# IN THE SUPREME COURT OF BANGLADESH HIGH COURT DIVISION (SPECIAL ORIGINAL JURISDICTION)

### WRIT PETITION NO. 12514 OF 2017

#### IN THE MATTER OF:

An application under article 102 of the Constitution of the People's Republic of Bangladesh.

### -AND-

### IN THE MATTER OF:

Fatema Zohora.

..... Petitioner

-Versus-

Bangladesh represented by the Secretary, Ministry of Health and Family Welfare Affairs, Bangladesh Secretariat, Ramna, Dhaka and others. ......Respondents

Ms. Rashna Imam with Mr. Reshad Imam, Advocates .....For the petitioner

Mr. Saifuddin Khaled, DAG with Mr. Muhammad Shah Newaj, AAG and Mr. Md. Sirajul Alam Bhuiyan, AAG ....For the respondent no. 1

Mr. Z. I. Khan Panna with Mr. Md. Shahinuzzaman, Advocates ...For the intervener Ain o Shalish Kendra (ASK)

> Heard on 07.11.2019 and 21.11.2019. Judgment on 05.12.2019.

Present: Mr. Justice Moyeenul Islam Chowdhury -And-Mr. Justice Khandaker Diliruzzaman

## **MOYEENUL ISLAM CHOWDHURY, J:**

On an application under article 102 of the Constitution of the People's Republic of Bangladesh filed by the petitioner, on 24.08.2017, a Rule Nisi was issued calling upon the respondents to show cause as to why their inaction/failure in effectively regulating the donation and transplantation of organs should not be declared to be without lawful authority and of no legal effect and why sections 2 (ga), 3 and 6 of মানবদেহে অঙ্গ-প্রত্যঙ্গ সংযোজন আইন, ১৯৯৯ (Act No. 05 of 1999) should not be declared to be void and *ultra vires* the Constitution of the People's Republic of Bangladesh and/or such other or further order or orders passed as to this Court may seem fit and proper.

Subsequently at the instance of the petitioner on 07.08.2018, this Court issued a further Rule Nisi calling upon the respondents to show cause as to why sections 2(4), 4, 7, 8 and 9 of মানবদেহে অঙ্গ-প্রত্যঙ্গ সংযোজন (সংশোধন) আইন, ২০১৮ (Act No. 01 of 2018) should not be declared to be void and *ultra vires* the Constitution and/or such other or further order or orders passed as to this Court may seem fit and proper.

The case of the petitioner, as set out in the Writ Petition, in short, is as follows:

The petitioner is a conscious and law-abiding citizen of Bangladesh. She is the mother of a 24-year-old female kidney patient in dire need of a kidney transplant. The petitioner's daughter was diagnosed with kidney disease in 2013 at a tender age of 20 while she was studying Zoology at the University of Dhaka. The disease progressively deteriorated leading to the failure of her both kidneys which necessitated her undergoing a kidney transplant in 2015. The donor was the petitioner herself. But unfortunately the kidney problem of the donor's daughter resurfaced. She is currently undergoing dialysis which is extremely expensive and unsustainable in the long run especially given that the petitioner has already incurred hefty medical expenses amounting to more than Tk. 5,00,000/- on her daughter's kidney treatment. Owing to the unreasonably restricted definition of organ donors in the existing law, that is to say, Act No. 05 of 1999, she has not been able to obtain a kidney till date for her 24-year-old daughter. While Bangladesh does not have any study that states the actual prevalence of kidney disease and the need for transplant, some estimates suggest at least 20 million people suffer from some form of kidney disease in Bangladesh and 35,000 to 45,000 of them die of kidney failure every year. The annual demand for kidney transplant is estimated to be anywhere between 5,000 to 9,000. The reason for this high demand is the merit of kidney transplant as a method of treatment for kidney failure over dialysis. Different types of dialysis exist. It can be hospital or clinic-based and home or office-based. It costs anywhere between Tk. 40,000/- to Tk. 1,00,000/- per month depending on the hospital or clinic. On an average, 90% of the patients discontinue treatment due to financial hardship within three years. In addition, the capacity of local hospitals and clinics to provide this service is extremely limited compared to the demand for such service at any given time. It is pertinent to note that there are additional costs involved in running monthly medical tests and weekly erythropoietin injections to treat haemoglobin deficiency, not to mention travel costs as patients, in aggregate, require 2 to 3 dialysis sessions per week. Besides, dialysis significantly reduces the quality of life of kidney patients. A kidney transplant costs around Tk. 2,00,000/- to Tk. 7,00,000/- in Bangladesh. If successful, this is a one-off cost as opposed to the running costs involved in dialysis. This is not only a

much better treatment for kidney failure medically and economically, but also it is much less time-consuming, being a one-off treatment, if successful; and the chance of a successful transplant is high. There is a huge gap between supply and demand in relation to kidney donation in Bangladesh. It is estimated that only 120 to 130 patients (of end-stage renal failure requiring kidney transplant), on an average, can manage live donors to undergo kidney transplant against the annual demand of estimated 5000. This is not only causing death from kidney failure; but also creating a market for illegal kidney trade where abuses are rife.

