldest cases under the IBC process, which has lasted for about 900 days. The Supreme Court set aside the NCLAT decision and upheld the decision of the committee of creditors on how the proceeds of ArcelorMittal's Rs 42,000-crore bid would be distributed among creditors. Insolvency and bankruptcy law is largely settled in this important litigation.

The final decision of the Control Committee was that both resolution candidates were denied the submission of resolution plans, because their submitted plans violate Section 29A of the Code.

But using its extraordinary powers under Article 142 of the Constitution of India, the SC gave a last chance to the resolution applicants to release all outstanding dues in their NPA accounts within two weeks of the SC's decision.

The outcome of the Essar Steel case will give a major boost to efforts to revive several distressed companies. It also places an important duty on NCLT and NCLAT to look into IBC related cases beyond legal issues and financial claims. In exercising the discretionary powers of these authorities, one must remember the impact and consequences on creditors, stakeholders, promoters and anyone whose interests depend on the recovery of the company. This judgment sets a precedent for other companies that are going through the insolvency process and are awaiting a decision on the distribution of assets among various creditors.⁹

3.Dewan housing finance case:-

Under Section 14 of the Insolvency and Bankruptcy Act, 2016 ("IBC"), the National Company Law Tribunal ("NCLT") is required to declare a moratorium barring any suit or action on the commencement date of insolvency. Continuation of any pending action or proceeding against the Company, including the enforcement of judgments or orders in any court, tribunal, arbitration or other body.

That issue arose in Dewan Housing Finance Corporation Limited ("DHFL") v. SEBI, in the Securities Appellate Tribunal ("SAT"), the issue was whether SEBI could initiate or continue proceedings against a corporate debtor where the debtor had breached a contract. Securities Act. The purpose of this article is to analyze the case through this question.

⁹<https://lawcirca.com/essar-steel-case/amp/>

The SEBI adjudicator's order referred to the observation made in the Insolvency Law Commission's 2018 report that a proceeding initiated to determine or assess a liability is different from recovery of an assessed or assessed liability. A moratorium on liabilities may not have been the intention of the IBC. The SAT found that the judge should not have been referred to the 2018 report of the Insolvency Board, as external interpretations should only be considered in cases of ambiguity.

It was further held that when a moratorium is imposed under Section 14 of the IBC, the Adjudicating Officer has no jurisdiction to file a suit. Therefore, the order of the SEBI Adjudicator, the recovery proceedings under section 28A for non-payment and SCN are set aside as the suit cannot be instituted after the moratorium imposed under section 14 of the IBC.

From the above analysis, it can be concluded that SAT was right in holding that SEBI cannot initiate proceedings against a company after imposing a moratorium under Section 14 of the IBC. This decision of the SAT helps to preserve the assets of the corporate debtors and allows to effectively use the available resources to complete the CIRP.¹⁰

Conclusion:-

The subject of this article is a description of all the procedures leading to bankruptcy. Some cases related to bankruptcy are described at the beginning of the article. Actions to be taken before evaluating the final report. In the main part, some of the costs of the bankruptcy estate are outlined and the income is briefly described. The following section describes the steps the court must take in negotiating and finalizing the final report. A separate section is dedicated to the distribution of bankruptcy assets. The terms of a petition similar to a bankruptcy petition are defined to the extent that its proper subject matter and use are partially mentioned. The next section explains the cycles required to fulfill a requirement. Focusing on the final report, all steps are presented using a specific business example without stopping the activity. Costs and revenues are defined by individual records. You may also face objections to the final report, the integrated withdrawal process and the legal guardianship application. The topic is filled with a concrete example that leads to bankruptcy. This article is the last of the professional works already presented, which mainly focuses on the bankruptcy procedure of the Czech Republic. Gradually, the basic features of declaration of insolvency, bankruptcy, bankruptcy assets, bankruptcy law, bankruptcy distribution, etc. When you finish, you will learn about the normalization of the new bankruptcy law, which went into

¹⁰<https://blog.ipleaders.in/dewan-housing-finance-corporation-ltd-v-sebi-case-analysis/>

effect on July 1, 2007. The new bankruptcy law represents a comprehensive legal regulation that replaces the current bankruptcy law. Bankruptcy law strengthens the hand of the bankrupt creditor and makes all bankruptcy proceedings easier and faster.¹¹

¹¹https://www.researchgate.net/publication/294486884_Bankruptcy_conclusion

FERTILITY, ABORTION LAWS, MATERNAL MORTALITY RATIO

By Prajakta Jadhav

FERTILITY

Fertility is the ability to have babies or to reproduce. When fertility rates in a community increase, more babies are born.

