

PROPOSAL FOR LEGISLATION ON ORGAN AND TISSUE DONATION

A MALTESE GOVERNMENT WHITE PAPER

CONSULTATION DOCUMENT



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RESPONSES WILL BE RECEIVED BY: 20TH MAY 2015



PARLIAMENTARY SECRETARIAT
FOR HEALTH



In the preparation of this White Paper the Hon Mr Chris Fearne Parliamentary Secretary for Health provided leadership to the following team:

Hon Dr Etienne Grech
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OVERVIEW

This consultation seeks responses to the Maltese Government's proposal on organ donation. This White Paper has the following four main objectives:

- Introducing a system, which aims to increase the number of organ donations in the Maltese Islands, thus allowing more lives to be saved and improve the quality of others.
- Respecting and safeguard the decision of persons who want to donate their organs after their demise.
- Shifting the burden of the decision of whether or not the organs of the deceased should be donated from the grieving relatives onto the deceased himself/herself.
- Creating a legal framework that supports our organ donation principles, that is accepted by the Maltese people and in alignment with the Maltese culture of generosity and altruism.

Your responses will be given due consideration.

HOW TO RESPOND

The consultation responses will be received on e-mail: consultations.meh-health@gov.mt

Responses are welcome in either English or Maltese.

Responses to this consultation should be sent by not later than 20th May 2015.

Responses in the form of a letter will also be accepted at: Director Healthcare Standards, Superintendence of Public Health, Ex-OPD Department, Level 1, St Luke's Hospital, Gwardamangia.

Large print, Braille and Maltese versions of this document are available on request.

CONTACT DETAILS

Superintendence of Public Health

Healthcare Standards Directorate

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DATA PROTECTION

Any response sent to us will be seen in full by Maltese Government staff dealing with this consultation.

The Maltese Government intends to publish a summary of the responses to this document. As per norm adopted in these consultation processes, the name and address of a person participating will be coded, but the name of an organisation that sends a response will be published with the response. If one does not want his/her organisation's name or address published, s/he should inform us in writing when the response is sent.

The Freedom of Information (FOI) Act allows the public to request access to information held by public bodies, including the Maltese Government. This includes information which has not been published. However, the law allows the withholding of information in some circumstances.

It is the FOI commissioner who decrees what information is released or not. Requests for information not to be published are treated with due importance however there might at times be cogent reasons why, notwithstanding, someone's name and address are published.

FOREWORD



It has famously been said that the gift of organ donation is the greatest gift of all. Indeed organ and tissue donation can save lives. But the benefits of organ and tissue donation go beyond rescuing a life. Organ donation provides a singular opportunity not only to individuals at the end of the line of hope, but also to their families, friends, colleagues and acquaintances.

For the recipient, a donated organ often means a second lease on life, allowing many to return to a normal lifestyle. For others, a tissue transplant signifies the recovery of mobility and freedom from pain or disease.

It has been 30 years since the first transplants were performed in Malta. Unequivocal and steady progress has been made during these decades. Yet, the legal framework regulating this process remains incomplete. And although Malta has a relatively high rate of organ donation, there is still an unmet demand for more donations. For the healthcare workers and professionals working in this field, there is also the need for a clear legal framework in which they can continue to offer their service.

The release of this White Paper on Organ and Tissue Donation and the process of consultation that will ensue reflect the Government's outright commitment to stakeholder participation in the development and formulation of health policy. Whilst we recognise that people want to make their own decisions, it is the Government's duty to help by creating the right framework. This consultation document essentially presents four principal options for discussion. The consultation in turn will lead to legislation regulating organ and tissue donation in Malta.

I invite you to participate in the discussion.

A handwritten signature in black ink, which reads "Chris Fearne". The signature is fluid and cursive, with a distinct flourish at the end.

Chris Fearne
Parliamentary Secretary for Health

EXECUTIVE SUMMARY

In Malta, as in many other countries, the gap between the demand and supply of human organs for transplantation is on the rise, despite the efforts of governments and organ donor associations to promote donor registration. The Maltese Government is proposing this White Paper for consultation to enact a legislative framework addressing organ donation for the Maltese Islands, which will reflect the evaluated response after consultation is closed.

The proposed options for organ donation in the Maltese Islands fall under four main categories.

OPTION 1 – SOFT OPT-IN SYSTEM: (EXPRESSED CONSENT)

The Soft Opt-in system is one in which the removal and use of organs is permissible only after the deceased has shown his/her wish to be a donor during his/her lifetime, for example by registering for a donor card, or by obtaining consent from the deceased's closest relative after the former's death. In Malta, although the area is unregulated, it is common practice to use the soft opt-in principle.

As things stand in Malta, everyone over 18 years can apply for an organ donor card, thereby making an informed choice to donate their healthy organs after their death. However, even if a deceased person is in possession of such a donor card, the final decision as to whether their organs are to be donated or not currently remains in the hands of that person's closest relative.

OPTION 2 – THE HARD OPT-IN SYSTEM

The Hard Opt-in system is one in which the removal and use of organs is permissible only when the deceased has shown his/her wish to be a donor during his/her lifetime. However, after a person's death, relatives are not allowed to reverse the deceased's decision. Under this system a donor card or its equivalent is given legal status.

OPTION 3 – THE SOFT OPT-OUT SYSTEM

The Soft Opt-out system is one in which the removal and use of organs is permissible unless the deceased opted out during his/her lifetime. Individuals have a formal mechanism for registering that objection. After death, relatives are involved in the decision-making process around donation. By taking the family decision into account, this system has the possibility to reverse the decision previously taken by the deceased.

OPTION 4 – THE HARD OPT-OUT SYSTEM

The Hard Opt-out system is one in which the removal and use of organs is permissible unless the deceased objected during his/her lifetime. Individuals have a formal mechanism for registering the objection. After death, relatives are not involved in the decision-making process around donation. The wishes of the deceased are always respected.

The assumption is that everyone in the country is willing to donate their organs unless they explicitly opt-out before their death. The donor's consent under the opt-out system is presumed. Nowadays, such presumed consent is used in many European countries. In Spain, for example, it has been adopted with relatives being allowed the last word to refuse or accept organ donation after death (the soft opt-out principle). In Austria, on the other hand, the views of the family after death are not considered (the hard opt-out principle). Wales will be adopting the soft opt-out principle in December 2015, following a consultation process held amongst the Welsh people.