The Act No. 05 of 1999, though enacted in response to incidents of abuse, are fraught with inadequacies which defeat the very purpose for which it was enacted. Section 3 read with section 2(ga) and section 6(1) of the Act No. 05 of 1999 provide a very narrow definition of donor, that is to say, "near relative". The already large gap between demand and supply of kidneys is further increased by this narrow definition of donors leading to kidney patients dying without any transplant. The large gap particularly affects the poor by creating a black market for kidneys where abuses are rampant. According to Washington-based Global Financial Integrity (GFI), many in Bangladesh, particularly in the rural areas, are compelled to sell their organs primarily to settle debts or for brief moments of financial respite. They are poor, uneducated, desperate and unaware of the post-sale complications. Some of them end up with chronic health complications. A few are better off. The brokers downplay the risk of future complications, sometimes the doctors even tell potential vendors that their kidneys will grow back. Serious post-operative complications, such as infection, chronic pain, fatigue and impaired function of the remaining kidney are common. As

such a provision must be made for exceptional circumstances when a donor can be someone from outside the group of "near relative" and "exceptional circumstances" must be defined and/or criteria laid down for its determination. The Act No. 05 of 1999 does not provide for the formation of a central authority for regulation of the removal and use of organs for transplantation. Such an authority is imperative to curb abuse which is the very reason why the Act No. 05 of 1999 was enacted. An example of such an authority is the Human Tissue Authority (HTA) in the United Kingdom (UK). Because of the inadequacies in the Act No. 05 of 1999, kidney patients are left with no option but to travel abroad with donors (who do not fall within the narrow definition of "near relative" in the Act) for the purpose of transplantation in breach of the Act; kidney transplant abroad being very expensive compared to the cost of getting it done locally and therefore not affordable by many. This is leading to illicit financial flows out of the country as pointed out in various news reports and people are resorting to dialysis as a method of treatment which is economically and medically unsustainable in the ultimate analysis, and patients generally discontinue treatment within three years. So it is imperative that some guidelines are formulated and eventually amendments are made to the Act No. 05 of 1999 to address this crisis of kidney donation and transplantation to ensure that 35,000 to 45,000 lives are not lost every year for reasons that are completely avoidable.

In the application for further Rule filed by the petitioner, it has been averred that the Act No. 05 of 1999 was amended by the Act No. 01 of 2018. The originally impugned sections 2(ga), 3 and 6 have all been amended and substituted by sections 2(4), 4 and 7 of the Act No. 01 of 2018. Two changes

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that have been made by the Act No. 01 of 2018 have slightly widened the definition of donor pool. Section 2(4) of the Act No. 01 of 2018 has slightly expanded the definition of "near relative" given in section 2(ga) of the Act of 1999 to include grandfather, grandmother, grandson, No. 05 granddaughter and first cousins who are related by blood. Section 7 of the Act No. 01 of 2018 has modified section 6 of the Act No. 05 of 1999 to extend the age limit for dead donors from 2-65 years to 2-70 years. However, the age limit for live donors is still between 18 years to 65 years. The aforesaid expansion of the definition of "near relative" is unlikely to make any notable or significant difference to the huge gap between the demand and supply of organs, in particular, of kidneys in Bangladesh. Anyway, there is a global trend in relation to widening the pool of donors by introducing altruistic and/or emotional donation by living unrelated donors so as to reduce the gap between the demand and supply of kidneys. Countries like the United Kingdom, United States, India, France, amongst others, all allow emotional and/or altruistic donations. In view of the huge mismatch between the demand and supply of kidneys in Bangladesh, Bangladesh should follow suit and further amend the Act No. 05 of 1999 to widen the pool of donors. As the impugned sections 2(4), 4, 7, 8 and 9 have violated the right of life of the petitioner for the narrow definition of "near relative" even after its expansion by the Act No. 01 of 2018, those sections should be declared void and violative of Article 32 of the Constitution.

The respondent no. 1 has contested the Rule by filing an Affidavit-in-Opposition. The case of the respondent no. 1, as set out in the Affidavit-in-Opposition, in brief, runs as under:

If section 2(4) is further amended, it will create anarchy in organ transplantation sphere of our country. The Act No. 01 of 2018 has created a Cadaveric National Committee (section 7(kha)) which will monitor all cadaveric kidney transplants in Bangladesh. Pursuant to the Act No. 05 of 1999, the Government has already formulated মানবদেহে অঙ্গ-প্রত্যঙ্গ সংযোজন বিধিমালা, ২০১৮ (briefly, the Rules of 2018) in order to carry out the purposes of the Act No. 05 of 1999. In view of the global trend of widening the pool of organ donors and the high prevalence of kidney disease in Bangladesh and the huge gap between the demand and supply of kidneys in Bangladesh, this Court felt the necessity of receiving the opinions of some experts in disposing of the Rule Nisi. So this Court, by its order dated 28.08.2019, directed 7(seven) high-profile experts in the relevant fields to give their opinions. Accordingly the experts submitted their consolidated written opinion in the Court. In public interest, the respondent no. 1 will follow and comply with the opinion of the experts. Besides, if any directive comes from this Court, the Government will abide by the same. As such, the Rule may be disposed of.

The intervener Ain o Salish Kendra (ASK) has also filed an Affidavitin-Opposition in this case. ASK has made some statements in its Affidavitin-Opposition which may be summarized as follows:

The petitioner's daughter was diagnosed with kidney disease in 2013 at the age of 20. Due to the failure of both the kidneys, she had to undergo a kidney transplant in 2015. The donor was the petitioner herself. Unfortunately her daughter's kidney problem resurfaced and she was in need of undergoing another kidney transplant. Owing to the restrictive definition of organ donors under the existing law, the petitioner has not been able to

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obtain another kidney for transplantation for her daughter till date. On 22.08.2017, the petitioner filed the Writ Petition challenging section 3 read with section 2(ga) and section 6(1) of the Act No. 05 of 1999 and seeking to expand the definition of "near relative". Under the existing law as amended by the Act No. 01 of 2018, the pools of donors and recipients have been extended up to maternal and paternal grandfathers, grandmothers, grandsons, granddaughters, first maternal and paternal cousins. On 29.08.2019, ASK became an intervener in this Writ Petition by referring to its on-site factfinding report dated 12.09.2011 and the news reports published in different daily newspapers relating to the sale of human organs in Kalai Upazilla of Joypurhat District with the assistance of the middlemen of the localities and Dhaka. The investigation unit of ASK conducted another on-site fact-finding in Joypurhat District on 03.09.2019 and 04.09.2019 and found that the illegal kidney trade is still in place in different villages of Kalai Upazilla of Joypurhat District. The report published on 09.11.2019 in "The Daily Prothom Alo" under the headline "জয়পুরহাটের কালাইয়ে থেমে নেই কিডনি বিক্রির প্রবণতা" states that the poor and indebted villagers of Kalai Upazilla in Joypurhat District are selling their kidneys till date. Few middlemen have been arrested and awareness seminars have been held by the Kalai Police Station in order to prevent the selling of kidneys. As illegal trading of organs, in particular, kidneys is still in place, the definition of "near relative" as given in section 2(4) of the Act No. 01 of 2018 need not be extended further.