Fertility is the quality of a human's ability to produce offspring, which is dependent on age, health, and other factors. The noun can also refer to the state of a plant or animal's being capable of reproduction. When you hear about "fertility rates," it means the number of births that happen during a certain time period in a specific location. The Latin root word is fertilis, "bearing in abundance or fruitful," from ferre, "to bear

ABORTION

Abortion laws vary widely among countries and territories, and have changed over time. Such laws range from abortion being freely available on request, to regulation or restrictions of various kinds, to outright prohibition in all circumstances. Many countries and territories that allow abortion have gestational limits for the procedure depending on the reason; with the majority being up to 12 weeks for abortion on request, up to 24 weeks for rape, incest, or socioeconomic reasons, and more for fetal impairment or risk to the woman's health or life. As of 2022, countries that legally allow abortion on request or for socioeconomic reasons comprise about 60% of the world's population.

MATERNAL MORTALITY

Maternal death or maternal mortality is defined in slightly different ways by several different health organizations. The World Health Organization (WHO) defines maternal death as the death of a pregnant mother due to complications related to pregnancy, underlying conditions worsened by the pregnancy or management of these conditions. This can occur either while they are pregnant or within six weeks of resolution of the pregnancy. The CDC definition of pregnancy-related deaths extends the period of

consideration to include one year from the resolution of the pregnancy. Pregnancy associated death, as defined by the American College of Obstetricians and Gynecologists (ACOG), are all deaths occurring within one year of a pregnancy resolution. Identification of pregnancy associated deaths is important for deciding whether or not the pregnancy was a direct or indirect contributing cause of the death.

Abortion in India: A Literature Review

This report reviews and synthesizes the peer-reviewed literature, as well as important grey literature, published between 2002 and 2014 on abortion in India. Over the past decade, some key policy developments have contributed to improved availability, accessibility and safety of induced abortion services; these include revised regulations expanding services to primary health centers, the approval of medical abortion for terminating early pregnancies, and the promotion of manual vacuum aspiration as the preferred method for early surgical abortion.

(<https://www.guttmacher.org/sites/default/files/pdfs/pubs/Abortion-India-LitReview.pdf>)

According to the Sample Registration System Bulletin-2016, India has registered a 26.9 per cent reduction in maternal mortality ratio (MMR) since 2013. The MMR has declined from 167 in 2011-2013 to 130 in 2014-2016,

