

## COMMENTARY

# Leadership, management, quality, and innovation in organ donation: 2019 Kunming recommendations for One Belt & One Road countries

Chloe Ballesté<sup>1,2,3</sup>  | Aurora Navarro<sup>4</sup>  | José Luis Escalante<sup>5</sup>  |  
 Arantxa Quiralte<sup>3</sup>  | Elisa Vera<sup>3</sup>  | Ana França<sup>6</sup>  | Danica Avsec<sup>7</sup>  |  
 Alan Leitchman<sup>8</sup>  | Ricard Valero<sup>1,9,10,11</sup>  | Melania Istrate<sup>1,3</sup>  |  
 María Paula Gómez<sup>3</sup>  | Minkang Zhou<sup>3</sup>  | Estephan Arredondo<sup>3</sup>  |  
 Reginaldo Boni<sup>3,12</sup>  | José María Domínguez-Roldán<sup>3,13</sup>  | Hongtao Zhao<sup>14</sup>  |  
 Haibo Wang<sup>14</sup>  | Miao Pu<sup>14</sup>  | Wei Lu<sup>14</sup>  | Li Li<sup>15</sup>  | Martí Manyalich<sup>1,2,3</sup>  |  
 The Kunming Recommendations Group<sup>1</sup>

<sup>1</sup> Surgery and Surgical Specializations Department, Faculty of Medicine, University of Barcelona, Barcelona, Spain

<sup>2</sup> Medical Direction, Hospital Clínic de Barcelona, Universitat de Barcelona, Barcelona, Spain

<sup>3</sup> Donation and Transplantation Institute (DTI), Barcelona, Spain

<sup>4</sup> Notify project-WHO, Barcelona, Spain

<sup>5</sup> Hospital General Universitario Gregorio Marañón, Madrid, Spain

<sup>6</sup> Portuguese Institute for Blood and Transplantation, Lisbon, Portugal

<sup>7</sup> The Institute for Organ and Tissue Transplantation of the Republic of Slovenia, Ljubljana, Slovenia

<sup>8</sup> Arbor Research Collaborative for Health, Ann Arbor, Michigan, USA

<sup>9</sup> Department of Anesthesiology, Hospital Clínic de Barcelona, Universitat de Barcelona, Barcelona, Spain

<sup>10</sup> Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain

<sup>11</sup> Centro de Investigación Biomédica en Red Salud Mental (CIBERSAM), Spain

<sup>12</sup> Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil

<sup>13</sup> Hospital Virgen del Rocío, Sevilla, Spain

<sup>14</sup> China Organ Transplantation Development Foundation, Beijing, P. R. China

<sup>15</sup> The First People's Hospital of Kunming and The Affiliated Ganmei Hospital of Kunming Medical College Kunming, P. R. China

## Correspondence

Chloe Ballesté, Surgery and Surgical Specializations Department, Faculty of Medicine, University of Barcelona, Barcelona, Spain.  
 Email: [chloeballeste@ub.edu](mailto:chloeballeste@ub.edu)

# The Kunming Recommendations Group (members by alphabetical order and country): P. MacDonald (Australia); H. Ur-Rashid (Bangladesh); O. Kalachik (Belarus); R. Jashari (Belgium); N. Mujacic (Bosnia & Herzegovina); R. Boni, E. Rocha (Brazil); W.M. Chan, Z.

## Abstract

The findings and recommendations of the 2019 consensus conference in organ donation, held in Kunming, China, are here reported. The main objective of the conference was to gather relevant information from experts involved in the field. The data and opinions provided allowed to propose a series of recommendations for “One Belt & One Road Countries” on how to achieve self-sufficiency in organ donation. Leadership in organ donation should be results-oriented and goal-driven based on the principles of excellence, empowerment, and engagement, providing the means, resources,

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial-NoDerivs](https://creativecommons.org/licenses/by-nc-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2021 The Authors. *Clinical Transplantation* published by John Wiley & Sons Ltd.