At the outset, Ms. Rashna Imam, learned Advocate appearing on behalf of the petitioner, submits that the petitioner is a donor and a mother of a 24-year-old female kidney patient and in dire need of a kidney for her daughter and her fundamental right to life and that of thousands of others are being affected by the impugned provisions of the Act No. 05 of 1999 as amended till date and the impugned failure of the respondents in regulating organ donation and transplantation and therefore, the petitioner has sufficient interest in filing this Writ Petition as a Public Interest Litigation.

Ms. Rashna Imam also submits that at least 20 million people of this country suffer from some form of kidney disease and 35,000 to 45,000 of them die of kidney failure every year and the annual demand for kidney transplant is estimated to be anywhere between 5,000 to 9,000 and the reason for this high demand is that kidney transplant is economically, medically and emotionally a much better treatment than dialysis.

Ms. Rashna Imam next submits that the fear that organ trading and trafficking will increase if emotional/altruistic donation is permitted is unfounded in view of the fact that trading or trafficking of organs, in particular, kidneys is booming as there is a market for organs due to the huge gap between demand and supply and a major reason for this huge gap is the narrowness of the definition of "near relative" in the Act No. 05 of 1999 as amended till date.

Ms. Rashna Imam further submits that if donation from any living unrelated donor is legalized and the State-controlled and regulated compensation is given, that is, a regulated market is set up, that will cut out middlemen and prevent exploitation.

Ms. Rashna Imam also submits that the law must make proper organs available and in order to take adequate safeguards to prevent exploitation of the poor and uneducated masses, the law ought to be further amended by legalizing donations from living unrelated donors.

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Ms. Rashna Imam next submits that as per law, a donor has to be a "near relative"; but in exceptional circumstances (where no "near relative" does not wish to donate or cannot donate for medical reasons), a donor may be anyone from outside this group who may wish to donate for emotional and/or altruistic reasons.

Ms. Rashna Imam further submits that in the United Kingdom, USA, India, Iran and France, emotional and/or altruistic donations of kidneys and other organs are prevalent and in order to bridge the huge mismatch between the demand and supply of kidneys, Bangladesh may follow any of the examples of those countries by making necessary amendments in the Act No. 05 of 1999.

Ms. Rashna Imam also submits that the functions of the Authentication Board as introduced by the Act No. 01 of 2018 should include verification of whether exceptional circumstances exist and guidance on how to verify exceptional circumstances which may be obtained from the Indian Transplantation of Human Organs and Tissues Rules, 2014.

Ms. Rashna Imam next submits that the setting up of a regulated market of organs will minimize exploitation by ensuring adequate compensation, safe surgical and medical procedures for the donors (contrary to what a donor in the black market is exposed to), post-operative care, free health insurance, etc. and in Iran within the first year of the establishment of this system, the number of transplants had almost doubled; nearly four-fifths were from living unrelated sources and in addition to payment from the Government, donors also receive free health insurance and often payment from the recipients and in the USA, a donor's immediate medical care is covered by the recipient's insurance and the donor is given priority in the waiting list.

Ms. Rashna Imam further submits that given the current shortage of organs worldwide, this has received both popular and scholarly attention and human organs should be bought and sold in a well-regulated market as any other material properties belonging to individuals inasmuch as such a wellregulated market addresses the grave shortage of organs and respects the freedom of the individuals to choose to do whatever they want with their body parts.

Ms. Rashna Imam also submits that only one cadaveric kidney transplant was performed in Bangladesh in 2019 with the assistance and under the supervision of a Korean Kidney Transplant Team and since Bangladesh lacks necessary infrastructural facilities and skilled manpower in the field of cadaveric kidney transplant, Bangladeshi kidney transplant surgeons, nurses and other support staff must enhance their skill and efficiency in this field and as cadaveric kidney transplant is in its nascent stage in Bangladesh, the petitioner cannot have any cadaveric kidney for the purpose of transplantation in her daughter.

Ms. Rashna Imam further submits that there is a need for promotion of cadaveric kidney transplants and had cadaveric kidney transplants been in place on a wide scale in Bangladesh as in developed countries, the petitioner would not have come up with the instant Writ Petition being in dire need of a kidney for transplantation in her daughter.

Ms. Rashna Imam next submits that there is a system called 'opt-out' system in France, Belgium, Spain, Austria and Wales where consent to donate on death is presumed unless a citizen opts out by entering his or her name in a register kept for the purpose and if this 'opt-out' system as prevalent in those countries is adopted in Bangladesh by amending the Act No. 05 of 1999, then there will be no dearth of kidneys for transplantation.

Ms. Rashna Imam also submits that because of the huge mismatch between the demand and supply of kidneys, a large number of people go to neighbouring countries, particularly, India with the donors and recipients for necessary kidney transplantation which entail a huge amount of money and this leads to illegal flow of money from Bangladesh to that country.

Ms. Rashna Imam next submits that Bangladesh can also follow the model of Iran with regard to kidney transplantation where kidneys are easily available for the purpose and the donors receive compensation from the Government for this act of charity and as there is no embargo on kidney donation in Iran, the end-stage kidney failure patients do not suffer owing to dearth of kidneys for the purpose of transplantation.