Table of contents

Overview.....	3
How to respond.....	3
Contact details.....	3
Data Protection.....	4
Foreword.....	5
Executive Summary.....	6
Option 1 – Soft Opt-In System: (Expressed Consent).....	6
Option 2 – The Hard Opt-in system.....	6
Option 3 – The Soft Opt-out system.....	6
Option 4 – The Hard Opt-out system.....	7
Organ donation in Malta.....	10
Option 1-Soft-Opt In System (Expressed consent).....	10
Cadaveric and live organ donations.....	12
Organ transplant waiting list.....	15
Live organ donation.....	16
Age applicable for live organ donation.....	16
Types of live organ donation for kidney transplantation.....	17
Live organ donation in Malta.....	17
Live Organ Transplant Advisory Committee (LOTAC).....	19
Policy addressing live organ donations in Malta.....	20
Compensation to cover expenses or loss of income by the donor.....	20
The legal framework regulating organ transplantation in the Maltese islands.....	21
L.N. 271 of 2006: Human Blood and Transplants Act, 2006 (ACT NO. IV OF 2006).....	21
L.N. 345 of 2012 Human Blood and Transplants Act (CAP. 483): Organ Transplants (Quality and Safety) Regulations, 2012.....	21
L.N. 222 of 2014: Human Blood and Transplants Act (Cap. 483).Human Tissues and Cells (Quality and Safety) (Amendment) Regulations, 2014.....	22
L.N. 262 of 2014 Human Blood and Transplants Act (CAP. 483): Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) (Amendment) Regulations, 2014.....	22
Underground markets surrounding organ trafficking.....	22
Ensuring an equitable approach to organ donation.....	24
Specific proposals of the various systems as they would be applicable to the Maltese islands.....	25
The Opt-out system.....	25
What an Opt-out system will not change.....	27
Keeping an Opt-out system up to date.....	27
Potential advantages of an Opt-out system.....	27
Increase in Organ donation.....	28
Reviewing the current Opt-in organ donation system (Expressed consent).....	28
The Soft principle for organ donation.....	28
Required request.....	29
The Living Will.....	29

Children under 18 years of age in relation to organ donation in the Maltese islands.....30
Possible options.....31
Consent.....31
Ability to understand.....31
Timetable.....32
Public awareness campaign.....33
Consultation questions.....34
Questions related to organ donation proposals.....34
Conclusion.....36

ORGAN DONATION IN MALTA

OPTION 1 – SOFT OPT-IN SYSTEM: (EXPRESSED CONSENT)

In 1983 the first kidney transplant was carried out in Malta through a live-to-live donor approach. This was followed in 1984 by a cadaver to live donor approach. Both procedures were carried out by foreign surgeons. As time went by, local surgeons were eventually trained to perform organ transplantation in Malta.

Many organs are now harvested for donation, including kidney, cornea, heart, liver, lung, pancreas, intestine, bone, skin, heart valves, tendons, ligaments, and saphenous veins. However, in Malta only kidney, cornea and heart transplants are carried out. Certain organs are sent abroad through agreements reached between Malta and Italy/England. At present, cadaveric organs are only retrieved if permission from the family is obtained as the donor card signed by the deceased does not give doctors the right to harvest organs automatically, so the patient's wishes may not be respected if his/her family decide against organ donation.

Up till early in the year 2000, the registration of organ donors was in the hands of the Lions Club (Malta) but this was mainly restricted to the cornea of the eye.

In 2000, a small voluntary organisation, the Transplant Support Group was set up. The Transplant Support Group is clearly doing excellent work within the inevitable limits of its resources. It organises meetings for transplant recipients of organs both locally and abroad, brings to the attention of the authorities any shortcomings and ethical issues concerning organ transplantation and raises awareness to encourage more people in Malta to come forward as organ donors. This organisation used to keep private information of people who decided to apply for an organ donor card, but in 2007, because of the Data Protection Act, this was prohibited and thus discontinued. In Malta we do not currently have an up to date official organ donor register but some statistical figures are available. Around 2,000 people sign up to be organ donors every year (table 1), giving Malta one of the highest donor rates in Europe. Therefore, an average of 2,000 people applying for a donor card each year will add up to approximately 30,000 registered donors since the year 2000.

PEOPLE APPLYING FOR AN ORGAN DONOR CARD 2008-2013	
2008	2,405
2009	4,447
2010	1,132
2011	2,032
2012	2,515
2013	2,013

Table 1

Members of the public can apply for an organ donor card in a variety of ways, including:

- a. Registering online through the Transplant Support Group website,
- b. By contacting the Renal Unit at Mater Dei Hospital (MDH), or
- c. By registering with a GP or during any events organised by the Transplant Support Group or the Lifecycle group.

At the moment, the Transplant Support Group and Renal Unit are the main distributors for these donor cards. Unless these cards become legally binding, organ donor cards are of little value, if any, when surviving relatives may disapprove.

CADAVERIC AND LIVE ORGAN DONATIONS

Organs can be transplanted from cadaveric and live organ donors.

Cadaveric donation comprises organ donation from deceased persons, that is, taking organs (heart, lungs, kidneys, liver, pancreas) from brain dead people, as well as tissue donation, which involves taking tissues (skin, corneas, tendons, bone) from brain dead, as well as heart dead people. In Malta the Harvard principle of Brain Death is very often adopted. Amongst other signs, the Harvard criteria for brain death include:

- a. unreceptivity and unresponsiveness,
- b. no movement or breathing,
- c. no reflexes,
- d. flat electroencephalogram (confirmatory),
- e. body temperature $\geq 32^{\circ}$ C,
- f. absence of CNS depressants.

Only organs considered optimal are transplanted locally. This is because when transplanting a suboptimal organ the chances of organ failure or rejection are greater and due to antibody formation it would reduce the chances for another organ transplant to be possible. Organs which are not transplanted locally are offered abroad where the pool of possible suitable recipients is much larger.

The organ transplant procedure from brain dead patients is done by surgeons in the operating theatre. For cadaveric donation, different ethical and practical issues must be considered.