Chen, X. Fan, X. Gao, Z. Gao, Y. Gou, K. He, X. He, J. Huang, X. Huang, W. Jiang, L. Jin, X. Jing, X. Kuang, C. Li, L. Li, W. Li, L. Liang, J. Liao, Y. Liao, L. Liu, X. Pan, G. Ren, X. Ren, H. Shi, B. Sun, D. Sun, S. Tan, H. Tian, H. Wang, W. Wang, X. Wang, X. Wei, Q. Xie, J. Xiong, Y. Yali Tan, Y. Yan Xie, H. Yang, X. Tao, Y. Ying Shi, Y. Yinjia Wang, W. Yue, K. Zhang, L. Zhang, H. Zhao, X. Zhao, J. Zhu (China); A.N. Murcia (Colombia); E. Pokorna (Czech Republic); R. Kamel (Egypt); A. Leichtman (Ethiopia); G. Tomadze (Georgia); I. Tsagkaris (Greece); R. García Gallont (Guatemala); N. Gracious, A.R. Mahaldar, D. Mirza, V. Palaniswamy, A. Seth (India); O. Ghobadi, K. Najafizadeh (Iran); H. Suroto (Indonesia); M. Cardillo, F. Procaccio (Italy); A.H. Breizat (Jordan); J. Jushinskis (Latvia); T. Tamošūitis (Lithuania); M.M. Mijovska (Macedonia); J.K. Koon, O. Sulaiman (Malaysia); G. Battsetseg (Mongolia); C. Ahn (South Korea); I. Laouad (Morocco); C. Cuero (Panama); A. França (Portugal); C. Pantis (Romania); D. Avsec (Slovenia); C. Ndhlovu and D. Thomson (South Africa); E. Arredondo, C. Ballesté, J.M. Domínguez, J.L. Escalante, M.P. Gómez, M. Manyalich, A. Navarro, M. Palou, D. Paredes, M. Peiró, A. Quiralte, I. Roselló, C. Soler, I. Tintoré, R. Valero, E. Vera, M. Zhou (Spain); L.N. Seneviratne (Sri Lanka); B. Ericzon (Sweden); B. Saeed (Syria); B. Elcock-Straker (Trinidad and Tobago); M.S. Ben Ammar (Tunisia); J.A. Holmberg, A. Leichtman, H. Shan, Y. Wu (USA).

and strategies necessary to reach the goal in earnest. Management includes good governance and transparency of a national registry of patients in the waiting list, donors, transplants, transplant teams, quality, and safety programs with continuous educational training of health care professionals. Mandatory monitoring, auditing and evaluation of quality must be incorporated into donation practices as relevant points in innovation, as well as the adoption of already established and novel processes and technologies. Achievement of self-sufficiency in organ donation is a crucial step to fight against transplant tourism and to prevent organ trafficking. Based on recommendations arising from the conference, each country could review and develop individualized action plans adjusted to its own circumstances and reality.

#### KEYWORDS

consensus conference, leadership, management, organ donation, quality, transplantation

## 1 | INTRODUCTION AND RATIONALE FOR CONSENSUS CONFERENCE

The Third Global Consultation on Organ Donation and Transplantation organized by the World Health Organization (WHO) which was held in Madrid, Spain, in 2010 stated that every country is responsible for meeting their transplantation needs. It was also declared the donation from deceased donors should be the primary source of organs to be transplanted.<sup>1</sup> Self-sufficiency in organ donation is every nation's goal and understanding organ donation as every patient's right is the first step towards achieving self-sustainability in organ donation. Each country or region should strive to provide a sufficient number of organs from within its own population, guided by WHO ethics principles.<sup>2</sup> From another perspective, achievement of self-sufficiency in organ donation is a crucial step to fight against transplant tourism and to prevent organ trafficking.<sup>3</sup> In this respect, one of the principles of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism clearly states that "countries and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation".<sup>4</sup>