Ms. Rashna Imam further submits that the petitioner has already donated one of her kidneys to her daughter for transplantation and after transplantation in 2015, her kidney problem has resurfaced and she direly needs another kidney for transplantation and in the absence of any "near relative" as defined in the Act No. 05 of 1999 as amended by the Act No. 01 of 2018 and in the virtual absence of cadaveric transplant in Bangladesh, the petitioner's daughter is practically dying of end-stage kidney failure and at present she is incurring a prodigious amount of money on account of two or three sessions of dialysis every week for her survival, apart from the diminished quality of her life and given this panorama, this Court has to decide the fate of the daughter of the petitioner as to the predicament she has landed in. Ms. Rashna Imam next submits that right to life (Article 32) has been broadly defined in constitutional case laws to include preservation of the environment (BELA's Case) (*Dr. Mohiuddin Farooque...Vs... Bangladesh,* 49 *DLR (AD) 1*), right to livelihood (*Olga Tellis and others...Vs...The Mumbai Municipal Corporation, AIR 1986 SC 180*), anything without which life can hardly be enjoyed, etc. and must be interpreted and read with Article 15 (to attain a steady improvement in the material and cultural standard of living of the people with a view to serving its citizens: the provisioning of basic necessities of life, including food, clothing, shelter, education and medicine) and Article 18 (it is a primary duty of the State to improve public health) and the fundamental principles of State policy should not only be applied by the State in the making of laws, but should also serve as a guide to the interpretation the Constitution and the other laws.

Ms. Rashna Imam also submits that as the impugned sections 2(4), 4, 7, 8 and 9 of the Act No. 01 of 2018 are *ultra vires* Article 32 of the Constitution, they are liable to be declared as such.

Per contra, Mr. Saifuddin Khaled, learned Deputy Attorney-General and Mr. Md. Sirajul Alam Bhuiyan, learned Assistant Attorney-General appearing on behalf of the respondent no. 1, submit that the respondent no. 1 is very much in tune with the consolidated opinion dated 29.10.2019 given by the committee of experts and the definition of "near relative" as amended by the Act No. 01 of 2018 has expanded the pool of donors to a great extent, much to the relief of the petitioner.

Both Mr. Saifuddin Khaled and Mr. Md. Sirajul Alam Bhuiyan further submit that there is a need for promotion of cadaveric kidney transplant in Bangladesh and the committee of experts has also laid stress on the promotion of cadaveric kidney transplant and if cadaveric kidney transplant is carried out on a large scale in the future, there will be no dearth of kidneys for the purpose of transplantation.

Mr. Z. I. Khan Panna, appearing in person on behalf of ASK, submits that the expansion of the donor pool by the Act No. 01 of 2018 is appreciable; but even then, it is evident from the news report dated 09.11.2019 and the fact-finding report dated 03.09.2019 and 04.09.2019 that illegal kidney trading is still going on in the remote areas of Kalai Upazilla, though selling of human organs is completely prohibited in our country.

Mr. Z. I. Khan Panna also submits that following the experts' opinion dated 29.10.2019, if cadaveric transplantation is practised, then kidney donation from any unrelated living donor is not needed and further expansion of the definition of "near relative" to "any physically fit and healthy individual" will merely increase the possibility of unlawful kidney trading in Bangladesh exponentially.

Mr. Z. I. Khan Panna next submits that even if some guidelines or criteria are provided for such wholesale transplantation, illegal trading of kidney cannot be prevented as it will open up the floodgate of kidney trading by the poor and the marginalized people for economic reasons.

We have heard the submissions of the learned Advocate for the petitioner Ms. Rashna Imam and the counter-submissions of the learned Deputy Attorney-General Mr. Saifuddin Khaled and the learned Assistant Attorney-General Mr. Md. Sirajul Alam Bhuiyan for the respondent no. 1 and the intervener Mr. Z. I. Khan Panna on behalf of ASK and perused the Writ Petition, Affidavits-in-Opposition filed by the respondent no. 1 and the intervener (ASK) and relevant Annexures annexed thereto.

To begin with, we want to put on record that prior to 1999, there was no law in Bangladesh as to kidney transplantation. For the first time, the Act No. 05 of 1999 was enacted in Bangladesh for the purpose of regulation and transplantation of kidneys in kidney patients. In the Act No. 05 of 1999, there is a donor pool called "near relative"; but that definition of donor pool (near relative) has been further expanded by the Act No. 01 of 2018. Although the Act No. 05 of 1999 was enacted about 19 (nineteen) years back, yet the fact remains that the Rules of 2018 have been framed recently for carrying out the purposes of the Act No. 05 of 1999. Of course, the framing of the Rules of 2018 is very belated. However, this is a welcome step.

There is no gainsaying the fact that a booming illegal kidney trade is in place in Bangladesh. It is further undisputed that the annual demand of kidneys is around 5,000 whereas the kidney patients numbering about 120-130 undergo live kidney transplants in this country. It is also admitted that there was only one cadaveric kidney transplant performed in 2019 under the supervision of a Korean Kidney Transplant Team in Bangladesh. The huge mismatch between the demand and supply of kidneys for the purpose of transplantation in Bangladesh, as we see it, is due to the narrow definition of "near relative" in the Act No. 05 of 1999 to a considerable extent. It is also due to virtual non-performing of cadaveric kidney transplantation either from live donors or from cadavers, they are in dire need of kidneys. Now a pertinent question arises: how will the end-stage kidney failure patients get kidneys for transplantation in view of the huge mismatch between the demand and supply of kidneys? In order to answer the above question posed, there should be a national campaign for raising awareness of cadaveric kidney donation in Bangladesh. If the patients in Intensive Care Units (ICUs) of all public and private hospitals are mandatorily required to give declarations as to donation of their organs including kidneys, the acute crisis of kidney shortage will be minimized to a great extent. In some of the developed countries, the end-stage kidney failure patients receive about 50% kidneys from live donors and the remaining 50% from the cadavers of brain-dead persons. But unfortunately this is not the scenario of Bangladesh.

