

NATIONAL STRATEGIC PLAN

ON ORGAN, TISSUE

&

CELL TRANSPLANTATION

2022 - 2026



MINISTRY OF HEALTH



NATIONAL STRATEGIC PLAN ON ORGAN, TISSUE AND CELL TRANSPLANTATION OF SRI LANKA

2022 – 2026



Ministry of Health - Sri Lanka

Background

Sri Lanka has experienced a shift in the patterns of morbidity over the last few decades, due largely to epidemiologic and demographic transitions of the population. This has resulted in an increased prevalence of non-communicable diseases and a growing number of patients with end-stage organ failure, leading to poor quality of life and premature deaths. Accordingly, advancements in the medical field and expansion of treatment facilities have focused on improving the quality of life of these individuals and prolonging their life expectancy.

Organ, tissue, and cell transplantation (hereinafter referred to as organ transplantation) are identified and practiced as a successful and life-saving therapy for patients with end-stage organ failures of organs including kidney, liver, heart, lung, pancreas, and intestine throughout the world. Organ and patient survival rates continue to improve as a result of advances in the donor-recipient selection, better surgical management, rational use of immuno-suppressants, and better management of post-transplantation infections and other complications. Organs are obtained from suitable living or deceased donors. According to the World Health Organization majority of transplanted organs across the world are from live donors. The number of organs transplanted from deceased donors is high in high-income countries. In most low and middle-income countries, almost all kidney transplants are from live donors.

End-stage organ diseases were a death sentence for many Sri Lankans until organ transplantation was established in India in the 1980s. From there onwards, those few who could afford the cost and could meet many other factors underwent organ transplantation still based availability. Despite all, there were many claims about the success rate and post-surgical complications of these interventions. The need to provide organ transplantation services in Sri Lanka was mounting and in 1985 the first kidney transplant was conducted. Starting from the first transplant, which was a success, it led to a steady program that has expanded to reach its current status.

There are many positive factors in the Sri Lankan health system, including the availability of a strong public sector, with the potential of implementing a ‘Transplant Program’ as established in high-income settings.

There is a high burden of non-communicable diseases (NCDs) in Sri Lanka, with a high epidemiological predisposition for diabetes mellitus and coronary heart diseases in the population. In addition, the prevalence of chronic kidney diseases (CKD) is on the rise due to reasons such as the high prevalence of diabetes, hypertension, and etiologies of unknown origin.

Therefore, demand for organs has risen over the years due to several reasons, including the high prevalence of non-communicable diseases and increasing life expectancy, whereas supply has not increased comparably. In recent years, this demand has further increased due to improvements in medical technology, which have increased the success of transplantation, further widening the gap between demand and supply. The shortage of organs for transplantation has led to greater use of organs from living donors. It has also led to unhealthy and unethical practices and rampant commercialization in the processes of transplantation.

In Sri Lanka, the Eye Donation Society was established in 1955 under the Corneal Grafting Act No 38 of 1955, following which the Eye Bank was established in 1961. In recent years, organ transplantation has become available as a successful treatment option with an increasing success rate. The en bloc kidney, liver, and heart transplant were successfully conducted in Sri Lanka in the recent past.

There are nine hospitals performing transplant surgeries including two main national centers in Colombo and Kandy. At present, there are clinicians in the health system, in the disciplines of surgery and medicine who have developed special skills and trained in performing transplant surgeries e.g. transplant surgery, vascular & transplant surgery, gastro-intestinal surgery with a special interest in hepato-biliary surgery, urology & transplant surgery, transfusion medicine, and cardiac anesthesia. Further, transplant coordinators have been identified and trained at all hospitals with ICUs to enhance the organ donation process. There is a possibility of conducting advanced transplantation procedures such as multi-visceral transplantation and introducing new services to the local context in the future i.e., lung and small bowel transplantation.

Organ donation and transplantation are socio-culturally acceptable and viewed favorably by the majority of Sri Lankans. Currently, a greater proportion of organ donors in Sri Lanka is live donors. It is possible to retrieve nine organs and 75 tissues from a single deceased donor. There is a vast potential to increase the transplantation from deceased donors to meet the need for organs. Moreover, human resources and expertise i.e., transplant surgeons, cardiothoracic surgeons, nephrologists, anesthetists, transfusion physicians, etc., and other support teams that are necessary for conducting transplant surgeries in Sri Lanka need to be strengthened further.