Assessment of donation rates at international level shows a large variation in deceased donation rates, ranging from 45 to less than five donors per million population.<sup>5</sup> These disparities are mostly related to structural differences in health care systems at country level, legal

frameworks, and sociocultural factors affecting organ donation, as well as other circumstances involving mortality rates for organ donation as road and work accidents, cerebrovascular diseases, etc. However, a crucial aspect is how the organ donation program is organized in the country, regions, and hospitals.<sup>6</sup> Organization around the process of deceased donation is the key for success. This approach has been totally or partially replicated by many countries and regions, resulting in a progression in the pursuit of self-sufficiency in transplantation.<sup>7,8</sup> In this context, leadership in the organization, the way the system is managed, the use of management quality systems, or the incorporation of innovations along the donation process are indispensable elements to achieve self-sufficiency.<sup>9-11</sup>

The purpose of this manuscript to provide a summary of the 2019 Consensus conference on leadership, management, quality and innovation in organ donation, that was sponsored by China Organ Transplantation Development Foundation (COTDF), the final objective of which was to outline a set of future priority actions that will contribute to improve donation governance worldwide.

Some of the factors conditioning the transplantation programs in the countries who participated in the meeting included the limited budgets dedicated to transplantation, an excessive reliance on living donation, a limited human resources and expertise, known cultural barriers to donation or lack of public trust/education. All these aspects that may limit the novelty of the proposals should be considered according to the diversity of the participating countries, most of which were facing

on the initial steps of development in the field of organ donation. The study was centered in the evaluation of quality, management, leadership and innovation from a basic and universal perspective of establishing the minimum requirements as a starting point to reach self-sufficiency in organ transplantation. For this reason, other interesting aspects, such as opt in/opt out models, compensation of donor families, etc. were out of the scope of this starting step.

## 2 | METHODS IN BRIEF

The consensus conference was held in Kunming, China, on December 4–6, 2019, in which 81 experts from 33 countries worked together towards the common objective of establishing essential recommendations<sup>12–14</sup> for achieving self-sufficiency in organ donation through interventions for improving leadership, management, quality, and innovation. These four topics constituted the scientific content of the conference and were extensively discussed during the meeting. Participating countries were selected from the Belt & Road Initiative and were those with any transplantation activity already established. Participation was voluntary.

A core group of four international organ donation experts constituted the scientific committee. The scientific committee established and structured specific questions regarding the four main topics to be presented to the attendees at the Kunming's meeting as a pre-congress survey. This survey targeted specific issues with international relevance aiming at receiving maximum insights. The survey included 46 open and close questions, which was submitted to a two round Delphi process.<sup>15–19</sup> The Kunming survey is included in the Supplementary material. Representatives from organizations directly involved in organ donation and transplantation, especially targeting leaders and decision-makers at hospital, regional, and national levels participated in the survey. Based on the analysis of answers and results of the survey, the scientific committee presented a set of recommendations for leadership, management, quality, and innovation in organ donation.

During the meeting, participants were distributed into the four working groups (21–22 participants per group) considering the individual expertise on each topic (Leadership, Management, Quality, and Innovation) and ensuring also that all continents were represented. In addition, each working group had three nominated faculty members that conducted the sessions, ensured active debates and participation in the working groups, answered doubts and gather the conclusions. In addition, one spokesperson was predefined for each working group to present the final recommendations at the end of the workshop and during the conference.

The working groups analyzed recommendations and assigned a conceptual domain for the value of each recommendation (e.g., equity, accountability, transparency, justice, effectiveness, etc.). In addition, for each recommendation, they assigned one of three levels of requirement: compulsory, advisable, and excellence. Compulsory was defined when the recommendation met the criteria of high impact and high feasibility, advisable when the recommendation met the criteria of high

impact or high feasibility, and excellence when the criteria of impact and feasibility met by the recommendation were not high. Finally, all 81 participants stated whether or not they agreed with each recommendation.