In the United States, the National Conference of Commissioners on Uniform State Laws (NCCUSL) met in 1968 and drafted the Uniform Anatomical Gift Act (UAGA). Together with the National Organ Transplant Act, 1984 (NOTA), the UAGA provides the foundation for organ donation in the United States. Altruistic donation is a common phenomenon, where an unrelated donor like a friend, well-wisher, close associate etc. can donate. About 2% of the annual living donations in the USA are altruistic.

Until 2006, the only people who were allowed to donate their organs were relatives and close friends of the people suffering from kidney dysfunction in the United Kingdom. In the United Kingdom, non-directed altruistic donation was introduced in September, 2006 when the Human Tissue Act set out a legal framework for anonymous donors. The law enables a healthy person to donate an organ or part-organ to a stranger. Donor and recipient remain anonymous before donation, but can make contact with each other afterwards if they so wish. Potential donors have to undergo rigorous mental health assessments. If approved, the donor's name is registered on a national database and matched to a recipient. Out of 3,800 living donations since then, 52 have been altruistic and all of those 52 donations have been those of kidneys.

In France, the law allows altruistic/emotional organ donation. The following relatives of the recipient may be authorized to donate organs: father, mother, spouse, brother, sister, son, daughter, grandparents, uncle, aunts, first cousins, spouse's father or mother. The donor may also be any person who provides proof of having lived with the recipient for at least two years (Article L. 123-1 of the French Public Health Code).

The Washington-based Global Financial Integrity (GFI) in a report dated 30.03.2017 says that a kidney can be available in Bangladesh for 2000 US dollars. According to the GFI, many in Bangladesh, particularly in the rural areas, are compelled to sell their organs primarily to settle debts or for brief moments of financial respite. The self-same report of the Washingtonbased GFI further says that some estimates suggest that at least 20 million people suffer from some form of kidney disease in Bangladesh and 35,000 of them die of kidney failure every year. The annual demand for kidney transplant is estimated to be 5,000, but on an average, only around 120 people can manage kidneys from their relatives to undergo transplants in Bangladesh. Doctors have been calling upon the Government to promote cadaveric organ donation in Bangladesh as they find living relatives are becoming less interested in donating kidneys.

One Dr. Fatema Ahmed along with other doctors penned an article under the caption "<u>Brain Death Diagnosis In Adult For Potential Cadaveric</u> <u>Organ Donation In Bangladesh</u>" which was published in the Bangladesh Critical Care Journal in the month of March, 2017. The abstract of that article is as follows: "Aim: The objectives of this study were (i) To increase knowledge of the epidemiological and clinical features of patients diagnosed with brain death for potential cadaveric organ donation (ii) To determine the compliance of guidelines of brain death based on neurological criteria (iii) To analyze process of clinical decisionmaking regarding continuation of life support after brain death diagnosis.

Materials and Method: A prospective observational study was carried out in a 12bed adult ICU of a tertiary care hospital with neurosurgery services in Bangladesh over a period of 2 years from January 2015 to December 2016. All patients admitted during this period were scrutinized for identification of brain death and impending brain death. They were analyzed for causes of brain death, diagnosis of brain death, and the use of ancillary testing. Potential for organ donation was also kept in mind.

Results: During the study period, a total of 1387 patients were admitted into the study ICU and there were 329 deaths. And out of them, 69 were diagnosed as brain death. The main of brain death causes were intracerebral haemorrhage (32/69, 46%),followed by ischemic stroke (11/69,16%), subarachnoid haemorrhage (11/69,12%), traumatic brain injury (8/69,12%) and brain tumor and CNS infection. The diagnosis of brain death was made in 33(47%) cases in the first 48 hours and 23 (33%) cases in 48-96 hours of ICU admission. With the exception of two cases, all study patients had GCS score  $\leq 8(97\%)$ . Brain death was diagnosed according to American Academy of Neurology (AAN) 2010 guidelines. Only in two cases, Electroencephalography was done on family request. All life-sustaining measures were withdrawn in 67(97%) cases with consent of family.

Conclusion: There is no scarcity of brain death cases in our country according to our study. We need to promote and popularize the cadaveric organ transplant along with living donor transplantation."

Another article titled "<u>Anonymous Altruistic Living Kidney Donation</u> <u>In The US: Reality and Practice</u>" was published in the International Journal of Transplantation Research and Medicine by Abby S Kazley and others. The abstract of that article is quoted below: "Living kidney donors have emerged as the best option to overcome the severe shortage transplantable kidneys. A growing of number of these living donor kidneys come from anonymous altruistic donors who are not related to the recipients according to UNOS data. This study examines the process of anonymous altruistic kidney donation and identifies barriers and variance in transplant center practices. Using a mock patient caller, 73 transplant centers were contacted and asked about the process of altruistic anonymous kidney donation and then scored using objective and subjective metrics. We use SRTR data to measure the relationship between altruistic donation and transplant volume, competition, and quality and scored responses as subjective (how nice and responsive the person was) and objective (follow up, etc.). Sixty-seven of the 73 transplant centers contacted perform anonymous altruistic donations. The mean subjective score was 53.60, and the mean objective score was 53.88. A majority of centers were willing or highly willing to answer questions (56.8%), but more than

half (56.8%) answered them inadequately or used jargons. Models including a center's characteristics (competition, waitlist and transplant volume and quality measures) were capable of significantly predicting which programs would have higher objective (C-stat 0.846) and subjective scores (C-stat 0.749). The process for anonymous altruistic donation is highly variable by center. These inconsistencies in practice can potentially lead to confusion, public misperception and discourage motivated individuals from donation."