t

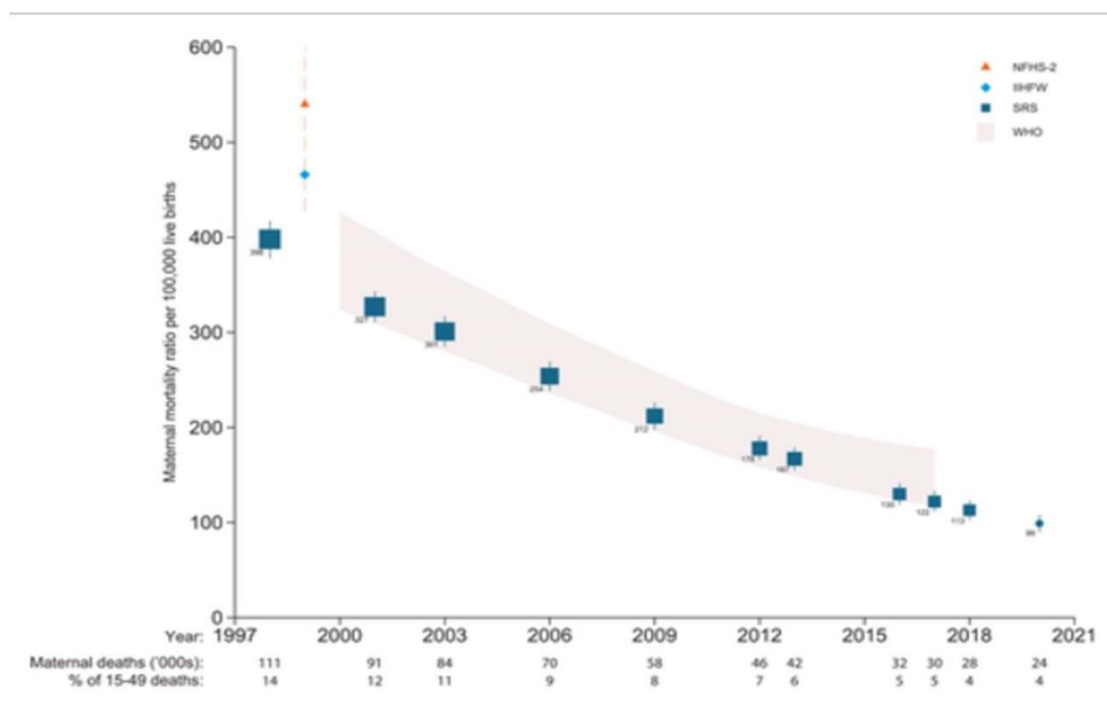
MMR (per 100,000 live births)	2004-06 ^[23]	2007-09 ^[24]	2010-12 ^[25]	2011-13 ^[26]	2014-16 ^[27]	2015-17 ^[28]	2016-18 ^[29]	2018-20 ^[30]
India Total	254	212	178	167	130	122	113	97
Assam	480	390	328	300	237	229	215	195
Bihar	312	261	219	208	165	165	149	118
Jharkhand						76	71	56
Madhya Pradesh	335	269	230	221	173	188	173	173
Chhattisgarh						141	159	137
Odisha	303	258	235	222	180	168	150	119
Rajasthan	388	318	255	244	199	186	164	113
Uttar Pradesh	440	359	292	285	201	216	197	167
Uttarakhand						89	99	103
<i>EAG & Assam Subtotal</i>	<i>375</i>	<i>308</i>	<i>257</i>	<i>246</i>	<i>188</i>	<i>175</i>	<i>161</i>	<i>137</i>
Andhra Pradesh	154	134	110	92	74	74	65	45
Telangana					81	76	63	43
Karnataka	213	178	144	133	108	97	92	69
Kerala	95	81	66	61	46	42	43	19
Tamil Nadu	111	97	90	79	66	63	60	54
<i>South Subtotal</i>	<i>149</i>	<i>127</i>	<i>105</i>	<i>93</i>	<i>77</i>	<i>72</i>	<i>67</i>	<i>49</i>
Gujarat	160	148	122	112	91	87	75	57
Haryana	186	153	146	127	101	98	91	110
Maharashtra	130	104	87	68	61	55	46	33
Punjab	192	172	155	141	122	122	129	105
West Bengal	141	145	117	113	101	94	98	103
Other States	206	160	136	126	97	96	85	77
<i>Other Subtotal</i>	<i>174</i>	<i>149</i>	<i>127</i>	<i>115</i>	<i>93</i>	<i>90</i>	<i>83</i>	<i>76</i>

o 122 in 2015-17, to 113 in 2016-2018.

https://en.wikipedia.org/wiki/Maternal_mortality_in_

The MMR per 100 000 live births fell over the study period by more than 70%, from 398 (95% CI 378–417) in 1997–1998 to 113 (95% CI 103–123) in 2016–2018 (Figure 1), with an average annual rate of decline of 6.3% (95%CI 5.6–

7.0%). Projecting the observed decline for a further 2 years, we estimate an MMR of 99 (95% CI 90–108) by 2020. Overall, we estimate that about 1.30 million (95% CI 1.26–1.35) maternal deaths occurred in India between 1997 and 2020. The EAGA states accounted for 952 000 maternal deaths, whereas about 317 400 maternal deaths occurred in the other states. The number of maternal deaths fell from 110 800 (95% CI 105 200–116 100) in 1997 to an estimated 23 800 (95% CI 21 700–26 000) in 2020 (Table S1). The proportion of maternal deaths among deaths in women aged 15–49 years fell from about 12% to below 4% during this time period. The MMR declines were broadly consistent with the WHO modelbased estimates (Figure 1) and correlated with the expansion of the percentage of births occurring in facilities as well as the decline in neonatal mortality (Pearson correlations of 93% and 98%, respectively, each $P < 0.0001$; Table S2).