The trend of organ transplants conducted in government institutions over the years 2014 to 2018 is summarized below in Figure 1.

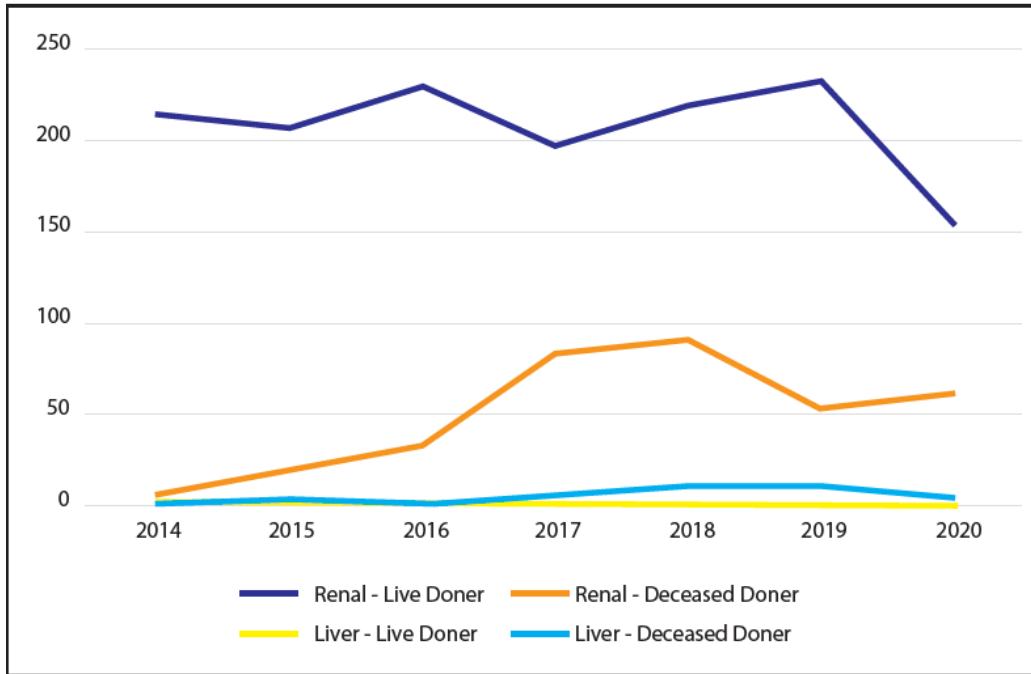


Figure 1. The trend of organ transplantation 2014-2020 (Source: Ministry of Health, Nutrition and Indigenous Medicine - unpublished data)

The low numbers of deceased donor organs retrieved in the country when compared to the number of potential donors could be due to different reasons including weaknesses in the mechanism to identify, optimize and diagnose potential deceased donors (brain dead patients), and very low rates of consent by next of kin in those patients who have been diagnosed. Low rates of diagnosis of brain death are partly due to the unavailability of ICU beds for those patients who have been deemed to have unsalvageable head injuries. Also, there are deficiencies in the current Human Act of Sri Lanka which is insufficient to create a conducive environment for deceased donor transplant programs.

Justification

Anecdotal evidence from Sri Lanka shows that there could be a high number of potential organ recipients considering the preventable deaths from chronic kidney and liver diseases. As an example, the number of people who died due to CKD that could have been saved by a kidney transplant is approximately 800 people per year. However, in the year 2017, only 281 kidney transplantations were carried out in government sector institutions. Furthermore, organ transplantation as a treatment option will reduce the direct and indirect costs of the services such

as dialysis, improve the quality of life of the patients and reduce the economic and social burden to the family and country. Although published evidence is scarce in the local context in relation to long-term survival, there are many evidences available internationally to strongly support organ transplantation as a definitive mode of treatment for end-organ failure.

The process for organ donation and transplantation must be strengthened to address the gaps in demand and supply of organs while strengthening the legal framework to prohibit organ trafficking. In this context, the availability of a national policy on transplantation for Sri Lanka is a much-felt requirement to improve the quality of life and safeguard the rights of donors and families, as well as recipients.

There was no legal framework for transplantation at the outset until 1987, although transplants were conducted. Appropriate legislation was presented to parliament by the then Health Minister as the Transplantation of Human tissues (THT) Act No 48 of 1987 and was enacted on 11th December 1987.