Another article captioned "<u>The Pinnacle of Altruism: Organ Donation</u> <u>and Transplantation</u>" by Reeta Dar (Khashu) and Sunil Kumar Dar was published in an International Journal of Multi-Disciplinary Research on 06.06.2014 in India. The abstract of that article is to the following effect:

> "This paper introduces us to the concept of altruism and describes the Indian scenario of altruism in the context of organ donation and transplantation. It further classifies living and deceased organ donation into directed and non-directed organ donation and explains them briefly. While encouraging altruism, this paper suggests some ways of increasing organ donation in

India akin to those prevalent in other countries like allowing Living Non-Directed Altruistic organ donation, only after evolving a system where the donor and recipient's identity are kept confidential and considering Living Directed Altruistic organ donation with utmost care keeping in view disparities the existing socio-economic between the rich and the poor, absence of national health insurance policy and the unabated organ trade rackets unearthed almost every year. In addition, this paper recommends allowing Deceased Directed Organ Donation or conditional donation of at least one organ and allowing first degree relative's priority in organ allocation in case family has previously contributed the through Deceased Non-Directed Altruistic organ donation as has been done in other countries for increasing the supply of organs in India."

All French citizens are now organ donors unless they opt out as per the report published in "<u>The Independent</u>", an English news portal on 04.01.2017. This 'opt-out' system is in vogue in Belgium, Spain, Austria and Wales as well. The essence of this system is that consent to donate on death is presumed unless a citizen opts out by entering his or her name in a register kept for the purpose. In other words, people must sign up to a refusal register if they do not want to be donors. Precisely speaking, every citizen in France has automatically become an organ donor unless he decides to opt out.

There is another article titled "Paying Kidney Donors: Time To Follow Iran" published in McGill Journal of Medicine (MJM) on 11.01.2008. This article was written by one Rupert WL Major, an undergraduate fourth year medical student at the University of Leicester. According to that article, one of the few countries that has legalized the sale of organs is Iran. The first kidney transplant in Iran took place forty years ago. However, in the following twenty years, only one hundred were performed overall within Iran. This was mainly due to the lack of infrastructure available to develop and maintain a kidney transplant network within the country. In the early 1980's, the Iranian Government recognized the increasing strain on dialysis resources as the end-stage renal failure population grew in Iran. The Government began to pay for its citizens to have living related transplants abroad, the majority in the UK. Four hundred such transplants were funded in a five-year period. As these costs started to spiral, a small network of renal transplantations teams was set up within Iran and about one hundred transplants were carried out per year from 1985 to 1987. The development of an Iranian renal transplant network of this size was a drop in the ocean compared to over 25,000 people living with endstage renal disease in Iran, many of which live in rural areas and do not readily have access to medical care.

In 1988, Iran legalized Living Non-Related Donation (LNRD) of kidneys and established an associated transplantation system. This

Government-organized system regulated and funded the transplantation process and compensated the donors for their organs. A third-party independent association was set up to arrange contact between donors and recipients. This agency, the Dialysis and Transplant Patients' Association (DTPA), still carries out this function to this day and is staffed on a voluntary basis by end-stage renal failure patients. An important problem with this system is that Human Leucocyte Antigen (HLA) matching of tissues, necessary to improve the chance of graft survival and prevent host rejection, is not routinely performed.

The end-stage renal failure population continues to increase in most countries, putting an increasingly heavy load on medical infrastructure. Compensation for living non-related donors, once a taboo subject, has now begun to be discussed openly in transplantation meetings and medical literature. The advocates for legalization argue that each of us has autonomy over our own body in every aspect of our health and that from this stems the right to donate a kidney to a related or non-related patient.

There is another article named "<u>Organ Donation: Presumed Consent</u> and Focusing On What Matters" posted by one Rebecca Brown on 25.09.2017. It that post, Rebecca Brown spelt out:

> "For some time, discussion around how to increase rates of organ donation has centred around whether or not a system of presumed consent should be adopted. Presumed consent systems are in place in a number of countries, including Spain, Belgium, France, Austria and, as of late 2015, Wales.

Presumed consent is sometimes described as an 'opt-out' system for organ donation. It works by assuming that, unless people express a wish otherwise, they are willing to donate their organs. In England, there is currently an 'opt-in' system, which means that unless someone provides explicit consent for her organs to be donated, it is assumed that she does not consent. The organ donor register is used to record consent or refusal to donate. Presumed consent systems often have a lot of support, with people citing higher donation rates in countries with such systems, and the fact that many actually sign up to the organ donor register.

#### .....

In fact, almost all countries with presumed consent systems adopt a 'soft opt-out' system whereby family members are always approached to confirm that the deceased would not object to their organs being donated. This creates the opportunity for 'family overrule', even where an individual has expressly signed up to be an organ donor. Rarely do countries adopt a system where the family has no right to overrule the

presumed or declared wishes of a donor."

'The Daily Star' of Bangladesh carried a news report titled "<u>Transplant of Kidney From Brain-Dead To Begin Soon</u>" published on 22.08.2019. This report runs as follows:

> "Bangladesh is all set to begin kidney transplant from brain-dead to partially meet the demand of kidney transplant.

> The move came after the organ donation law was amended last year allowing collection of organs from the brain-dead with the consent from the relatives.

> A Korean surgical team is scheduled to arrive in Bangladesh to-day to conduct the first ever kidney transplant from the brain-dead jointly with a group of local physicians.

> Dr. ASM Tanim Anwar, coordinator of the Bangladesh-Korea Kidney Transplantation Team, said, 'The South Korean team will be here on February 10... They will conduct the first cadaveric organ donor transplantation in the country if braindead donor is found and family members permit.'

> Terming it a major landmark of the country's kidney treatment, he said, 'The annual demand for kidney transplantation in Bangladesh right now is estimated to be 5000, but on an average annually,

only around 120 people can manage kidneys from their relatives to undergo transplants.'

'Kidney transplantation from living donors is not a new thing for us since we have been doing it from 1982. Now, we are prepared to do it from braindead persons that had already been started even in our neighbouring India and Sri Lanka, apart from other developed countries,' he said.