According to the National Transplant Registry (NTR) housed within the Directorate of Health Information and Research, there are on average ten cadaveric donors each year and organ donations from 2.5 live donors each year as per Table 2 below. The National Transplant Registry collects data and keeps a register of **all organs harvested** on the islands of Malta and Gozo, whether transplanted locally or abroad. Its main sources of information are the Transplant Co-ordinator and Ophthalmic Department at MDH.

The types and numbers of organs transplanted locally from 1999-2013, as well as those sent abroad are presented in Table 3.

Transplants are performed at all age groups, with persons in the 55-64 age group undergoing most transplants (Figure 1). The majority of transplants in the older age groups (75+) are corneal transplants.

YEAR	GENDER	TYPE of DONOR		Total
		Live	Cadaver	
1999	<i>male</i>	1	7	8
	<i>female</i>	1	4	5
2000	<i>male</i>	0	8	8
	<i>female</i>	1	0	1
2001	<i>male</i>	0	8	8
	<i>female</i>	0	3	3
2002	<i>male</i>	1	8	9
	<i>female</i>	1	1	2
2003	<i>male</i>	1	7	8
	<i>female</i>	0	1	1
2004	<i>male</i>	1	2	3
	<i>female</i>	3	3	6
2005	<i>male</i>	1	8	9
	<i>female</i>	1	3	4
2006	<i>male</i>	3	9	12
	<i>female</i>	2	5	7
2007	<i>male</i>	0	2	2
	<i>female</i>	2	2	4
2008	<i>male</i>	2	8	10
	<i>female</i>	1	2	3
2009	<i>male</i>	1	8	9
	<i>female</i>	2	4	6
2010	<i>male</i>	2	5	7
	<i>female</i>	1	6	7
2011	<i>male</i>	3	7	10
	<i>female</i>	3	7	10
2012	<i>male</i>	0	8	8
	<i>female</i>	1	3	4
2013	<i>male</i>	2	8	10
	<i>female</i>	1	4	5
Total	<i>male</i>	18	103	121
	<i>female</i>	20	48	68

Table 2 (source: Malta National Transplant Registry)

Year	Organs transplanted locally				Offered Abroad				
	Kidneys from deceased donor	Kidneys from live donor	Cornea transplants	Heart transplants	Heart offered abroad	Liver offered abroad	Kidney offered abroad	Pancreas offered abroad	Lung offered abroad
1999	8	2	20	1	2	4	1	1	2
2000	9	1	11	1	2	3	0	0	0
2001	11	0	18	1	0	3	0	1	0
2002	12	2	12	1	0	1	0	0	0
2003	7	1	10	0	2	2	2	0	0
2004	6	4	10	0	0	4	0	0	0
2005	5	2	17	1	2	3	0	0	0
2006	12	4	22	1	2	10	4	0	0
2007	5	2	9	1	0	1	1	0	0
2008	8	3	10	0	0	6	2	0	0
2009	6	4	21	1	0	9	6	0	0
2010	10	3	9	1	2	6	4	0	0
2011	12	6	14	1	1	11	4	0	0
2012	8	1	6	0	1	7	10	1	2
2013	10	3	9	0	0	8	10	0	4

Table 3

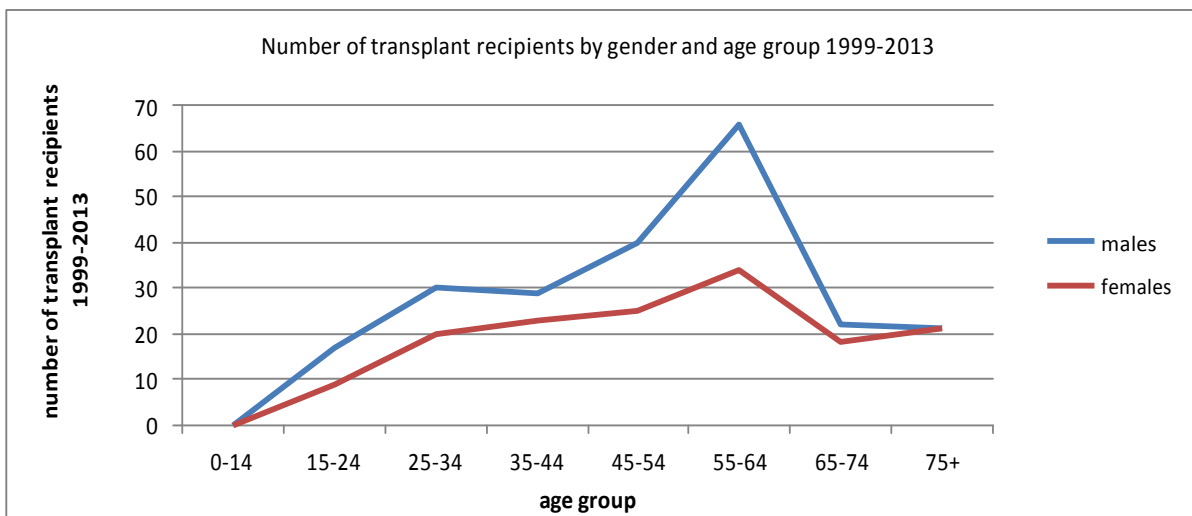


Figure 1

ORGAN TRANSPLANT WAITING LIST

The waiting list of patients needing a kidney transplant is the longest and most complex. Once assessed, a patient is considered as being either an active recipient or an inactive one; a status based on the patient's current condition. A patient suffering from renal failure is placed on the transplant list from the first day s/he initiates renal dialysis. An active status signifies that should an organ become available and is compatible, a kidney transplant will be performed immediately. Nonetheless if the patient happens to be suffering from a condition or infection that could jeopardise his/her wellbeing post operatively, s/he is given a temporary inactive status until the patient's condition improves and it is safe to perform a transplant. Allocation of kidneys is at the discretion of the nephrologists and according to patient's current health condition.

Organs are harvested from either living or cadaveric donors. Live organ donations can include degenerative tissues such as bone marrow, or in the case of one of a pair organs, such as kidneys.

LIVE ORGAN DONATION

Living donation in Europe represents 17% of kidney transplant activity and 5% of liver transplantation. Although living donors have always been critical for transplantation, the donations from living donors have dramatically increased over recent years. This may be due to the scarcity of organs available for transplantation.