<https://obgyn.onlinelibrary.wiley.com/>

Medical Termination of Pregnancy Act

The Indian Parliament passed the Medical Termination of Pregnancy (MTP) Act in 1971 with the goal of regulating and ensuring access to safe abortion. As of this writing, this law permits only registered allopathic medical practitioners at

certified abortion facilities to perform abortions to save a woman's life or to preserve her physical or mental health; it also permits abortion in cases of economic or social necessity, rape, incest, fetal impairment or the failure of a contraceptive method used by a married woman or her husband. Consent for the abortion is not required from the woman's husband or from other family members, however a guardian's consent is required if the woman seeking an abortion is either younger than 18 or mentally ill. The act allows an unintended pregnancy to be terminated up to 20 weeks' gestation; however, if the pregnancy is beyond twelve weeks, a second doctor's approval is required. There are exceptions to this: If the provider is of the opinion that an abortion is immediately necessary to save a woman's life, the gestational age limit does not apply and the second opinion is not required

Providers of Legal Abortion Services

Under the MTP Act Current abortion policy in India excludes health care workers who are not allopathic physicians from being trained as abortion providers or legally providing abortions. Only obstetrician-gynecologists and other allopathic physicians who have completed a bachelor of medicine/bachelor of surgery degree, have undergone specific government approved training in abortion provision and have received certification are permitted to legally provide abortion. To meet government criteria, a training center must perform a minimum of 600 procedures per year and have all necessary equipment. The recommended duration of training for surgical abortion is two weeks, and each trainee must observe at least 10 abortion procedures, assist with five, perform at least five under supervision and perform another five independently. Abortion provision is allowed at all public facilities, as long as the provider is certified in abortion provision. The MTP Act mandates that each state provide abortion services at tertiary-level health care centers (medical colleges) and secondary-level health care centers (district hospitals and first referral units) up to 20 weeks' gestation. Private-sector facilities are permitted to provide first- and second-trimester abortion services after receiving government approval as a registered abortion facility. The Medical Termination of Pregnancy Rules and Regulations of 1975, which operationalized the MTP Act, define the criteria and procedures for approval of

an abortion facility, which applies exclusively to private sector facilities, in addition to outlining the procedures for consent and confidentiality requirements, record-keeping and reporting.

Amendments to the MTP Act

Since 1971, the government of India has taken steps to increase access to legal and safe abortion services by implementing policies designed to expand the number of legal abortion providers. Despite the legality of abortion provision in the public sector, actual provision at lower level public facilities (such as primary health centers) was scarce prior to 2000. In 2000, the National Population Policy officially recommended expanding the provision of abortion up to eight weeks' gestation to all public facilities, including primary health centers. A decade later, community health centers continue to be the main providers of abortions up to eight weeks' gestation, and provision at the lower level remains a challenge because most primary health centers are not staffed with certified abortion providers

Additional amendments to the MTP Act and Rules and Regulations were made in 2002 and 2003 in an effort to streamline registration of private doctors as abortion providers and thereby further expand access to safe abortion services.^{24,25} The 2002 amendment to the MTP Act decentralized the regulation of abortion facilities from the state level to District Level Committees, and the subsequent amended Rules streamlined the facility registration process by creating facility inspection deadlines to which the district-level committees must adhere—policy changes that were expected to speed up the process of certifying private facilities. The Rules also changed the physical standards for facilities providing first-trimester abortion services: Facilities are no longer required to have onsite capability for managing emergency complications, but must have personnel trained to recognize complications and be able to refer patients to another facility for emergency care. After the decentralization of the registration and certification processes, local governments became empowered to regulate abortion services. Operationally, however, implementation has been uneven because many District

Level Committees are nonfunctional; in addition, the devolution to the local level also implies there may be differences in regulations across states.

<https://citeseerx.ist.psu.edu/>

Objectives

The transition to small family size is at an advanced phase in India, with a national TFR of 2.2 in 2015–16. This paper examines the roles of four key determinants of fertility—marriage, contraception, abortion and postpartum in fecundability—for India, all 29 states and population subgroups.

Methods

Data from the most recent available national survey, the National Family Health Survey, conducted in 2015–16, were used. The Bongaarts proximate determinants model was used to quantify the roles of the four key factors that largely determine fertility. Methodological contributions of this analysis are: adaptations of the model to the Indian context; measurement of the role of abortion; and provision of estimates for sub-groups nationally and by state: age, education, residence, wealth status and caste

Results

Nationally, marriage is the most important determinant of the reduction in fertility from the biological maximum, contributing 36%, followed by contraception and abortion, contributing 24% and 23% respectively, and postpartum infecundability contributed 16%. This national pattern of contributions characterizes most states and subgroups. Abortion makes a larger contribution than contraception among young women and better educated women.