Dr Anwar, Nephrologist of Dhaka Medical College Hospital, said the Korean specialized team from the hospital will impart a hands-on training on cadaveric transplantation to a group of Bangladeshi doctors during their visit.

In this regard, the Organization of Islamic Cooperation (OIC), however, endorsed the campaign as the basic principles of Islam always upheld humanitarian causes.

Islamic scholar Maulana Abdullah Al-Maruf referred to the decision of the OIC's Islamic Council which ruled that one can donate his or her organs before or after death 'for the welfare of human beings.'

'A man, however, cannot sell his organs according to Islamic principles, but he can donate... This is because human organs are highly precious in the eye of Islam and they cannot be regarded as commercially tradable objects,' he said."

It is admitted that so far only one cadaveric kidney transplant was performed in Bangladesh a few months back this year (2019) with the assistance and under the supervision of a South Korean Kidney Transplantation Team. This South Korean Kidney Transplantation Team, according to "The Daily Star" newspaper report dated 22.08.2019, imparted a hands-on training on cadaveric transplantation to a group of Bangladeshi doctors during their visit. So it seems that Bangladesh lacks the necessary expertise and skilled manpower in this field of cadaveric kidney transplant. The Bangladeshi kidney transplant surgeons, nurses and other support staff must be given training so as to enhance their competency, efficiency and expertise in the field of cadaveric kidney transplant. In such a posture of things, it can be said that cadaveric kidney transplant in Bangladesh is now in its nascent stage. That is, according to us, one of the main reasons for acute shortage of kidneys in Bangladesh for the purpose of transplantation.

Besides, the declaration of brain-dead persons at all public and private hospitals and clinics must be made mandatory under the law. If it can be made mandatory under the law, then hopefully there will be no dearth of kidneys and other organs of brain-dead persons for the purpose of transplantation. The committee of experts in their consolidated opinion dated 29.10.2019 has articulated that all over the world, the organs of the deceased donors in ICUs including kidneys are transplanted that have been provided for in the present law. The kidney of a brain-dead person may be given to a related and unrelated person and as a result, Bangladesh can proceed to transplant the kidney of a brain-dead person. Against this backdrop, the declaration of brain-death must be made mandatory in all the ICUs of public and private hospitals and computerized network of organ sharing needs to be established in the ICUs of those hospitals as we see in developed countries. So if cadaveric transplantations are available stemming from brain-dead persons, then the crisis of kidney shortage will be solved to a great extent in Bangladesh.

Moreover, the committee of experts has opined that the donor pool will be increased, if a provision is made for "ABO Incompatible Transplantation" system. In an ABO incompatible kidney transplant, the donor's blood type and the recipient's blood type are not compatible...With an ABO incompatible kidney transplant, the recipient receives medical treatment before and after his kidney transplant to lower antibody levels in his blood and reduce the risk of antibodies rejecting the donor kidney. So this ABO incompatible kidney transplantation system may also solve the crisis of shortage of kidneys in Bangladesh.

The committee of experts in their consolidated opinion is of the view that the donor age limit may be extended up to 70 years from 65 years, that means further 5(five) years for increasing the donor pool. So in this way, the age limit of donor may be extended up to 70 years from 65 years by making necessary amendment in the Act No. 05 of 1999.

Anyway, the committee of experts further opines that there is no scope to expand the kidney donor pool in any other way in Bangladesh, for example, by emotional non-related donor; otherwise organ trafficking will be increased and the rich people will exploit the poor people commercially. Pressure will be exerted on the poor people to sell their kidneys and consequently the lives of the poor people will be at stake. They will be victims of physical and mental torture and ultimately the social structure will be broken and the health of the poor people will be at risk and an unhealthy social system will be developed.

The committee of experts in the consolidated opinion has referred to the Istanbul Declaration of 2008 made by SOT that "Organ trafficking Transplant tourism and transplant commercialism threaten to undermine the nobility and legacy of transplantation worldwide because of the reality associated with these practices. The vulnerable in resource-poor countries (such as the illiterate and impoverished, undocumented immigrants, prisoners and political or economic refugees) are exploited for their organs as a major source of organs for the rich patient tourists who are prepared to travel and can afford to purchase organs."

In the Act No. 05 of 1999, the definition of "near relative" has been given in section 2(ga); but subsequently the definition of "near relative" has been expanded by the Act No. 01 of 2018. In other words, the pool of donors has been expanded to some extent by the Act No. 01 of 2018.

According to the assertion of the petitioner, the pool of donors needs to be further expanded to cope with the demand of the time and to meet certain exceptional circumstances as the petitioner is faced with. It is understandable that the petitioner of this Writ Petition is a hapless mother of a hapless daughter. At the age of 24, the daughter had to undergo a kidney transplant donated by the petitioner and as the transplanted kidney stood rejected after 1 (one) year, she needs another kidney for transplantation for her very survival. She does not find any near relative within the definition of "near relative" as expanded by section 2(4) of the Act No. 01 of 2018. Besides, as already observed, cadaveric kidney transplantation is in its nascent stage in Bangladesh. So there is no possibility for cadaveric kidney transplantation of the petitioner's daughter in Bangladesh right at this moment. Over and above, it is admitted on all hands that the costs of dialysis twice or thrice a week are very high ranging from Tk. 40,000/- to Tk.1,00,000/- especially in private hospitals of Bangladesh. This being the situation, how will the petitioner's daughter be supplied with a kidney for transplantation? This question needs to be answered, of course, having regard to the socio-economic and cultural realities of Bangladesh.

In view of the socio-economic and cultural realities of Bangladesh, we are hardly prepared to accept the 'opt-out' system as prevalent in France, Spain, Austria, Belgium and Wales. The people of this country, because of their conservative outlook, will not come forward to endorse this 'opt-out' system; rather the 'opt-in' system as prevalent in the UK is virtually in vogue in Bangladesh too.