## 3 | LEADERSHIP: KEY POINTS

- The government is the responsible organization for the organ donation program in each country. It must ensure that the system is accessible to the population as a whole (domains: effectiveness, transparency, equity; category: advisable; agreement 97%).
- Leadership in organ donation should be results-oriented and goal-driven based on the principles of excellence, empowerment, and engagement. It should be far-sighted and realistic, anticipating challenges and opportunities in the short-term and in the long-term, promoting quality, research and innovation (domains: excellence, effectiveness, trust; category: advisable; agreement 94%).
- The main goal of leadership in organ donation should be to achieve self-sufficiency, providing the means, resources, and strategies necessary to reach the goal in earnest (domains: confidence, responsibility, effectiveness; category: advisable; agreement 90%).
- Locally, transplant/donor coordinators should be empowered to lead the donation process in their own center, region, and country (domains: knowledge, enthusiasm, teamwork; category: excellence; agreement 70%).

## 4 | MANAGEMENT: KEY POINTS

- Appropriate management in organ and tissue donation should always be based on ethical principles. Transplantation is a right for every person and organ trafficking is forbidden (domains: equity, justice, transparency; category: advisable; agreement 93%).
- Effective management requires an established public and governmental national system organized at different levels and should be integrated into the national/regional health care system guaranteeing its correct functioning and its self-sufficiency (domains: accountability, effectiveness, transparency; category: advisable; agreement 97%).
- The public authorities should be responsible for providing and managing a general structure for the development of organ donation activities including legislation, funding, coordination, accountability, accreditation, ethics, and activities' control (domains: responsibility, efficiency, excellence; category: advisable; agreement 99%).
- Responsible management requires good governance and transparency of a national registry of patients in the waiting list, donors, transplants, transplant teams, quality and safety programs with continuous educational training of health professionals (domains: transparency, excellence, safety; category: advisable; agreement 94%).
- Efficient management should be based on financial support and qualified professionals and facilities (domains: productivity, teamwork, safety; category: advisable; agreement 91%).

## 5 | QUALITY: KEY POINTS

- Mandatory monitoring, auditing and evaluation of quality must be incorporated into donation practices to optimize efficacy, efficiency, and safety of all processes at institutional, regional, and national levels (domains: efficacy, efficiency, safety; category: advisable; agreement 94%).
- National authorities are responsible for the management and for the legal framework necessary to enhance quality initiatives. Institutional leadership is responsible for collaboration with healthcare professionals for the implementation of quality monitoring systems within their institutions (domains: mandatory, engagement, monitoring; advisable; agreement 97%).
- Each component of a donation program must include quality standards; particularly the key donation person must be well trained, recognized, and empowered (domains: standard, accountability, empowerment; category: advisable; agreement 95%).
- Quality metrics regarding outcomes, volumes, adherence to standard operating procedures, complications, compliance with regulations, resources, etc. must be transparent, and public, accessible to those in need of quality monitoring information, discussed, and used (domains: transparency, accessibility; category: advisable; agreement 90%).
- To optimize performance, and outcomes, quality must be continuously improved (domains: performance, outcome, continuity; category: compulsory; agreement 99%).

## 6 | INNOVATION: KEY POINTS

- Innovation should achieve safety and quality standards while respecting ethical and legal framework for donors and recipient's benefit (domains: safety, equity; category: compulsory; agreement 92%).
- Innovation should be the result of a multidisciplinary effort through the engagement of professionals with diverse skills, expertise, and perspectives (domains: teamwork, transparency, knowledge; category: compulsory; agreement 97%).
- Innovations may include the adoption of already established processes and technologies in some health systems and the application of novel technologies in other health care systems (domains: efficacy, excellence, safety; category: compulsory; agreement 95%).
- Innovation should be based on the implementation of new concepts, methods, and processes, in a culturally and socially appropriate way (domains: transparency, equity, excellence; category: advisable; agreement 96%).
- All donation and transplantation projects should incorporate research and development in their design, implementation, and evaluation (domains: efficacy, excellence, knowledge; category: advisable; agreement 80%).