This act and the circulars issued later by the Ministry of Health on organ transplantation lay down procedures for the donation and removal of human bodies, organs, and tissues for therapeutic, scientific, educational, and research purposes.

However, the current Act needs to be revised due to many reasons including to coop with the new developments in the field. For example, the act does not address specific practical issues such as retrieving organs from deceased donors with medico-legal issues needing judicial post-mortems. Most deceased donors have significant medico-legal issues and non-resolution of the judicial post-mortem leads to wastage of organs from this large group. Therefore, there is a large requirement of in-force regulations pertaining to ethical aspects and detailed guidelines on the process of transplantation. To rectify these issues, in the year 2010 Ministry of Health - Sri Lanka issued a circular providing detailed guidance for health care practitioners to retrieve organs from deceased donors at an institutional level. Therefore, these aspects should be incorporated in the proposed National Transplant Policy, creating an enabling environment to amend the relevant Act/Acts and regulation/s to provide maximum benefit to the needy communities.

Some of the other gaps identified in the practice of organ transplantation in the country are; mal-distribution of services, lack of a mechanism for central coordination between the institutions to facilitate and regulate transplantation, and lack of awareness on organ transplantation as the preferred mode of treatment for end-organ failure among health professionals and the community.

In formulating this policy World Health Assembly resolution number 57.18 (57th WHA) and the WHO Guiding Principles on Human Organ Transplantation were also taken into consideration.

At the end of 2021

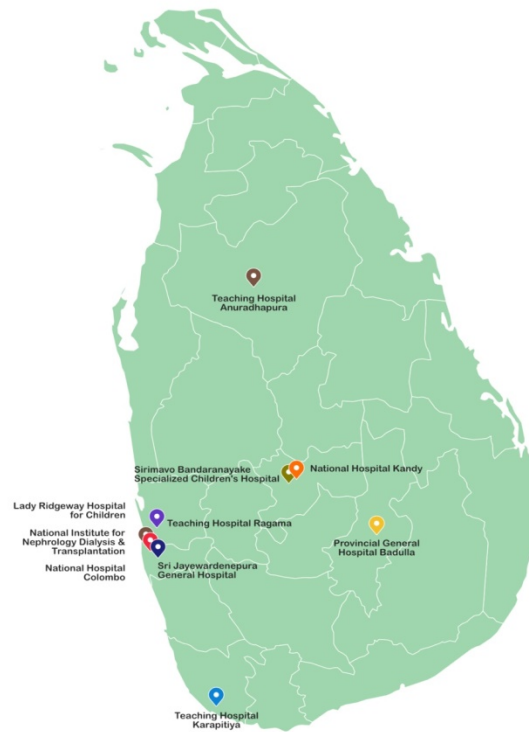


Figure 2.3: State hospitals performing transplant surgeries in Sri Lanka

Table 1 : Number of Transplant Surgeries Carried out in Government Hospitals From 2014-2020

Hospital	Organ	Live/ Deceased	2014	2015	2016	2017	2018	2019	2020
NHSL	Renal	Live	61	95	64	55	46	61	68
		Deceased	01	05	02	02	20	20	38
	Liver			03	01	03	07	04	11
NINDT Maligawatte	Renal	Live	30	06	35	30	54	48	04
		Deceased	07	14	06	22	15		

SJGH	Renal	Live	20	23	22	17	18	31	27
		Deceased	-	-	01	15	10	08	6
CNTH-Ragama	Liver	Deceased	02	-	-	04	04	03	04
		Live	78	42	65	50	54	60	43
TH -Kandy	Renal	Deceased	-	-	18	32	36	02	12
		Live	03	07	10	10	12	03	03
TH-Peradeniya	Renal	Deceased	-	-	-	01	02		
		Live	09	17	21	26	23	21	04
TH-Karapitiya	Renal	Disease	-	-	-	-	01		
		Live	11	17	12	09	12	06	04
TH-Anuradhapura	Renal	Deceased	-	-	05	05	-		
		Live			01	03	03	03	03
LRH	Renal	Deceased						01	01

Cabinet approval was obtained for the “National Policy on Organ, Tissue and Cell Transplantation of Sri Lanka” in 2022.

Certification of Authorization

Cabinet Memorandum No 21/2284/309/133 dated 28th December 2021 had been approved by the Cabinet of Ministers of Democratic Socialist Republic of Sri Lanka on 01st February 2022.