Several types of tissues/organs can be obtained from live donors, such as kidneys, blood, bone marrow, lobes of lung and lobes of liver. It is well known that the medical and economic benefits of live donor as opposed to cadaveric transplantation include shorter hospitalisation, elimination of waiting time, avoidance of dialysis, improved patient graft survival, and cost-effectiveness.

However, in general one considers the use of an organ from a live donor only if the following conditions are met:

- a) surgery to remove the organ is not dangerous,
- b) donor's life can continue normally after the donation,
- c) donor will not need prolonged and chronic medical care,
- d) success rate in the recipient is quite high.

AGE APPLICABLE FOR LIVE ORGAN DONATION

To be a live organ donor, an individual must be over 18 years. There is no real upper age limit to live organ donation. However, older donors are more likely to be considered unsuitable for two reasons: older persons are more likely to have less than perfectly healthy organs even if they themselves feel perfectly well and older persons are more likely to suffer from conditions (like heart problems) which make the operation involved more risky. In spite of this, donors in their 70's have successfully donated organs such as kidneys. One important consideration is the age of the recipient, as an older person is more likely to be considered a suitable donor if the potential recipient is of comparable age. The most common organ donated by living people is a kidney, as a healthy person can lead a completely normal life with only one functioning kidney.

TYPES OF LIVE ORGAN DONATION FOR KIDNEY TRANSPLANTATION

A. Directed donation, where an organ is donated to an identified recipient. This may occur in the following circumstances:

- I. **Genetically related donation**, where the potential donor is a blood relative of the potential recipient (e.g. parent, sibling).
- II. **Family related**, but not genetically related donation (e.g. spouse, in-law).
- III. **Emotionally related donation** in cases of a long established emotional relationship (such as a friend, partner, neighbour, co-worker).
- IV. **Paired donation**, where a relative, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient and they are matched with another donor and recipient in a similar situation, so that both patients in need of a transplant receive a compatible organ.
- V. **Pooled donation**, a form of paired organ donation whereby the pair are matched with other donors and recipients from a pool of pairs in similar situations, and more than two donors and two recipients are involved in the swap, so that more than two people in need of a transplant receive a compatible organ.

B. Altruistic non-directed donation, a form of living donation whereby a kidney is donated by a healthy person who does not have a relationship with the recipient and who is not informed who the recipient will be.

LIVE ORGAN DONATION IN MALTA

A donor need not be a blood relation of the recipient. To qualify as a donor an individual must first be certified by a doctor that s/he is willing to donate a particular organ to a particular patient. The doctor must ascertain and declare that the donor fully understands the nature and consequences of the donation. The doctor shall not certify any donor who due to mental incompetence cannot understand the nature and consequences of the donation. Furthermore, in the case of children, who due to their young age lack the capacity to understand the nature and consequences of the donation, the doctor may only certify that donor as approved for a live organ donation in cases of bone marrow transplant. The clinician must be convinced that the legal guardians of that donor understand the nature and consequences of the donation.

Compatibility tests covered by an informed consent are only carried out after the application has been processed and approved by the Committee.

Sometimes a domino transplant is necessary. A domino transplant occurs when different patients with kidney failure, along with their relatives, participate in a chain operation to swap transplants. In these cases, the clinician responsible for the donor sends an application to the committee. The application must contain the following information:

- a. Donor's name and surname;
- b. Title;
- c. Identity Card number;
- d. Address;
- e. Date of birth;
- f. Organ to be made available for transplant;
- g. Place of organ removal;
- h. Full name of clinician responsible for donor;
- i. Registration number;
- j. Principal appointment;
- k. Place where held;
- l. Contact number;
- m. The form attesting that no payment, coercion, duress or inducement has been or is being offered or made which must be signed in the presence of the clinician.

Once the transplant operation has been carried out the clinician responsible for the recipient shall provide the committee with the following information:

- a. Name and surname of recipient;
- b. Identity Card Number;
- c. Date of birth;
- d. Address;
- e. Date of transplant;
- f. Place and unit where transplant took place;
- g. Full name of clinician performing the transplant;
- h. Registration number;
- i. Principal appointment;
- j. Contact number.

LIVE ORGAN TRANSPLANT ADVISORY COMMITTEE

Live Organ Transplant Advisory Committee (LOTAC) was set up in 2003 by the Department of Health to process all applications for live organ transplantation, most of which tend to be for kidneys.

The Committee is composed as follows:

- a. Chairperson (a medical doctor not involved in transplantation),
- b. Ethicist,
- c. Clinician,
- d. Surgeon,
- e. Lawyer
- f. Psychologist

The Committee interviews both donor and recipient with a view to ascertain that the following ethical principles are respected:

- a. The donor is willing to donate the organ (principle of autonomy);
- b. The donor is well informed by his specialist and consents freely (principle of free and informed consent);
- c. The donor is not being subjected to coercion or duress (principle of non-coercion);
- d. The donation is free and is not subject to a financial or material consideration (principles of dignity, integrity and non-commercialisation);
- e. The risk to the donor's health is acceptable (principle of non-maleficence);
- f. The recipient will benefit from the procedure (principle of beneficence).

Donors and recipients are referred to the Committee by a consultant; the specialist responsible for the donor is always different from the one responsible for the recipient. The consultant will have ascertained and declared that the donor fully understands the nature and consequence of the donation. This certification is accompanied by declarations, signed both by the donor and also by the recipient, authorising LOTAC to:

- have unlimited access to confidential information regarding the financial state of affairs, including transactions of the parties; and
- subject both parties to any examination and/or interview to be conducted by any person deemed appropriate by the Committee to determine the appropriateness of the parties or either of them for the donation.