## 7 | SUMMARY OF MEETING

This international meeting on organ donation for transplantation held in Kunming, China, successfully achieved the expectations gathering institutions, scientific societies, and experts under the umbrella of the Belt & Road initiative led by China. The experts that participated showed great motivation and enthusiasm on sharing experiences to find global strategies on how to reach self-sufficiency in the Belt and Road countries. Moreover, the four topics proposed to elaborate the recommendations for achievement of self-sufficiency (leadership, management, quality, and innovation) enlarged the perspectives and enlighten the need of professionalization, engagement of local institutions, use of indicators to measure the procedures, and enhance development for innovation. Consolidation of national organ donation and transplantation programs is the keystone to ensure self-sufficiency, which is an indispensable approach to preserve ethical standards and to fight against trafficking in human organs and transplant tourism. However, topics focused on organ trafficking and transplant tourism were not included in this meeting.

There was significant interest in furthering the collaborative international relationship between the participants and scientific societies from all continents to convert these comprehensive recommendations into specific actions. This was a great success and is the starting point for further international initiatives that will support local programs in initiating or consolidating donation activity to enable citizens to be transplanted. Finally, based on recommendations arising from the conference, each country could review and develop individualized action plans adjusted to its own circumstances and reality.

### ACKNOWLEDGMENTS

The authors wish to thank the Chinese institutions that made possible such a high and international level meeting: the China Organ Transplantation Development Foundation; The First People's Hospital of Kunming and The Affiliated Ganmei Hospital of Kunming Medical College Kunming; the World Health Organization; all scientific societies that agreed to participate: Asian Society of Transplantation (AST), The Middle East Society for Organ Transplantation (MESOT), African Society Of Transplantation (ASOT), Latin American and Caribbean Transplantation Society (STALYC), European Society for Organ Transplantation (ESOT), The Transplantation Society (TTS), European Donation and Transplant Coordination Organization (EDTCO), and International Society for Organ Donation and Procurement (ISODP). We thank Marta Pulido, MD, PhD, for editing the manuscript and editorial assistance.

### CONFLICT OF INTEREST

The authors of this manuscript have no conflicts of interest to disclose.

### DATA AVAILABILITY STATEMENT

Data of the study are available from the authors (C. Ballesté) upon request.

## ORCID

Chloe Ballesté  <https://orcid.org/0000-0001-5283-3926>  
 Aurora Navarro  <https://orcid.org/0000-0003-4774-9337>  
 José Luis Escalante  <https://orcid.org/0000-0002-6287-1907>  
 Arantxa Quiralte  <https://orcid.org/0000-0002-7291-0180>  
 Elisa Vera  <https://orcid.org/0000-0002-4328-5814>  
 Ana França  <https://orcid.org/0000-0001-6925-0196>  
 Danica Avsec  <https://orcid.org/0000-0002-5680-2120>  
 Alan Leitchman  <https://orcid.org/0000-0003-0658-0248>  
 Ricard Valero  <https://orcid.org/0000-0001-7875-9496>  
 Melania Istrate  <https://orcid.org/0000-0002-5033-0417>  
 María Paula Gómez  <https://orcid.org/0000-0002-1425-3186>  
 Minkang Zhou  <https://orcid.org/0000-0002-6841-5101>  
 Estefhan Arredondo  <https://orcid.org/0000-0002-6694-1108>  
 Reginaldo Boni  <https://orcid.org/0000-0003-3755-9222>  
 José María Domínguez-Roldán  <https://orcid.org/0000-0003-1933-1478>  
 Hongtao Zhao  <https://orcid.org/0000-0003-3147-3129>  
 HaiBo Wang  <https://orcid.org/0000-0003-0818-138X>  
 Miao Pu  <https://orcid.org/0000-0002-9929-3215>  
 Wei Lu  <https://orcid.org/0000-0003-1395-392X>  
 Li Li  <https://orcid.org/0000-0002-2505-8212>  
 Martí Manyalich  <https://orcid.org/0000-0003-2019-3121>