Conclusion

Findings argue for improvements across all states and subgroups, in provision of contraceptive care and safe abortion services, given the importance of these mechanisms for implementing fertility preferences. In-depth studies are needed to identify policy and program needs that

depend on the barriers and vulnerabilities that exist in specific areas and population groups.

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8820640/>)

REGULATIONS OF DONATION OF ORGANS IN INDIA*By- Vishwas Deshmukh***INTRODUCTION:**

Organ donation is a life-saving process that can help many people who are suffering from organ failure. India has a large number of patients who require organ transplantation, but there is a shortage of donors. The act of donating one's organs or tissues after death to help save the lives of others who are suffering from organ failure or other medical conditions. Organ donation has the potential to save or improve the lives of many people who are in need of vital organs such as the heart, liver, kidneys, and lungs, among others.

The demand for organs for transplantation is very high in most countries, including India, where thousands of people are waiting for life-saving organ transplants. Unfortunately, the supply of organs is limited, and many people die while waiting for a transplant. Organ donation can significantly increase the supply of organs for transplantation and provide hope for people suffering from organ failure.

It is the process of removing organs or tissues from one person, who is either deceased or alive, and transplanting them into another person who has organ failure. Organ transplantation is a life-saving procedure that can significantly improve the quality of life of a person suffering from organ failure. In India, the demand for organ transplantation is increasing, but there is a significant shortage of donors. Therefore, the government of India has implemented several regulations to promote and regulate organ donation.

History Overview

Organ transplantation in India has a shorter history compared to the most developed countries in the world. The kidney transplant was first performed in India in the 1970s. Transplantation activities picked up in the 80s and early 90s but it was mainly restricted to live donor kidney transplants in selected urban areas. Slowly, with new clinics coming up and an increase in the availability of trained staff, kidney transplantation activities increased. However, this led to the famous kidney trade in India in the 80s which caught a wide media coverage. Foreigners patients started to flock to India for transplantation from a paid donor.

Considering the ongoing kidney scam in India, in 1991, the Central Government constituted a committee to make a report, which would be going to be the basis of legislation governing organ transplantation all over India. Moreover, it was also done to give a better definition of the term 'brain death'.

In 1994, The Transplantation of Human Organs Act (THOA) was promulgated by the government of India. Moreover, the Transplantation of Human Organs Rules followed in

1995 and were last amended in 2014, increasing the scope of donation and including tissues for transplantation. The act made commercialization of organs a punishable offence and legalized the concept of brain death in India allowing deceased donation by obtaining organs from brain stem dead person.

REGULATIONS ON ORGAN DONATION IN INDIA:

The primary legislation governing organ donation in India is the Transplantation of Human Organs and Tissues Act (THOTA) 1994. The act was enacted to regulate the removal, storage, and transplantation of human organs and tissues for therapeutic purposes and to prevent the commercialization of organs.

One of the key regulations is the requirement for brain death certification before any organ donation can take place. This certification must be made by a team of medical professionals to confirm that the person is brain dead. The consent of the donor or their family members is also mandatory before any organ donation can take place. This regulation ensures that organ donation is voluntary and not forced upon anyone.

The THOTA also prohibits the commercial trade of organs in India. The sale and purchase of organs are illegal, and violators can face imprisonment and fines. This regulation aims to prevent organ trafficking and exploitation of vulnerable individuals.

Another critical regulation is the allocation of organs. Organs are allocated based on medical urgency, compatibility, and waiting time. The National Organ and Tissue Transplant Organization (NOTTO) is responsible for coordinating organ and tissue transplantation activities in India. NOTTO is also responsible for maintaining a National Registry of Donors and providing information on organ donation and transplantation.

Furthermore, the THOTA mandates the creation of various committees and authorities to oversee and regulate organ donation and transplantation in India. These committees include the Authorization Committees, which evaluate applications for organ transplantation, the State Organ and Tissue Transplant Organization (SOTTO), which regulates organ donation and transplantation at the state level, and the NOTTO, which coordinates organ and tissue transplantation activities at the national level.

The regulations governing the donation of organs in India are primarily governed by the Transplantation of Human Organs and Tissues Act, 1994, and the Transplantation of Human Organs and Tissues Rules, 2014. These regulations define the legal framework for organ donation and transplantation in India.