A form has to be signed by the donor attesting that no payment, coercion, duress or inducement has been or is being offered or made. This form is signed in the presence of the clinician. A similar form has to be signed by the recipient, attesting that no payment of money or of money's worth has been made or will be made to him/her or to any other person and that no such money or money's worth has been made or will be made by him/her or by any other person to the prospective donor. **The appropriateness of the donor remains confidential by the committee throughout and shall not be divulged to third persons.**

POLICY ADDRESSING LIVE ORGAN DONATIONS IN MALTA

1. In the case of donation between blood relatives and family members who are not blood relatives, an organ is donated to an identified recipient.
2. In other non-related donations a pre-existent close emotional link has to be present between donor and recipient for such a donation to be acceptable.
3. In the case of anonymous donation the Committee adopts the principle of distributive justice, where scarce resources (such as organs available for transplantation) are distributed to each person according to the medical need of the potential recipient, irrespective of the socio-economic group that the recipient belongs to.
4. The Committee views transplantation as a selfless gift without expectation of remuneration.
5. A strong emphasis on altruism reinforces the philosophy of voluntary and unpaid donation, and solidarity between the donor and the recipient.
6. In the case of potential kidney donations that do not fall within the category of directed donation, a donated organ will fall into a pool from which any compatible prospective recipient may benefit according to his/her needs, and this will be based on the principle of distributive justice.

COMPENSATION TO COVER EXPENSES OR LOSS OF INCOME BY THE DONOR

The subject of payment, whether in the form of incentives, rewards or compensation for living donation, is a highly controversial topic which has been discussed even at EU level. The present legal situation in Malta is against any form of financial inducement and also against advertising, either with or without any financial inducement, for living organ donation to a directed recipient.

Introducing some form of financial compensation for expenses incurred and loss of income due to post-op recovery may be considered. However, the amount and the modality of such compensation will have to be in line with guidelines issued by the Superintendent of Public Health.

THE LEGAL FRAMEWORK REGULATING ORGAN TRANSPLANTATION IN THE MALTESE ISLANDS

Until 2012 there was no specific law on organ donation and transplantation even though it had been practised for a number of years. In 2002 organ donation and transplantation were only regulated from a criminal point of view. In 2012 a new legislation was formulated and transposed to the European Parliament and Council Directive 2012/53/EU of July 2012. “Organ Transplants (Quality and safety) Regulations.” Under the “Human blood and Transplant Act.” Article 16 (Cap 483).

The current legal notices address the following:

- a. regulation of the setting of standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- b. regulation of standards of quality and safety of human organs intended for transplantation;
- c. regulation of coding, processing, preservation, storage and distribution; and
- d. regulation of certain technical requirements for the testing of human tissues and cells.

The legal notices addressing organ donation are as follows:

L.N. 271 OF 2006: HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006)

The title of these regulations is the Tissues and Cells (Quality and Safety) Regulations, 2006.

The scope of these regulations is to transpose Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and Directive 2006/17/EC of the European Parliament and of the Council of the 8 February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

L.N. 345 OF 2012 HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483): ORGAN TRANSPLANTS (QUALITY AND SAFETY) REGULATIONS, 2012

The title of these regulations is the Organ Transplants (Quality and Safety) Regulations, 2012.

The scope of these regulations is to transpose the European Parliament and Council directive 2010/53/EU of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

L.N. 222 OF 2014: HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483).HUMAN TISSUES AND CELLS (QUALITY AND SAFETY) (AMENDMENT) REGULATIONS, 2014

The scope of these regulations is also to transpose Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells.

L.N. 262 OF 2014 HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483): HUMAN TISSUES AND CELLS (CODING, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION) (AMENDMENT) REGULATIONS, 2014

The title of these regulations is the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) (Amendment) Regulations, 2014, and these regulations shall be read and construed as one with the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, hereinafter referred to as "the principal regulations".

UNDERGROUND MARKETS SURROUNDING ORGAN TRAFFICKING

In many countries, in direct response to indefinite delays on the national transplantation waiting lists and an inadequate supply of organs, a growing number of terminally ill people who can afford to pay are turning to international underground markets and coordinators or brokers for organs. Vulnerable people such as inmates and the economically disadvantaged are the often compromised co-participants in the private negotiation process, which occurs outside the legal process. These individuals supply kidneys and other organs for people willing to shop and pay in the private process. Every effort is made by the Maltese Government to prevent the need for sick Maltese people to resort to such processes.

Countries all over Europe are very concerned about this phenomena and Malta is no exception. During a 2009 joint Council of Europe-United Nations study it was concluded that there is an urgent need to collect reliable data from official sources, and States should ensure traceability of all organs transplanted. It was also emphasised that professionals should report any suspicion of organ trafficking to relevant local authorities.

During this time the European Committee on organ transplantation also committed itself to:

- a. Assist member states in improving their organ transplantation services whilst promoting the principle of voluntary non-remunerated donations;
- b. Examine the organizational structures involved in organ donation and transplantation in order to address the causes of organ shortage;
- c. Ensure the transfer of knowledge and expertise throughout Europe;
- d. Contribute to raise awareness among health professionals and general population about the importance and benefits of organs, tissues and cells donation.

These measures are aimed at increasing the supply of organs available for transplantation. The challenge is implementing an organ procurement policy that will maximize the supply to its greatest potential. Meeting this demand will result in less probability of patients turning to underground illegal markets to obtain a much needed organ transplant.

Last year, the Committee of Ministers of the Council of Europe adopted an international convention to make trafficking in human organs for transplant a criminal offence, to protect victims and to facilitate cooperation at national and international levels in order to prosecute more effectively those responsible for trafficking. Malta regularly participates in EU conventions and meetings held for competent authorities, combined effort will help combat this illegal trade.

Exclusive reliance on the present altruistic tissue and organ procurement processes in many countries and also in Malta is not only rife with problems, but also improvident. This is one of the reasons why the Maltese Government is totally committed to give a legislative framework to tissue and organ donation in Malta, which expectantly would increase the availability of organs for transplantation. The Maltese Government is also seeking to establish as a criminal offence the illegal removal of human organs from living or deceased donors where:

- a. Consent is not obtained from the living donor or from the relatives of a deceased donor prior to the removal of an organ;
- b. A financial transaction to purchase or instigate an illegal organ donation practice takes place either to a living donor or to a third party in the case of a deceased organ donor.

This is pertinent because the obtaining legal position under the Maltese Criminal Code does not deal with trafficking in organs but with trafficking in persons for exploiting the said persons for the purpose of the removal of organs. The current relevant provision under the Criminal Code states:

Whosoever, by any means mentioned in article 248A(2), trafficks a person of age for the purpose of exploiting that person in the removal of any organ of the body shall on conviction be liable to the punishment of imprisonment for a term from six to twelve years.