## REFERENCES

1. WHO, Transplantation Society (TTS), Organización Nacional de Trasplantes (ONT). Third WHO global consultation on organ donation and transplantation: striving to achieve self-sufficiency, March 23–25, 2010, Madrid, Spain. *Transplantation*. 2011;91 Suppl 11:S27-S28.
2. Delmonico FL, Domínguez-Gil B, Matesanz R, Noel L. A call for government accountability to achieve national self-sufficiency in organ donation and transplantation. *Lancet*. 2011;378(9800):1414-1418.
3. Capron AM, Delmonico FL. Preventing trafficking in organs for transplantation: an important facet of the fight against human trafficking. *J Human Traffick*. 2015;1(1):56-64.
4. The declaration of Istanbul on organ trafficking and transplant tourism. *Indian J Nephrol*. 2008;18(3):135-140.
5. Newsletter Transplant 2019. International figures on donation and transplantation 2018. Published jointly with the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM), Council of Europe and Organización Nacional de Trasplantes 2019. Available at: <https://register.edqm.eu/freepub>. Accessed: January 2020.
6. Saidi RF, Hejazii SK. Challenges of organ shortage for transplantation: solutions and opportunities. *Int J Organ Transplant Med*. 2014;5(3):87-96.
7. Matesanz R, Domínguez-Gil B, Coll E, Mahillo B, Marazuela R. How Spain reached 40 deceased organ donors per million population. *Am J Transplant*. 2017;17(6):1447-1454.
8. Vasanthi R. Why NOTTO? The national organ and tissue transplant organisation and why it is crucial to regulate organ donation and transplantation in India. *Transplant Proc*. 2020.
9. Coll E, Czerwinski J, De la Rosa G et al., eds. Guide of recommendations for quality assurance programmes in the deceased donation process. Dopki Project (European Commission) Available at: [www.ont.es/publicaciones/Documents/DOPKI%20GUIA.pdf](http://www.ont.es/publicaciones/Documents/DOPKI%20GUIA.pdf)
10. National Transplant Organisation (Spain). Good practice guidelines in the process of organ donation, 2011 Available at: [www.ont.es/publicaciones/Documents/VERSI%C3%93N%20INGLESA%20MAQUETADA\\_2.pdf](http://www.ont.es/publicaciones/Documents/VERSI%C3%93N%20INGLESA%20MAQUETADA_2.pdf)
11. Project ODEQUS (Organ Donation European Quality System). Criteria & quality indicators in organ donation. Available at: [www.odequs.eu/pdf/odequs\\_Quality\\_Criteria-Indicators.pdf](http://www.odequs.eu/pdf/odequs_Quality_Criteria-Indicators.pdf)
12. Waggoner J, Carline JD, Durning SJ. Is there a consensus on consensus methodology? descriptions and recommendations for future consensus research. *Acad Med*. 2016;91(5):663-668.
13. Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. *Am J Public Health*. 1984;74(9):979-983.
14. Bloor M & Wood F Keywords in qualitative methods: A vocabulary of research concepts. Thousand Oaks, Calif: Sage Publications, 2006.
15. Hohmann E, Brand JC, Rossi MJ, Lubowitz JH. Expert opinion is necessary: delphi panel methodology facilitates a scientific approach to consensus. *AANA J*. 2018;34(2):349-351.
16. Tsang S, Roysse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi J Anesth*. 2017;11(1):S80-S89.
17. Bolarinwa AO. Principles and methods of validity and reliability testing of questionnaires used in social and health science researches. *Niger Postgrad Med J*. 2015;22(4):195-201.
18. Keeny S, Hasson F, McKenna HP. A critical review of the Delphi technique as a research methodology for nursing. *Int J Nurs Stud*. 2001;38(2):195-200.
19. Humphrey-Murto S, Varpio L, Gonsalves C, Wood TJ. Using consensus group methods such as Delphi and Nominal Group in medical education research. *Med Teach*. 2017;39(1):14-19.

**How to cite this article:** Ballesté C, Navarro A, Escalante JL, et al., Leadership, management, quality, and innovation in organ donation: 2019 Kunming recommendations for One Belt & One Road countries. *Clin Transplant*. 2021:e14470. <https://doi.org/10.1111/ctr.14470>