The main provisions of the THO act and the newly passed Gazette by the Government of India include the following:

For living donation - it defines who can donate without any legal formalities. The relatives who are allowed to donate include mother, father, brothers, sisters, son, daughter, and spouse. Recently, in the new Gazette grandparents have been included in the list of first relatives. The first relatives are required to provide proof of their relationship by genetic testing and/or by legal documents. In the event of there being no first relatives, the recipient and donor are required to seek special permission from the government appointed authorization committee and appear for an interview in front of the committee to prove that the motive of donation is purely out of altruism or affection for the recipient.

Brain-death and its declaration - brain death is defined by the following criteria: two certifications are required 6 hours apart from doctors and two of these have to be doctors nominated by the appropriate authority of the government with one of the two being an expert in the field of neurology.

Regulation of transplant activities by forming an Authorization Committee (AC) and Appropriate Authority (AA.) in each State or Union Territory. Each has a defined role as follows:

Role of Authorization Committee (AC) - The purpose of this body is to regulate the process of authorization to approve or reject transplants between the recipient and donors other than a first relative. The primary duty of the committee is to ensure that the donor is not being exploited for monetary consideration to donate their organ. The joint application made by the recipient and donor is scrutinized and a personal interview is essential to satisfy to the AC the genuine motive of donation and to ensure that the donor understands the potential risks of the surgery. Information about approval or rejection is sent by mail to the concerned hospitals. The decision to accept or reject a donor is governed by Sub Clause (3), Clause 9 of Chapter II of the THO act.

Role of Appropriate Authority (AA): The purpose of this body is to regulate the removal, storage, and transplantation of human organs. A hospital is permitted to perform such activities only after being licensed by the authority. The removal of eyes from a dead body of a donor is not governed by such an authority and can be done at other premises and does not require any licensing procedure. The powers of the AA include inspecting and granting registration to the hospitals for transplant surgery, enforcing the required standards for hospitals, conducting regular inspections of the hospitals to examine the quality of transplantation and follow-up medical care of donors and recipients, suspending or canceling the registrations or erring hospitals, and conducting investigations into complaints for breach

of any provisions of the Act. The AA issues a license to a hospital for a period of 5 years at a time and can renew the license after that period. Each organ requires a separate license.

Application Forms

The Transplantation of Human Organ Act clearly lays out various procedures; for this purpose, it has thirteen different forms [Table 1]. The Central Government has amended the Transplantation of Human Organs Act, 1994 (42 of 1994) to include certain changes called the Transplantation of Human Organs Rules, 1995 (GSR NO. 51(E), dt. 4-2-1995) [As amended vide GSR 571(E), dt.31-7-2008]. Given below are important excerpts from the rules.

Authority for removal of human organ

Any donor may authorize the removal, before his death, of any human organ of his body for therapeutic purposes as specified in Forms 1(A), 1(B), and 1(C). The new forms have been made more comprehensive and are to be submitted with proof of identity and address, marriage registration certificate, family photographs, etc. with attestation by a Notary Public.

The gazette states that before removing a human organ from the body of a donor before his death, a medical practitioner should satisfy himself that the donor has given authorization in Form 1(A) if the relative is a close relative i.e., a mother, father, brother, sister, son, or daughter. Form 1(B) is used for a spouse and Form 1(C) is used for other relatives. He should also confirm the following:

The donor is in a proper state of health and is fit to donate the organ. The registered medical practitioner should then sign a certificate as specified in Form 2.

The donor is a close relative of the recipient as certified in Form 3 and has signed Form 1(A). The donor has submitted an application in Form 10 jointly with the recipient and the proposed donation has been approved by the concerned competent authority. The relationship between the donor and recipient also needs to be examined to the satisfaction of the Registered Medical Practitioner in charge of the transplant center.

In the case of the recipient being a spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and the proposed donation has been approved by the concerned competent authority.

In the case of a donor who is other than a close relative, the donor has signed Form 1(C), submitted an application in Form 10 jointly with the recipient, and permission from the Authorization Committee for the donation has been obtained.

A registered medical practitioner shall, before removing a human organ from the body of a person after his death, confirm the following:

The donor had, in the presence of two or more witnesses (at least one of whom is a close relative of the recipient), unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body after his death for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority.

The person lawfully in possession of the dead body has signed a certificate as specified in Form 6.