Trafficking in persons for organ transplantation is a serious crime and a grave violation of human rights so it is required to bring national legislation and specific regulation targeting trafficking in organs.

ENSURING AN EQUITABLE APPROACH TO ORGAN DONATION

The system that will be adopted and given a legislative framework after this consultation will ensure an equitable approach with respect to:

- a. race, faith, and human rights;
- b. disability and age;
- c. sexual orientation, marriage and civil partnership, or gender and gender reassignment.

SPECIFIC PROPOSALS OF THE VARIOUS SYSTEMS AS THEY WOULD BE APPLICABLE TO THE MALTESE ISLANDS

THE OPT-OUT SYSTEM

The key features of the proposed opt-out system should it be chosen as the preferred one for the Maltese Islands, are as follows:

- The opt-out system for the Maltese Islands will apply to people aged 18 years or over who are residents of the Maltese Islands, and who have had the opportunity to make an objection to the donation of their organs and tissues in the event of their death;
- The Maltese Government proposes that the new arrangements will apply to people who have lived in the Maltese Islands for a sufficient time in order to gain knowledge and understanding of the system. It cannot be expected that people who visit the Maltese Islands will know of the arrangements, and have had the opportunity to object. Views on the period of time one needs to have spent as a resident of the Maltese Islands are sought as part of this White Paper. It is recognised that the legislation will need to provide certainty as to the meaning of living in the Maltese Islands. Whether a person is considered to be usually living in the Maltese Islands or not, will need to reflect their usual daily lives, and not be swayed by temporary absences (such as holidays, recreation and business). The mechanism devised will need to be clear to the clinicians and to the public.
- The persons included in this system must have the ability to understand the whole concept of the opt-out organ donation principle.

Persons who would not be included in the opt-out organ donation system:

- Persons who die in the Maltese Islands but who do not normally live in the Maltese Islands (for example, visitors);
- Persons who normally live in the Maltese Islands and die, but have not lived in the Maltese Islands for the required length of time;
- Persons who usually live in the Maltese Islands, but who die outside the Maltese Islands;
- Persons who cannot be identified at their death;
- Adults (those aged 18 or over) who do not have the capacity to understand and make a decision about objecting to donation during his/her lifetime; and
- Children and young people aged under 18 years.

The operational side of the opt-out system for the Maltese Islands must:

- maintain accurate records;
- be constantly kept up to date;
- inform every person on how to make an objection to organ donation. This system must be effective and have a secure system for individuals to make an objection to donation should they wish to, and such a system must enable objection to the donation of some or all organs.

In order to ensure that an individual has the opportunity to make an objection, there must be:

- access to and availability of information about the opt-out donation system;
- all methods put in place to enable an individual to make a confidential objection to donation in an easy and accessible manner;
- an ability on the part of the individual to understand the information available and how to reach a decision;
- an efficient system by which an objection can be made and is recorded; and
- the possibility for an individual to register his/her intentions to donate all organs and tissues or to select specific organs or tissues.

Two sub-options are possible. After death, families could be involved in the decision-making process around donation (commonly known as the soft Opt-out option). Another scenario would be to have total respect for the deceased individual's recorded decision not to donate organs as taken during his lifetime, without the involvement of any third parties after death (known better as the hard opt-out option).

There are often concerns that under an opt-out system individuals lose rights over their bodies, and power to remove organs for transplantation is in the hands of the state.

However, evidence shows that individuals are more likely to make decisions about donation during their lifetime under such a system. Individuals will also have their decision respected after death. Moreover, the hard opt-out option shifts the burden of making a decision about organ donation from the grieving relatives in the most difficult of circumstances, when they often have no clear indication of what the deceased would have wanted, to the deceased himself/herself.

The Maltese Government recognises that the record system put in place to support the operation of an opt-out system for the Maltese Islands must be integrated into, and work cohesively with, the operation of the organ and tissue donation arrangements for the Maltese Islands.

WHAT AN OPT-OUT SYSTEM WILL NOT CHANGE

The Maltese Government may only make legislation in relation to the Maltese Islands. Therefore, the opt-out system will apply in relation to the Maltese Islands only.

The Maltese Government's intention is that the proposals in this White Paper will not:

- change the way patients are cared for (including the medical treatment they will receive) up to and including the time of death;
- change the way in which death is confirmed – there are very clear and strict standards and procedures for confirming death;
- change the way organs and tissues are allocated;
- alter the clinical decision-making and processes associated with transplant;
- allow donated organs and tissues to be available for any purpose other than transplantation.

KEEPING AN OPT-OUT SYSTEM UP TO DATE

An opt-out system will need to be sufficiently flexible to accommodate changes. Such changes could include:

- an individual changing their mind, for example previously objecting but now wishing to donate;
- people who move to or from the Maltese Islands;
- young people reaching the age of 18.

The Maltese Government recognises that an opt-out system, if introduced, must acknowledge and enable these changes so as to ensure that the individual's choices are respected and followed in the event of death.

POTENTIAL ADVANTAGES OF AN OPT-OUT SYSTEM

An opt-out system can serve a number of purposes:

- It acts as an important safeguard; families may not be aware of a registered objection.
- It recognises the doctor's duty of care towards relatives, to relieve and not add to their distress and bereavement.
- Under an opt-out system of organ and tissue donation, in conjunction with an extensive public awareness programme, individuals are far more likely to have discussed their views with their families and to have made their views clear prior to death.

INCREASE IN ORGAN DONATION

International literature indicates that adopting the opt-out system leads to an increase in organ donation. Data from 24 countries over the period 1993-2006 estimated that countries with presumed consent legislation (The Opt-Out principle) have, on average, 13-18 percent higher organ donation rates than countries with informed consent legislation (Bilgel, 2012).

Mossialos et al (2012) analysed individual-level survey data from participants living in 15 European countries and found that individuals living in presumed consent countries were between 17-29 percent more likely to report willingness to donate their own organs and 27-56 percent more likely to report that they would be willing to consent to the donation of their relatives' organs, compared to respondents living in explicit consent countries.