All relevant stakeholders developed the “National Strategic plan on Organ, Tissue and Cell Transplantation of Sri Lanka” for year 2022-2026.

Guiding principle, vision, mission and objectives and strategic areas are compatible with the policy document.

Guiding Principles

1. Ethical principles - Justice, beneficence, non-malevolent, and autonomy.
2. Quality and patient safety to ensure good health outcomes for both donors and recipients.
3. Transparency in the entire transplantation process.
4. Financial risk protection for recipients and donors.
5. Multidisciplinary and multi-sectoral approach.
6. Community empowerment and engagement for organ, tissue, and cell transplantation.

Vision

An optimal supportive environment for organ, tissue, and cell transplantation in Sri Lanka

Goal

Establishing an optimal environment for organ donation, reception, and transplantation, ensuring safety, protection, and ethical conduct among all parties involved.

1. Objectives of the Strategic Plan

- 1.1. To reduce premature mortality among patients with end-organ failure.
- 1.2. To promote deceased donor organ transplantation as an established mode of treatment and to regularize live donor transplantation in Sri Lanka.
- 1.3. To strengthen ethical practices and regulations to safeguard the health and rights of the donors, recipients, and their families.

2. Key strategic areas for implementation

- 2.1 Ensure equitable access and transparency in organ, tissue, and cell transplantation, adhering to the highest ethical, professional, and quality standards.

- 2.2 Develop national and sub-national level institutional coordination mechanisms, institutional registries, and a national database for allocation of organs, tissues, and cells to compatible recipients.
- 2.3 Strengthen and standardize human resources, infrastructure, medical supplies, and technologies required for transplantation.
- 2.4 Strengthening of National Blood Transfusion Services and laboratory services in organ, tissues, and cell transplantation.
- 2.5 Protect the health, welfare, and rights of living donors and recipients.
- 2.6 Revision of the existing legal tools and systematizes medico-legal authorization for deceased organ and tissue transplantation.
- 2.7 Regulation and accreditation of private service providers for effective contribution to organ, tissue, and cell transplantation.
- 2.8 Community empowerment to promote tissue and cell donation from deceased donors, ensuring rights of deceased donors and their families.
- 2.9 Collaboration with international experts and organizations in organ, tissue, and cell transplantation for capacity building.
- 2.10 Promote research related to transplantation for evidence-based advocacy and practice an 'Annual National Auditing' to improve practices and services.

Key strategic areas that are to be achieved under each strategic objective are outlined below.

2.1 Ensure equitable access and transparency in organ, tissue, and cell transplantation, adhering to the highest ethical, professional, and quality standards

- 2.1.1 Promote organ transplantation as the preferred treatment for end-stage organ failure, considering its cost-effectiveness and health benefits for good quality of life.
- 2.1.2 Maintain the highest standards of safety and quality by all clinicians involved in the transplantation process.
- 2.1.3 Establish a mechanism to avoid any conflicts of interest in the process of confirmation of brain death and in obtaining approval for organ retrieval.
- 2.1.4 Establish affordable mechanisms to transport organs and the body of deceased donors.
- 2.1.5 Ensure all the live donors have standardized care and long-term well-being.
- 2.1.6 Ensure confidentiality and privacy of donors and recipients.
- 2.1.7 Prohibit commercialization of organ, tissue, and cell transplantation and any activity that may indirectly promote or lead to commercial transaction/s.

2.2 Develop national and sub-national level institutional coordination mechanisms, transplant registries, and a national database for allocation of organs, tissues, and cells to compatible recipients

- 2.2.1 To establish a national organ donation and transplantation program for promotion, coordination monitoring, and regulation of the practice of transplantation
- 2.2.2 Maintenance of updated institutional registries, and a national database of recipients and donors to implement an organ allocation system.