The wholesale altruistic donation as prevalent in some countries of the world such as the United Kingdom, United States, India and France will not also be compatible with the socio-economic and cultural realities of Bangladesh. If the definition of pool of donors (near relative) is expanded without any restriction whatsoever, that will definitely spur the illegal kidney trade in Bangladesh to an unimaginable extent. So any wholesale expansion of the definition of pool of donors (near relative) cannot be countenanced.

In Iran, there is a regulated market of sale of various human organs including kidneys. In that country, kidney donors are compensated by the Government. Now kidney transplants are carried out on a massive scale there to meet the growing demands of end-stage renal patients. In the 1<sup>st</sup> place, at the moment, Bangladesh being a resource-constraint country cannot afford to pay compensation to each and every kidney donor. Secondly, a regulated market of sale of various human organs including kidneys as found in Iran, in our view, will not be welcomed by the people of Bangladesh, lest the illegal organ trade flourishes here.

Even if ABO incompatible kidney transplant is practised in Bangladesh to an appreciable extent, that is unlikely to improve the over-all scenario and reduce the acute kidney shortage.

However, having regard to the growing number of kidney patients and especially end-stage renal patients, a sort of mechanism must be evolved to provide succour to them. In this connection, it may be recalled that there is an annual demand of around 5,000 kidneys for transplantation; but in reality, we get only 120 to 130 kidneys for transplantation. So a large number of end-stage renal patients with recipients go abroad for kidney transplantation resulting in illegal flow of money. Again many end-stage renal patients depend on costly dialysis and most of them, due to financial stringency, discontinue dialysis within three years or so resulting in their eventual death. So this state of affairs cannot be allowed to continue sine die. Under the circumstances, we think, only emotional kidney donation by a related or known donor (but not altruistic) can be permitted by making necessary amendments in the Act No. 05 of 1999. But in order to determine and verify the authenticity of such emotional donation, there should be an inquiry thereinto in the light of the guidelines that may be enumerated below:

(1) The exceptional circumstances as in the case of the present petitioner may be determined by the Authentication Board in Bangladesh (equivalent to the Authorization Committee in India) established under section 7(ka) of the Act No. 01 of 2018. In this regard, we may profitably refer to the Transplantation of Human Organs and Tissues Rules, 2014 of India wherein some guidelines on how the Authorization Committees in India regulate emotional donation. In Bangladesh, we can adopt those guidelines which are spelt out as follows:

- (a) Evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person;
- (b) Prepare an explanation of the link between them and the circumstances which led to the offer being made;
- (c) Examine the reasons why the donor wishes to donate;
- (d) Examine the documentary evidence of the link;
- (e) Examine old photographs showing the donor and the recipient together;
- (f) Evaluate that there is no middleman or tout involved;
- (g) Evaluate the financial status of the donor and the recipient by asking them to give

evidence in support of their vocations and the income for the previous three financial years and any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;

- (h)Ensure that the donor is not a drug addict; and
- (i) Ensure that the near relative or if near relative is not available, any adult person related to the donor by blood or marriage interviewed regarding awareness about his/her intention to donate an organ/tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong views or disagreement or objection of such kin shall also be recorded and taken note of.

Besides, we think, there should be an evaluation of the mental health of the donor and the Authentication Board will have to apprise the intended donor of the possible adverse effects, if any, of kidney donation.

If following the above-mentioned guidelines, the authenticity of an emotional donation by a known or related donor (but not unknown or unrelated) is ascertained rigorously by the Authentication Board, there will be a check and balance and the possibility of illegal kidney trade will be greatly minimized. In a word, the donor must donate his kidney to the recipient under a well-regulated legal regimen. In this regard, the Act No. 05 of 1999 and the Rules of 2018 must be amended accordingly.

The petitioner has impugned sections 2(4), 4, 7, 8 and 9 of the Act No. 01 of 2018. In other words, the vires of those sections have been challenged by her. It is well-settled that there is a presumption of constitutionality in favour of the impugned provisions of those sections. But of course, that presumption is a rebuttable presumption. The petitioner could have challenged the constitutionality of section 2(4) only on the ground of the narrowness of the definition of "near relative". In other sections, that is to say, sections 4, 7, 8 and 9, because of the presence of the expression "near relative", the petitioner has impugned the same as well. In our view, it would have been sufficient if the petitioner would have challenged the vires of section 2(4) only. If section 2(4) of the Act No. 01 of 2018 is declared void and *ultra vires* the Constitution, the expression "near relative" will automatically go occurring in the other sections, namely, sections 4, 7, 8 and 9. But we are not inclined that we should decide this question of vires of those sections in this Writ Petition.

In the case of Bangladesh Agricultural Development Corporation represented by the Chairman, Krishi Bhaban, 49-50 Dilkusha Commercial Area, Dhaka and others...Vs...Md. Shamsul Haque Mazumder & others reported in 14 MLR (AD) 197, it was held in paragraph 33:

> "33. In the instant case, the vires of Regulation 55(2) though challenged, the High Court Division declined to declare the

Regulation as *ultra vires* as the High Court Division thought it prudent to dispose of the case otherwise than by striking down the Regulation. The approach of the High Court Division is appreciated because when a case can be decided without striking down the law but giving the relief to the petitioners, that course is always better than striking down the law."

In view of the above 'ratio' enunciated by the Appellate Division in the decision reported in 14 MLR (AD) 197 (supra), we are fortified in our opinion that we need not go into the question of constitutionality of sections 2(4), 4, 7, 8 and 9 of the Act No. 01 of 2018.

With the above observations, guidelines and findings, the Rule is disposed of without any order as to costs.

The respondents are directed to take steps to make further amendments to the Act No. 05 of 1999 and the Rules of 2018 in the light of the observations, guidelines and findings made and recorded in the body of this judgment within 6(six) months from the date of receipt of a copy of this judgment.

Let a copy of this judgment be immediately transmitted to each of the respondents for information and necessary action.

### <u>KHANDAKER DILIRUZZAMAN, J:</u>

I agree.