

# Perception of Health-Care Professionals on Presumed Consent in Formulation of Proper Organ Transplantation Regulatory System

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## ABSTRACT

**Background:** Owing to the advancement in organ transplantation, treating an individual with organ failure in today's world has become possible. However, organ transplantation is lagging in the absence of adequate organ donations. Shortage of organs for transplantation is a challenge to developing countries like Nepal and developed countries like the USA and UK. Despite various efforts to increase the rate of organ donation, the problem persists. The primary reason for the failure to accomplish adequacy in organ donation is the immediate dependency on an available donor. On top of that, reluctance to decide on organ donation after death, regarded as an onerous moment, at least by the general public, has another impact on the subject. Some countries have shifted while some are planning to change from an informed consent system to a presumed consent system, in which if an individual does not make any decision during lifetime, it is presumed that his/her organ can be removed for organ transplantation after death.

**Objective:** To perceive the perception of healthcare professionals of the tertiary care centre of eastern Nepal regarding the presumed consent system.

**Methods:** Purposive sampling of 221 health care professionals (Faculties, Nursing In-charges, Lab- technicians, and Radiology technicians) participated in the study.

**Results:** Most healthcare professionals (90.5%) support using a presumed consent system in Nepal and agree on considering the family's opinion in the decision-making for cadaveric organ donation.

**Conclusion:** Most healthcare professionals have shown their perception in favors of presumed consent to support the increasing organ donation rate.

**KEYWORDS:** Informed consent; Organ donation; Organ transplantation; Presumed consent

## INTRODUCTION

Organ transplantation offers patients all appropriate and available treatment options [1]. The field of transplantation medicine throughout the world has achieved a breakthrough [2]. However, a dire need for organ donors has prevented potential patients from realizing this progress [1]. Despite extensive efforts to increase donation, the supply of organs has not kept up with de-

mand, and thousands of people die each year while waiting for a transplant [2] for example 6679 died in the USA in 2002 [3]. Therefore, it is morally unjustified to perpetuate a system that falls short of increasing the availability of organs to people who might get a chance to live from transplantation [4]. The shortage of human organs for transplantation has become one of the most pressing health policy issues in many developed countries [3]. WHO guiding principles state that cadaveric organ removal can be done through the informed and presumed consent system [3, 4]. Studies have not only shown that the presumed consent system increases organ donation levels [5, 6] but also suggested that countries with pre-

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sumed consent systems have higher rates of organ donation than those without presumed consent system [7, 8]. In many countries, including the U.S., U.K., Australia and Germany, cadaveric organ donation is carried out as per the informed consent principle [3], under which organ removal needs the donor's explicit consent before death [3]. In contrast, most European countries, including Spain, Austria, and Belgium, have already adopted presumed consent legislation [9-12], under which consent for removal of the deceased's organ is presumed in the absence of opt-out decision [3]. Healthcare professionals and organ donation activists in the U.S., U.K., and several other nations have advised changing legislative defaults to presumed consent on organ donation [3]. Recently, the British Parliament discussed the proposition of a presumed consent system, which has received support from the medical community [13]. Thus, this research has been done to perceive the perception of healthcare professionals of the tertiary care centre of eastern Nepal regarding the presumed consent system.

## METHODOLOGY

Ethical clearance has been taken from the Institutional Review Committee, B. P. Koirala Institute of Health Sciences (BPKIHS), Dharan. It is a descriptive and cross-sectional study. A purposive sampling of 221 healthcare professionals participated in the study. Inclusion criteria: Faculties, Nursing In-charges, Lab- technicians, and Radiology technicians who gave informed consent. "Pre-established self-administered close-ended questionnaire" [14] was used among the participants (BPKIHS) from January 2020- March 2020. A Paper survey technique was used to collect data. The paper questionnaire doesn't include information related to the personal identity of the participants. Collected data were entered in Microsoft Excel and coded accordingly. The statistical analysis was performed to calculate frequency by statistical package for social science (SPSS).

## RESULTS

A total of five questions from the Questionnaire, which were related to the presumed consent system, were used, and the outcome of these questions not only presented the perception of this system but also clear the views on the different factors that are directly and indirectly, associated with this system. The calculated frequencies in the table are expressed in percentages.