REVIEWING THE CURRENT OPT-IN ORGAN DONATION SYSTEM (EXPRESSED CONSENT)

THE SOFT PRINCIPLE FOR ORGAN DONATION

The current opt-in system carries a soft principle by which relatives are consulted prior to the harvesting of a patient's organs. Strengthening of this system can be achieved by:

- a. creating a legislative framework to protect and respect the donor's wishes after his/her demise. As things stand in Malta, everyone can apply for an organ donor card, thereby making an informed choice to donate their healthy organs after their death. However, even if a deceased person is in possession of such a donor card, the final decision as to whether their organs should be donated or not currently remains in the hands of that person's family;
- b. giving the donor card a legal status. Such a status will make it possible for the individual's wishes to be totally respected after death.

With the current approach of the opt-in principle people may die in circumstances where donation of their organs and tissues would be possible but does not happen. This is not because the deceased person objected to donation, but because s/he had not got round to apply for an organ donor card. This may happen especially with patients who happen to have no relatives.

So, giving the opportunity to all Maltese residents to become organ donors, by actually asking each and every Maltese person to register as an organ donor, might have a direct positive impact towards organ donation in the Maltese Islands.

REQUIRED REQUEST

Required request refers to a law that mandates hospital personnel to discuss with the relatives of a deceased patient regarding the possibility of organ donation. Such a law would seek to increase the supply of cadaveric organ donations, especially corneas, while preserving the voluntary nature of such an act.

In other words 'Required request or referral' is defined as "that it shall be illegal, as well as irresponsible and immoral to disconnect a ventilator from an individual who is declared dead following brain stem testing without first making proper enquiries to the possibility of that individual's tissues and organs being used for the purposes of transplantation."

Such a policy should imply that opportunities for donation are less likely to be overlooked. Many individuals may be having their right to donate removed if their relatives are not approached. The next of kin also have a moral and legal right to know they can donate organs and tissue if they or the family so wish. Many families report that such a donation was helpful rather than harmful.

The aim of such an approach is to avoid the unwanted situation of patients dying while awaiting a donor organ and, on the other hand, that families of some potential donors are never informed or reminded of the possibility of organ donations.

This concept of required request does lead to challenges on several fronts, mainly clinical and psychological, but also socio-economic aspects.

It is of paramount importance that any discussions regarding organ donation prior to or after death are conducted with reasonable discretion and sensitivity, including regard for religious beliefs.

THE LIVING WILL

A living will/testament is a legal document that allows one to specify the conditions of his/her medical treatment in case s/he become too sick or injured to communicate these wishes him/herself.

Therefore, this would confirm that nobody will have the right to deny the wishes of those individuals who have opted in as donors, given explicit consent and are in possession of a donor card. In the absence of such a possibility, one's family may not know their wish to donate and therefore, may not do so on their behalf. Similarly, one's family may know of their wishes but may refuse to allow doctors to take their organs when they pass away. This concept will strengthen the opt-in system.

CHILDREN UNDER 18 YEARS OF AGE IN RELATION TO ORGAN DONATION IN THE MALTESE ISLANDS

Organ transplantation offers children in acute or chronic severe organ failure similar opportunities to adults. However, while the number who might benefit is relatively low, significantly fewer cadaveric donors exist for any given child compared with an adult.

Incompatible organ size and relatively low donation rates mean that despite living parental donation and innovations to reduce donated organ size, children die before organs become available. Facing up to the death of a loved one is hard. Having to make a decision about organ donation, unsure what that person would have wanted, can cause extra pain especially to parents of young adults who lose their life. There are people of all ages on the organ transplant waiting list and young people are better suited to receive organs from those close to their age and size.

Under the current soft Opt-in principle of organ donation in the Maltese Islands, and under Maltese law, any person under the age of 18 is considered to be a minor and is automatically excluded from registering for an organ donor card. Conversely, in other countries like the UK, parents and guardians can register their children and children can register themselves. There are currently two key laws governing organ donation and transplantation in the UK: The Human Tissue (Scotland) Act 2006 and The Human Tissue Act 2004 (England, Wales and Northern Ireland).

In Scotland any child aged 12 and over, who is able to make their own decisions, can give permission for their organs or tissue to be donated, but children under the age of 12 cannot give permission themselves. For a child under the age of 12, only their parent or guardian can give permission. Children over 12 in Scotland are considered legally competent to register themselves.

POSSIBLE OPTIONS

- a. In an opt-in system children over 12 years of age who are considered legally competent to register themselves can be given the opportunity to register as an organ donor but only after extensive education to empower educators, parents and guardians to discuss the issue is provided. In Scotland e-books are also provided on tablets that students use on a daily basis.
- b. In an opt-out system children between 16 years and 18 years of age could be included, but as all other adults, must be given the facility to opt-out.
- c. However, children under the age of 12 are not allowed to register as organ donors even if their parents consent and if a child under 12 years dies, an organ donation will only be possible if there is explicit consent by the parents or legal guardian.

CONSENT

Consent is central to most organ and tissue donation systems. This is because consent is generally seen as the ethical and legal justification for the removal and use of organs and tissues. Opt-out systems are sometimes referred to as a “presumed consent” system of organ and tissue donation. So unless an individual makes an objection to donation, their organs and tissues will be available for donation after their death. Therefore, consent for donation, in the absence of objection, is presumed.

Under the current opt-in system, consent for donation is given when individuals volunteer to become organ and tissue donors by actively registering to become organ donors after their death and will be issued an ‘Organ Donor Card’ “Expressed consent”. However, the relatives are always consulted prior to any form of organ donation.

ABILITY TO UNDERSTAND

The Mental Health Act, 2012 describes “Mental capacity” as “the patient’s ability and competence to make different categories and types of decisions and to be considered responsible for his actions.”

This principle will not be altered by the proposed opt-out system for organ and tissue donation. People may have the mental capacity to make decisions about some aspects of their life, but not others. It is recognised that some people may never have the mental capacity to make a particular decision, some may lose the mental capacity to make that decision others their mental, and for capacity may fluctuate.

TIMETABLE

This White Paper is a consultation document and the Maltese Government is inviting views on the proposals by **20th May 2015**.