2.3. Strengthen and standardize human resources, infrastructure, medical supplies, and technologies required for Organ, tissues and Cell transplantation

- 2.3.1. Establishment of a National Programme for transplantation.
- 2.3.2. Ensure availability, equitable distribution, and retention of the required cadres for the transplantation services.
- 2.3.3. Develop skills among the professionals who are involved in the transplantation
- 2.3.4. Strengthening the essential infrastructure facilities at the identified organ recipient and procurement institutes
- 2.3.5. Strengthening and streamlining of uninterrupted medical supplies, investigation facilities, technologies, and other supportive services that are essential for the transplantation processes.
- 2.3.6. Ensure a budgetary allocation for the implementation of transplantation activities in recipient institutions

2.4. Strengthening of National Blood Transfusion Services and laboratory services in organ, tissues, and cell transplantation

- 2.4.1. Establishment of a National cell and tissue bank.
- 2.4.2. Strengthening histocompatibility and immune-genetic diagnostics in Human organ, tissues, and cell transplantation.
- 2.4.3. Strengthening Immunohematology investigations related to the transplantation process.
- 2.4.4. Ensure transfusion Management and Apheresis based desensitization therapeutics related to pre and post-transplantation period.

2.5. Protect the health, welfare, and rights of living donors and recipients

- 2.5.1. Ensure living organ donors, transplantation recipients, and awaiting recipients receive appropriate assistance from both governmental and non-governmental stakeholders to ensure the best possible quality of life.
- 2.5.2. Strengthen the legal framework to protect the rights of the donors and recipients.

2.6. Revision of the existing legal tools and systematize medico-legal authorization for deceased organ and tissue transplantation

- 2.6.1. Revise the existing legal tools and strengthen the regulations to address the current gaps in the jurisdiction to optimize the legal framework for organ donation and improve ethical practices.
- 2.6.2. Improve awareness among all stakeholders on medico-legal aspects of organ donation.

2.7. Regulation and accreditation of private service providers for effective contribution to organ, tissue, and cell transplantation

- 2.7.1. Develop a code of conduct for the private institutions to adhere in conducting transplantation of human organs or tissues.
- 2.7.2. Develop accreditation and qualification standards to ensure organ and tissues transplantation is performed only in accredited centers which fulfill the standards.

2.8. Community empowerment to promote organ, tissue and cell donation, ensuring rights of deceased donors and their families

- 2.8.1. Promote organ, tissue, and cell donation for the treatment of appropriate diseases where evidence of effectiveness exists.
- 2.8.2. Continue education and promotion campaigns to the public to ensure the highest rate of organ donation exists in the country.

2.9. Collaboration with international experts and organizations in organ, tissue, and cell transplantation for capacity building

- 2.9.1. Build capacity of organ transplantation in Sri Lanka through collaborations with international technical experts and organizations.

2.10. Promote research related to transplantation for evidence-based advocacy and practice and ‘Regular National Auditing’ to improve practices and services.

- 2.10.1.** Build research capacity to gather evidence on organ transplantation in the country.
- 2.10.2.** Establish a national laboratory for transplant immunology and transplant medical laboratory purposes.

3. Implementation of the Policy: Action Plan on Human Tissue Transplantation (Annexure 1)

The policy will be implemented according to the action plan given in Annexure 1. Coordination of policy implementation is vested with the National Transplantation Programme. The overall guidance will be provided through the “National Advisory Council on Human Tissue Transplantation” chaired by the DGHS and appointed by the Honorable Minister of the Health. The period of this council is three years.

4. Monitoring and Evaluation

A national strategy and action plan with monitoring indicators will be developed to operationalize the policy implementation

Annexure 1 - Action Plan of the Human Organ, Tissue, and Cell Transplantation

Strategic Area 1 - Ensure equitable access and transparency in organ, tissue, and cell transplantation, adhering to the highest ethical, professional, and quality standards

No.	Key Strategic Area	Activity	2022	2023	2024	2025	2026	Responsibility
1.1	Promote organ transplantation as the preferred treatment for end-stage organ failure, considering its cost-effectiveness and health benefits for good quality of life	<ol style="list-style-type: none"> 1. Update existing circular to improve adherence to the 'preferred practice pattern' among service providers. 2. Develop and conduct an awareness creation campaign for the service providers 3. Appoint transplantation coordinators for institutional coordination and promotion of organ donation. 4. Donor coordination and health education by a dedicated health promotion officer in transplantation. 						DDG (MS-I) Director of Transplantation.