## DISCUSSION

Most healthcare professionals (90.5%) in our survey support using the presumed consent system in Nepal. A multi-national survey among transplant professionals showed a similar outcome, i.e., 75% of participants favors the presumed consent system [15], and this system was found to be the most efficacious method to increase donations, followed by public awareness [15]. This prodigious support for the presumed consent system from healthcare professionals is not just a subjective outcome; rather, it is an outcome backed up by various logical reasons presented in different studies. A study done by Mossialos E. et al has shown that some individuals might be reluctant to decide about becoming an organ donor since it requires thinking about an event they would rather prevent and not acknowledge its possibility of occurrence [1]. Unlike the informed consent system, individuals might not experience utility from thinking about death in the presumed consent system [1]. Similarly, deciding on donating organs might require some effort (e.g., filling out a form) as in an informed consent system, while reacting to or accepting the regulation, as in a presumed consent system, might be effortless [11]. Therefore, the presumed consent policy lends itself towards higher procurement levels [1]. Even the nations ensuing presumed consent system also vary in how organ donation law functions in practice, and the terms "hard" and "soft" have been used to specify how much priority is placed on relatives' opinion in these nations [16]. For example, in Spain, the presumed consent law is "soft" in that doctors take active

**Table 1:** Frequency distribution of the responses.

Q.N.	Questionnaire	Response (Frequency in percentage)		
		Yes (%)	No (%)	Cant say (%)
1.	Should "presumed consent" be used in Nepal?	90.5	5.42	4.07
2.	Should a "modified version of presumed consent" be used in Nepal?	88.23	6.33	5.43
3.	After the death of an individual, their family member showed a wish "not to donate an organ" should this wish of the deceased's family be considered in this "modified version of presumed consent" system?	96.38	1.81	1.81
4.	Does "Presumptively" address the loss of autonomy?	80.54	12.67	6.79
5.	Donor consented for a cadaveric transplant before his/her death, but his/her family members opted out after their death, should opt out of the decision of family member/s be allowed?	90.95	5.43	3.62

measures to ascertain that the next of kin do not object to organ recovery [16]. In Austria, the presumed consent legislation is comparatively "hard" in that family wish is not actively considered for cadaveric organ removal [16]. Austria considers the body of the deceased a property of the state; the deceased donation rates are substantially higher not only because the procurement process is well organized and efficient but also because the public tends to reconcile with the strict enforcement of consent legislation and internalize the practice of exclusion of the family from the decision-making process [13]. However, in practice, nations with a presumed consent system sought relatives' views, and the closest family member is permitted to overrule donation even if the deceased has previously consented for organ donation [13]. Our study outcome is also not different from what is in practice in most of countries regarding consideration of family's wishes under both systems, a modified version of presumed consent (96.38%) and informed consent (90.95%). The reason for considering families' decisions in the process has been to avoid public backlash, and liability suits and to show respect for the grieving family [17]. Public backlash followed by the abolishment of presumed consent legislation can be seen in Brazil, where many registers as

a non-donor because of the implementation of presumed consent legislation with a provision of not considering family's wishes which was later on reinforced with a threat of execution to the health-care professionals in disobeying the law [18]. Support with a shred of empirical evidence to a system of "soft" presumed consent can be seen in a study done by Oz et al which also concurs with the British Medical Association's view [19] during the transition from an informed to presumed consent legislation whereas empirical evidence for the success of "hard" presumed consent has yet to be examined [13]. Similarly, it can be seen that approximately half of the families that are approached to request donation refuse it in the U.S. and U.K. which are with informed consent legislation, compared to around 20% in Spain and around 30% in France where presumed consent is prevailed [3].

Perhaps the most controversial response from ethical, religious, and individual rights perspectives has been the presumed consent policy for organ donation [7,8,20] because the presumed consent system is believed to be encroaching on an individual's right by imposing a loss of autonomy of that individual. However, the majority (80.54%) of the health-care professionals in our study perceive that the loss

of autonomy can be addressed with the help of presumptively. Considering both positive and controversial aspects of this system, a nation can be advised to take perception of its population and implement accordingly. This has been done in Singapore, where those between 21 and 60 years old who die in accidents are assumed to be kidney donors unless they opt-out. Older people, as well as Muslims, are in a separate tier, and they must opt in [21]. This is a modified version of presumed consent and this way of implementation of presumed consent has also been supported in our study.

First Nepalese law regulating organ transplantation [22] had an informed consent system which was later modified [23,24] with the addition of a provision for organ removal even with the permission of deceased's relative in the absence of deceased's consent. However, in this system, the relative may feel guilty in approving because the absence of deceased's consent in an informed consent system unlike to that of the presumed consent system where the absence of deceased opt-out decision means an agreement for donation. A study done on the Belgian system has also shown that the family members find themselves in comfort position when their decisions are in accordance with the deceased choice instead of making a personal decision. If this is so, a presumed consent has an advantage of alleviating distressed family members of the burden of deciding on organ removal [4]. It is interesting to note that Belgium Presumed consent law is also applicable to non-Belgian citizens resident in the country for more than six months [25].

In conclusion, most healthcare professionals have shown their perception in favor of presumed consent to aid in formulating a proper organ transplantation regulatory system that supports the increasing rate of organ donation.

### Recommendations

Informing the strength and weaknesses of the presumed consent system to the general public, this type of survey is recommended to understand how our societies perceive and

respond to legislative changes of this nature.

### ACKNOWLEDGMENTS

Authors would like to acknowledge all the participants for their valuable responses, and Mr. Akash Shrestha for English language revision of this manuscript.

**CONFLICTS OF INTEREST:** None declared.

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