Following consideration of the consultation responses, a Bill will be brought forward by the Maltese Government and presented in Parliament. It is currently expected that there would be a lead-in period between the making of the legislation and the new system coming into force. Such a time period will enable the appropriate mechanisms and systems of operation to be established, and for a major public awareness campaign to be rolled out. The lead-in period is likely to be two years.

PUBLIC AWARENESS CAMPAIGN

This White Paper has set out the need for, and importance of, a major public awareness campaign during the consultation period and prior to a decision towards a legislative framework addressing organ donation in the Maltese Islands.

The Maltese Government will seek views on the proposed legislation through the following means:

1. through e-mail : consultations.meh-health@gov.mt;
2. through a series of public meetings across the Maltese Islands;
3. through extensive television, radio, press and online activities;
4. a version in Braille will be available on request;
5. The White Paper for consultation will be available both in the English and Maltese languages.

CONSULTATION QUESTIONS

As part of the consultation process, the Maltese Government is seeking responses on particular aspects of the different proposals for organ donation legislation presented in this White Paper. However, respondents are invited to provide any additional comments and evidence on the proposals as a whole.

QUESTIONS RELATED TO ORGAN DONATION PROPOSALS

1. Which system of organ donation do you think is most acceptable to the Maltese people, keeping in mind our culture and moral beliefs?
2. Do you agree that discussions between clinicians and family in the event of an individual's death will identify and safeguard the decision of the deceased because most probably s/he would have discussed the issue with his/her family?
3. Do you agree that the donor card should be given a legal status to safeguard the wishes of the individual after his/her death?
4. What is the role of the family in safeguarding the wishes of the deceased?
5. This White Paper proposes that 'individuals must have lived in the Maltese Islands for a sufficient period of time before being included within an opt-out system' (should an opt-out system be adopted). What factors should be taken into account when determining whether an individual 'lives in the Maltese Islands'? What should that period of time be?
6. Do you agree that an opt-out system for the Maltese Islands should only apply to persons aged 18 years and over? If not, why?
7. Do you feel confident that every effort is made to give everyone the opportunity to opt-out if s/he wishes to?
8. Do you think that the Maltese people are altruistic and generous enough to opt for an opt-out system by which everyone is considered a donor unless s/he opts out?
9. Do you think that there is a greater possibility that an individual will decide whether s/he wants to donate his/her organs after his/her demise, if an opt-out principle is introduced in the Maltese islands?
10. Which option do you think would improve the current situation leading to an increase in organs available for transplantation?
11. Do you have any suggestions on how to improve the current system?
12. In your opinion, what percentage of the Maltese population would prefer to improve the current system rather than opt for another system?
13. Does it bother you to think that when a person dies his/her organs are utilised to save the lives of others?
14. Do you believe in the principle that it is a waste to bury organs when in actual fact they can be used to give a life to someone needing an organ transplant?
15. Do you agree with the concept that the relatives of a prospective donor have the right to overturn the deceased wishes?

16. Do you agree that children over the age of 12 should be given the opportunity to register as an organ donor?
17. Using an appropriate approach, do you agree that children at an early age should be introduced to and educated on the subject of donating organs after death?
18. Do you agree with financial remuneration to live organ donors to cover expenses incurred due to loss of income and related matters? If in the affirmative should this state remunerate the donor, keeping in mind the big expenses saved to cover renal, dialysis, hospital bed days and medical treatment?

The Maltese Government has asked a number of specific questions. If you have any related issues which have not been specifically addressed, please record them in the space below.

CONCLUSION

In Malta, similar to everywhere else in the world, patients die whilst on the waiting list or following removal from the list due to deterioration in their health. While almost all of us would be willing to accept an organ or tissue transplant, only 8 percent of the population in the Maltese Islands are registered and were issued an organ donor card. Research suggests that many more people would like to join the register but have not yet done so. Perhaps creating an environment in which donation is the normal choice will enable more organs and tissues to be available when they are needed the most.

International comparisons illustrate a range of factors which influence organ donation rates and the introduction of an opt-out system is one of those factors. Research suggests that organ donation rates from deceased persons increase in countries where an opt-out system applies.

It is evident that more needs to be done if the dearth of organs for transplants (an issue not unique to Malta) persists. Malta must improve and regulate the whole area of organ donation by adopting a more proactive approach and by giving the organ donation issue a legal framework it very well deserves.

The opt-out system that is being proposed in this White Paper is one in which the removal and use of organs and tissues is permissible unless the deceased objected during his or her lifetime. Individuals will have a formal mechanism for registering that objection. After death, relatives will be involved in the decision-making process around donation if a soft opt-out system is adopted.

Different cultural attitudes to the disposal of bodies, greater provision of intensive care beds, more proactive donation programmes and the numbers of road deaths, each play their part in the number of organs that become available for organ donation. However, the single most important factor so far identified is ensuring that the relatives of potential organ donors are always approached, and approached by someone specifically trained for the purpose. Strengthening and improving the system through which families are approached after a death of a relative will definitely have a positive impact towards organ donation.

Spain is recognised as having a higher number of donors than the UK, and it is acknowledged by the director of national transplant organisation in Spain himself that the increase in organ donation during the 1990s could not be attributed to a change in legislation which had remained the same since 1979. The improvements in donor rates in Spain followed the implementation of a comprehensive national procurement system.

The United States follows **first-person consent**, whereby the recorded wishes of the donor are not allowed to be overridden by anyone, including healthcare providers. Meanwhile, each province in Canada has an anatomical gift act which gives the recorded wishes of the potential donor the same legal protection as an advance directive or living will. Moreover, a national public opinion survey revealed that 80 percent of Canadians did not want their wishes overturned by next of kin.

Given the complexity of decision making surrounding organ donation consent, it is unlikely that a single piece of legislation alone will be responsible for an increase in organ donation rates. However, it may be a contributory factor. An opt-out system changes the default position to be in line with the wishes of the majority and this may overcome the problem of inertia that limits explicit registration to opt-in, while providing a new opportunity for those who definitely do not wish to donate to record their wishes by opting out. Where legislation is changed, communications campaigns and factors related to the practical implementation of the policy at the ground level will likely be important factors in the legislation's success. Unfortunately the current evidence base provides little information on how these factors can be optimised.