		5. Motivate the transplant team through performance-based incentives for staff						
1.2	Maintain the highest standards of safety and quality by all clinicians involved in the transplantation process	<ol style="list-style-type: none"> 1. Develop Guidelines and SOPs on best clinical practices to regularize organ, tissue, and cell transplantations 2. Conduct periodic clinical audits to monitor the adherence to the prescribed guidelines/SOPs. 						DDG (MS-I) Relevant Professional Colleges
1.3	Establish a mechanism to avoid any conflicts of interest in the process of confirmation of brain death and in obtaining approval for organ retrieval	<ol style="list-style-type: none"> 1. Update existing circular to define and establish the multidisciplinary institutional team to confirm brain death of potential donors at intensive care units. 2. Identify the gaps and amend the existing Acts and Regulations to avoid restrictions in organ donation (i.e., ability to provide consent by the next-of-kin, etc.) 						DGHS DDG (MS-I) Relevant Professional Colleges Heads of recipient institutions
1.4	Establish cost-effective mechanisms to transport organs and the body of deceased donors	<ol style="list-style-type: none"> 1. Update existing circular define the multidisciplinary team for organ retrieval 2. Formulate a MOU between the MoH and Sri Lanka Air Force (Aircraft charter) to transport 						DGHS DDG(MS-I) Heads of recipient institutions

		<p>organs to the recipient institution when necessary.</p> <p>3. Update existing circular on establishing a mechanism to transport the body of a deceased donor from recipient institute to donor institute minimizing inconvenience to the family members</p>						Heads of procurement institutions
1.5	Ensure all the live donors have standardized care and long-term well-being	<p>1. Formulate criteria to define for eligibility to be a live donor</p> <p>2. Develop the content of a donor evaluation report including medical and psycho-social assessments</p> <p>3. Formulate a post-donation lifelong follow-up plan</p>						Relevant Professional Colleges DDG (MS-I)
1.6	Ensure confidentiality and privacy of donors and recipients.	<p>1. Establish a coding and decoding mechanism in the national transplantation registry to ensure the anonymity of donors and recipients</p>						DDG(MS-I) Head/National Center for Transplantation
1.7	Prohibit commercialization of organ, tissue, and cell transplantation and any activity that	<p>1. Disseminate the information through an internal circular for the state and non-state service providers.</p>						

	may directly/indirectly promote or lead to commercial transaction/s.	<ol style="list-style-type: none"> 2. Conduct a campaign to improve the awareness among the general public 3. Strengthen the Act by firm laws and penalties for illegal activities and cancellation of license to practice if conducted such activities / or in misconduct. 						
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Strategic Area 2 - Develop national and sub-national level institutional coordination mechanisms, institutional registries, and a national database for allocation of organs, tissues, and cells to compatible recipients

No.	Key Strategic Area/Strategic objectives	Activity						Responsibility
			2022	2023	2024	2025	2026	
2.1	Coordinate between donors, recipients, and institutions involved in transplantation through the National center	<ol style="list-style-type: none"> 1. Establish a National Transplantation Programme 2. Establish a National Centre for Transplantation 3. Develop a coordination mechanism to inform every transplantation to the National Transplantation center 						DGHS DDG(MS-I) Head/National Center for Transplantation

	for Transplantation	<ol style="list-style-type: none"> 4. Demarcate Organ Procurement zones in the country for organ transplantation under organ procurement centers 5. Establish a coordination mechanism (centrally coordinated) between the organ procurement centers and the recipient centers. 						
2.2	Maintenance of updated institutional registries and a national database of recipients and donors	<ol style="list-style-type: none"> 1. Establish a national transplantation registry for recipients, awaiting recipients, donors, and potential donors at the National Centre for Transplantation 2. Establish registries of recipients and awaiting recipients at the recipient institutions 3. Establish registries of donors and potential donors at the procurement institutions 					<p>Head/National Center for Transplantation</p> <p>Heads of recipient institutions</p> <p>Heads of procurement institutions</p>	

Strategic Area 3 - Strengthen and standardize human resources, infrastructure, medical supplies, and technologies required for transplantation.