A registered medical practitioner shall, before removing a human organ from the body of a person in the event of brain-stem death, confirm the following:

A certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts.

In the case of brain-stem death of a person of less than 18 years of age, a certificate specified in Form 8 has been signed by all the members of the Board of Medical Experts and an authority as specified in Form 9 has been signed by either of the parents the person.

Working Guidelines for the Authorization Committee

The new gazette clearly lays down the following guidelines:

1. Where the proposed transplant is between persons related genetically (close relative, i.e., mother, father, brother, sister, son, or daughter above the age of 18 years old), the following shall be evaluated:

Results of tissue typing and other basic tests

Documentary evidence of relationship e.g., relevant birth certificates and marriage certificate
Documentary evidence of identity and residence of the proposed donor e.g., Ration Card or Voters Identity Card, Passport, Driving License, PAN Card, or Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative

If the relationship is not conclusively established after evaluating the above evidence, direct further medical tests may be given as described follows.

- Test for Human Leukocyte Antigen (HLA), human leukocyte antigen-B alleles to be performed by the serological and /or polymerase chain reaction (PCR) based Deoxyribonucleic Acid (DNA) methods
- Test for human leukocyte antigen-Dr beta genes to be performed using PCR-based DNA methods.

Tests shall be done from a laboratory accredited with National Accreditation Board for Laboratories (NABL). When the tests referred to above do not establish a genetic relationship between the donor and the recipient, the same tests should be performed on both or at least one parent, preferably both parents. If parents are not available, the same tests should be performed on relatives of donor and recipient that are available and are willing to be tested failing which, the genetic relationship between the donor and the recipient will be deemed to have not been established.

When the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e., the person in charge of the transplant center must evaluate the fact and duration of marriage (marriage certificate, marriage and family photographs, birth certificate of children containing particulars of parents). When the proposed donor or recipient or both are not Indian Nationals/citizens whether close relatives or otherwise, the AC shall consider all such requests. A senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient. When the proposed donor and the recipient are not close relatives, the Authorization Committee shall evaluate that there is no commercial transaction between the recipient and the donor and the following shall specifically be assessed:

An explanation of the link between them and the circumstances that led to the offer being made

Reasons why the donor wishes to donate

Documentary evidence of the link, e.g., proof that they have lived together

Old photographs showing the donor and recipient together

There is no middleman or tout involved

The financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two must be evaluated with the objective of preventing commercial dealing.

The donor is not a drug addict or known person with criminal record

The next of kin of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation.

The AC should state in writing its reason for rejecting or approving the application of the proposed donor and all approvals should be subject to the following conditions:

The approved proposed donor would be subjected to all medical tests as required at relevant stages to determine his biological capacity and compatibility to donate the organ in question. Psychiatrist's clearance in such cases is deemed mandatory to certify the donor's mental condition, awareness, absence of any overt or latent psychiatric disease, and ability to give free consent.

All prescribed forms have been completed by all relevant persons involved in the process of the transplantation.

All interviews should be video recorded.

The AC is required to take a final decision within 24 hours of the meeting for grant of permission or rejection for transplant. Every authorized transplantation center must have its own website. The decision of the AC should be displayed on the notice board of the hospital immediately and on the website of the hospital or institution within 24 hours of making the decision.

Guidelines for composition of the AC

There shall be one State Level AC. It will provide approval or a no objection certificate to the donor and recipient to establish legal and residential status in a particular state. Additional ACs may be set up at various levels as per the requirements as follows:

No member from the transplant team of the institution should be a member of the respective AC.

The AC should be hospital-based in metros and big cities if the number of transplants exceeds 25 in a year at the respective transplantation centers. In small towns, there shall be state or district level committees if transplants are less than 25 in a year in the respective districts.

Composition of a hospital-based AC

Medical Director or Medical Superintendent of the Hospital

Two senior medical practitioners from the same hospital who are not part of the transplant team

Two members of high integrity, social standing, and credibility

Secretary (Health) or nominee and Director Health Services or nominee

Composition of State or District Level ACs

Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in a main/major government hospital of the district

Two senior medical practitioners who are residing in the concerned district and who are not part of any transplant team

Two senior citizens of high reputation and integrity residing in the same district
Secretary (Health) or nominee and Director of Health Services or nominee

CHALLENGES IN ORGAN DONATION IN INDIA:

Despite the government's initiatives to promote and regulate organ donation in India, there are several challenges that still need to be addressed. Some of the key challenges to organ donation in India are:

Lack of awareness and education: There is a lack of awareness and education about organ donation in India, particularly in rural areas. Many people in India do not understand the importance of organ donation, and some even have misconceptions about the process, such as the belief that organ donation can harm the donor or that their body will not be complete without all its organs.