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
3.1	Establish a National Cell, Tissue, and Organ Bank under the public sector.	1. Establishment of a National level Cell and Tissue Bank under the Ministry of Health - Sri Lanka						DDG (MS -1)
3.2	Ensure availability, equitable distribution, and retention of the required cadres for the	1. Create specially trained new carders and norms for clinical and supportive staff for organ transplantation considering the service needs and new developments in the field of transplantation.						DDG(MS-I) Head/National Center for Transplantation

	transplantation services.	2. Ensure equitable distribution of carder according to defined criteria						
3.3	Develop skills among the professionals who are involved in the transplantation	<ol style="list-style-type: none"> 1. Conduct in-service training/awareness programs for professionals (including consultants, Medical Officers, Nurses, Coroners) who are involved in the transplantation 2. Revise basic and post-graduate curriculum for professionals (Medical Officers, Nurses) who are involved in the transplantation 					DDG (ET&R) Head/National Center for Transplantation Relevant Professional Colleges	
3.4	Strengthening the essential infrastructure facilities at the identified recipient and procurement institutes	<ol style="list-style-type: none"> 1. Conduct regular facility surveys and coordinate with the MOH to fill the identified gaps in the essential infrastructure 2. Establish a National Reference laboratory capable of conducting essential supportive investigations in a national level clinical setting that should be available 24 x 7. 					DDG(MS-I) Head/National Center for Transplantation Heads of recipient institutions Heads of procurement institutions	

		3. Establish a National Reference laboratory (In National Blood Bank) for tissue typing and immunological investigations						
3.5	Strengthening and streamlining of un-interrupted medical supplies, investigation facilities, technologies, and other supportive services that are essential for the transplantation processes	<ol style="list-style-type: none"> 1. Identify and list out the medical supplies, investigation facilities, technologies, and other supportive services required for transplantation 2. Forecast, estimate, and include the essential medical supplies, investigation facilities, technologies for transplantation in the institutional annual estimates 						Relevant Professional Colleges Head/National Center for Transplantation Heads of recipient institutions Heads of procurement institutions
3.6	Ensure a budgetary allocation for the implementation of transplantation	<ol style="list-style-type: none"> 1. Forecast, estimate, and allocation of a budget for transplantation activities 						DDG(MS-I)

activities in recipient institutions							
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Strategic Area 4 - Strengthening of NBTS and laboratory services in organ, tissues and cell transplantation.

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
4.1	Strengthening histocompatibility and immunogenetics diagnostics in Human organ, tissues, and cell transplantation							
4.2	Strengthening Immunohematology investigations related to the transplantation process	estimate and include the essential, Immunohematology investigation facilities and technologies for transplantation in the institutional annual estimates						

4.3	Ensure transfusion Management and Apheresis based desensitization therapeutics related to pre and post-transplantation period.							
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Strategic Area 5 - Protect the health, welfare and rights of living donors and recipients

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
5.1	Ensure living organ donors, transplantation recipients, and awaiting recipients receive	1. Advocate to revise the existing criteria to identify the living organ donors, transplantation recipients, and awaiting recipients who need social and financial assistance by the						DDG(MS-I) Relevant professional colleges Head/National Center for Transplantation

	appropriate assistance from both governmental and non-governmental stakeholders to ensure the best possible quality of life	<p>Social Services Officer at the institutional level</p> <p>2. Identify possible funding sources and facilitate additional funding schemes through the government (President’s fund) and non-government stakeholders to priority living organ donors, transplantation recipients, and awaiting recipients.</p>						<p>Heads of recipient institutions</p> <p>Secretary of Health, Head Department of Social Services</p>
5.2	Strengthen the legal framework to protect the rights of the donors and recipients.	1. Amend relevant sections of the “Human tissue and organ transplantation act no. 48 of 1987” to fulfill the rights of the donors and recipients						

Strategic Area 6 - Revision of the existing legal tools and systematize medico-legal authorization for deceased organ and tissue transplantation

Targets to remove barriers that impede deceased donor organ donation and to bring in laws that empower the processes of deceased donor organ transplantation programs. In the revision process, it is expected to minimize the legal barriers and facilitate the organ retrieval process, to safeguard the healthcare workers, act for the benefit of the patients, and to shorten procedures for fast response.