Cultural and religious barriers: Organ donation is not widely accepted in some cultures and religions in India. For example, some Hindu beliefs suggest that the body should remain intact after death and that organ donation interferes with the cycle of reincarnation. Similarly, some Muslim beliefs prohibit organ donation, although many Muslim scholars have stated that it is permissible under certain conditions.

Lack of infrastructure and facilities: India has a shortage of hospitals and facilities that can perform organ transplantation surgeries. Many hospitals lack the necessary equipment and expertise to perform these surgeries, and patients may have to travel long distances to access the few hospitals that offer these services.

Legal and ethical issues: The legal and ethical issues surrounding organ donation can be complex, particularly when it comes to obtaining consent from the donor or their family members. Some families may be reluctant to give consent, and there have been cases of organ trafficking and exploitation in India, which can further erode trust in the system.

Financial barriers: The cost of organ transplantation can be prohibitively expensive for many people in India, and the government's health insurance schemes do not always cover these procedures. This can create financial barriers that prevent people from accessing organ transplantation surgeries.

GOVERNMENT INITIATIVES TO PROMOTE ORGAN DONATION:

The government of India has taken several initiatives to promote and regulate organ donation in the country. These initiatives aim to increase awareness about organ donation, improve the infrastructure for organ transplantation, and create a regulatory framework to prevent organ

trafficking and exploitation. Some of the key government initiatives to regulate organ donation in India are:

The Transplantation of Human Organs and Tissues Act (THOTA): The THOTA is the primary legislation governing organ donation in India. The act regulates the removal, storage, and transplantation of human organs and tissues for therapeutic purposes and prevents the commercialization of organs. The act mandates brain death certification before organ donation can take place and requires the consent of the donor or their family members. The THOTA also prohibits the sale and purchase of organs and establishes various committees and authorities to oversee and regulate organ donation and transplantation in India.

The National Organ and Tissue Transplantation Program (NOTP): The NOTP is a government-led initiative launched in 2014 to improve the availability of organs for transplantation and promote organ donation in India. The program aims to establish a network of organ retrieval centers and transplant hospitals, develop and maintain a national registry of organ donors, and increase awareness and education about organ donation.

The National Organ Donation Day: The government of India observes the National Organ Donation Day on November 27 every year to create awareness about organ donation and encourage people to pledge their organs for donation.

The National Organ and Tissue Transplant Organization (NOTTO): The NOTTO is a national-level organization established under the Ministry of Health and Family Welfare to coordinate organ and tissue transplantation activities in India. The NOTTO is responsible for maintaining the national registry of organ donors, allocating organs based on medical urgency and compatibility, and providing information on organ donation and transplantation.

The State Organ and Tissue Transplant Organization (SOTTO): The SOTTO is a state-level organization established in each state of India to regulate organ donation and transplantation activities at the state level. The SOTTO is responsible for authorizing and monitoring organ transplant centers in the state and coordinating with the NOTTO for the allocation of organs.

Awareness campaigns and education programs: The government of India has launched various awareness campaigns and education programs to promote organ donation in the country. These programs aim to dispel myths and misconceptions surrounding organ donation and increase awareness about the importance of organ donation.

CONCLUSION:

The regulation of organ donation in India is essential for promoting the practice of organ donation and transplantation and ensuring the safety and ethicality of the process. The

government has taken several initiatives to promote and regulate organ donation, including establishing regulatory bodies, implementing legal frameworks, and creating public awareness campaigns. These efforts have yielded some positive results, with the number of registered donors and transplant surgeries increasing in recent years.

However, there are still many challenges that need to be addressed to improve the organ donation and transplantation system in India. These challenges include the lack of awareness and education, cultural and religious barriers, the shortage of infrastructure and facilities, legal and ethical issues, and financial barriers. Addressing these challenges will require a concerted effort from the government, healthcare providers, and the general public.

Overall, the regulation of organ donation in India is an ongoing process, and there is still much work to be done. However, with sustained efforts to promote and regulate organ donation, India can overcome these challenges and establish a robust organ donation and transplantation system that can save countless lives.