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
6.1	Revise the existing legal tools and strengthen the regulations to address the current gaps in the jurisdiction to optimize the legal framework for organ donation and improve ethical practices.	<ol style="list-style-type: none"> 1. Establish a working group to identify the gaps and make recommendations for the existing Act “Human tissue and organ transplantation act no 48 of 1987” 2. Regularize the activities of the Technical Advisory Council on human tissue transplantation established under the Act. 3. Revise Act no 48 of 1987 to bring down the minimum age for consent as 18 years of age 4. Revise Act no 48 of 1987 to assess the eligibility of organ donation by the brain-dead victim/s of ongoing court cases. 5. Revise the means of provision of consent without limiting to paper-based consent forms and expedite the process of obtaining consent within 24 hours. 						DGHS, DDG(MS-I) Chief Legal Officer

	Improve awareness among all stakeholders on medico-legal aspects of organ donation	<ol style="list-style-type: none"> 1. Develop and conduct awareness programs for Transplant Coordinators at institutions and all stakeholders (including Magistrates and Coroners) on medico-legal aspects of organ donation 2. Establish a mechanism to ensure monitoring of the legal processes in authorizing organ donation through the National Transplantation Centre. 3. Develop and disseminate a circular on confirmation of brain death and harvesting of organs from a brain-dead donor (Annexure – Circular No). 						DDG(MS-I). Chief JMO Secretary - Ministry of Justice
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Strategic Area 7 - Regulation and accreditation of private service providers for effective contribution to organ, tissue, and cell transplantation

No	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
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7.1	Develop code of conduct for the private institutions to adhere in conducting transplantation of human organs or tissues	<ol style="list-style-type: none"> 1. Develop and disseminate code of conduct for transplantation at private institutions by amending relevant legal tools. 2. Establish Ethics Review Committees for each private institution authorized by the DGHS. 3. Revision of Transplantation Act and Migration Health Policy of Sri Lanka in the purview of conducting transplantation procedures within the country for non-citizens ensuring locally retrieved organs shall not be allocated for non-citizens and vice versa. 						DGHS, DDG(MS-I), Head/Private Health Sector Development
7.2	Develop accreditation and qualification standards to ensure organ and tissues transplantation is performed only in accredited centers which fulfill the standards.	<ol style="list-style-type: none"> 1. Appoint a technical working group to analyze the current situation and to develop criteria for the accreditation of institutions conducting transplantation. 2. Conduct regular supervision of the transplantation centers in the private sector through the National Transplantation Centre to ensure a high standard of practice 						

Strategic Area 8 - Community empowerment to promote organ, tissue, and cell donation from deceased donors, ensuring rights of deceased donors and their families

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
8.1	Promote organ, tissue, and cell donation for the treatment of appropriate diseases where evidence of effectiveness exists	<ol style="list-style-type: none"> 1. Organize awareness creation public campaigns in Sri Lanka on organ, tissue, and cell donation. 2. Improve knowledge among the community to facilitate rational decision making for organ, tissue, and cell donation 3. Incorporate consent for organ donation in the process of obtaining a driving license. 4. Appreciation of organ donors/ family members of diseased donors for promoting organ donation. 						DDG(MS-I) Head/National Center for Transplantation D/HPB Relevant professional colleges

8.2	Continue education and promotion campaigns to the public to ensure the highest rate of organ donation exists in the country.	1. Continue the above activities without any interruptions for a better outcome.							DDG(MS-I) Head/National Center for Transplantation D/HPB
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Strategic Area 9 - Collaboration with international experts and organizations in organ, tissue, and cell transplantation for capacity building

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
9.1	Build capacity of organ transplantation in Sri Lanka through collaborations with international technical	1. Establish a coordination mechanism through the National Centre for Transplantation						

	experts and organizations.	<ol style="list-style-type: none"> 2. Issue a circular regarding facilitating international technical experts to conduct human organ, tissue, and cell transplantation in the government sector 3. Issue guidelines on international technical experts to conduct human organ, tissue, and cell transplantation. 							
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Strategic Area 10 - Promote research related to transplantation for evidence-based advocacy and practice and ‘Annual National Auditing’ to improve practices and services.

No.	Key Strategic Area/Strategic objectives	Activity	2022	2023	2024	2025	2026	Responsibility
10.1	Build research capacity to gather evidence on organ transplantation in the country	<ol style="list-style-type: none"> 1. Identify the organ transplantation research as a priority area by the MOH 2. Capacity building on research methods related to organ transplantation among the health staff 						DDG – (MS-1) DDG (ET&R) Head/National Center for Transplantation

		3. Maintain a research repository to gather and disseminate evidence on transplantation from the local context to inform advocacy, policy, and practice						
10.2	Establish a national laboratory for transplant immunology and transplant medical laboratory purposes.	1. Establish a National Transplant Research Laboratory affiliated with the National Reference Laboratory of Transplantation.						DDG – (MS-1) DDG (ET&R) Head/National Center for Transplantation

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