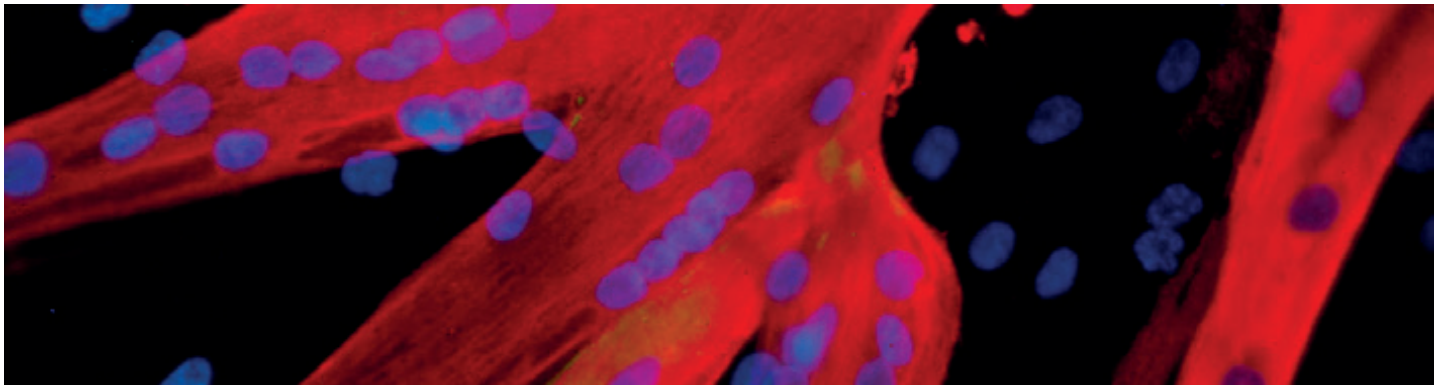
iap SCIENCE HEALTH POLICY

the interacademy partnership

# Statements 2019–2022



iap SCIENCE HEALTH POLICY

the interacademy partnership

# Statements 2019–2022

# Contents

**INTERACADEMY PARTNERSHIP STATEMENTS 2019-2022**

**IAP Statements Committee (2019-2022)**
Richard Catlow, Royal Society, UK (Chair)
Nadira Karunaweera, National Academy of Sciences Sri Lanka
Looi Lai Meng, Academy of Sciences Malaysia
Jukka Meurman, Council of Finnish Academies
Cherry Murray, National Academy of Sciences, USA
Jorge Alberto Neira, *Academia Nacional de Medicina*, Argentina
Mosto Onuoha, Nigerian Academy of Science
Administrative support: Muthoni Kareithi, IAP Secretariat

**Design & Art Direction**
Rado Jagodic, Studio Link
Trieste, Italy

**Printing**
La Tipografica srl
Udine, Italy

The InterAcademy Partnership is hosted by:

The World Academy of Sciences (UNESCO-TWAS)
ICTP campus
Strada Costiera 11
34151 Trieste, Italy

and

The US National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001, USA

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube
www.interacademies.org
iap@twas.org
secretariat@iapartnership.org

# Foreword

Science not only nourishes our minds and our souls, but also helps us to understand the world around us. It also provides us with the tools we need to achieve sustainable development. If we want to tackle big challenges such as the climate crisis and the dramatic loss of biodiversity and promote a healthier, longer life for all, we must in fact make sure that high-quality, independent information and advice reaches policymakers at regional, local and global levels.

We hope that, in the coming years and decades, evidence-based decision making will indeed play a key role in shaping our societies, and we, members of the global scientific community, must play our part.

This is really the central focus of the mission of the InterAcademy Partnership (IAP): under the IAP umbrella, member academies reach out to society and participate in discussions on critical global issues in which science plays a crucial role. This is why, since its inception in 1993, IAP has been producing statements on issues of fundamental importance to humanity. These statements – which are released only once the majority of IAP member academies endorse them – are both a reflection of the major issues that confront society and evidence of IAP's ongoing commitment to society.

This publication collects the IAP Statements launched between the 2019 IAP General Assembly that took place in Songdo, Korea, and the 2022 IAP General Assembly, organised in Oracle, Arizona, USA. We would like to express our sincere gratitude to the academies that led the development of these IAP Statements, the experts who developed the texts and peer-reviewed them, and the academy members who made sure that they reached elected officials, policy makers, academic leaders, the media and the public.

We urge once again academies and other stakeholders to disseminate our IAP Statements widely, translate them in local languages and to follow up on the recommendations of each one of them[1].

One of the key roles of IAP is as a mechanism for allowing academies worldwide to speak with one voice on issues of global significance. We firmly believe that IAP Statements are a testament to our shared commitment to making our world a better place.

**Depei Liu**
*IAP Co-president*

**Richard Catlow**
*IAP Co-president*

1 Dating back to 1994, more than 30 IAP Statements on critical development issues – many of them still relevant today – are freely available on the IAP website at www.interacademies.org/science-advice/statements.

iap SCIENCE HEALTH POLICY
the interacademy partnership

# A call for action to declare trauma as a disease

**Acute injuries have been considered the "number one killer and major cause of disability of children and young people" for more than 20 years[1] and the "neglected disease of modern society" for more than 50 years[2]. In those countries that have replaced the concept of "accident" by "facts and injuries" and focused on acute injury/trauma as an integral, inclusive and undivided entity, significant progress has been made in the reduction of deaths and disability[3,4]. However, in most countries, acute injuries (trauma) are still typically considered as "accidents" with little research effort committed to studying and reducing this disease. Considering trauma as a disease with an integrated comprehensive approach in the health agenda will allow countries not only to control but to prevent trauma. It is time for all countries to make this transition and declare trauma as a disease.**

## Introduction

Trauma (acute injury) has been the leading cause of death in young people for the last 50 years[2]. However, it has received limited attention from the medical community[5] and when reported[6], it is still described by category (vehicle crashes, homicides, suicides, falls, drowning, etc.). Consequently, the healthcare community fails to consider trauma as a single disease. In contrast, while cancer has many different manifestations and aetiologies, healthcare systems have unified their prevention and control strategies.

Acute injury (trauma) is defined as the physical damage that results when a human body is exposed to levels of energy (kinetic, thermal, chemical, electrical or radiant, the causal physical

agents) in amounts that exceed the threshold of mechanical/physiological tolerance and/or the impairment of normal function resulting from a lack of oxygen (drowning, smoke inhalation or strangulation) or heat resulting in hypothermia (trench foot, environmental hypothermia, freezing, etc.)[7].

This definition of trauma remains valid[8] and there is a clear need to consider the diverse categories of acute injury not as different entities, but as particular aspects of the same disease model. Injuries have been neglected within the global health agenda for many years, despite being largely predictable and preventable9.

There have been significant improvements in some countries and even though they have not redefined trauma as a disease, they have acted as though it is. For instance, Canada, Germany and the USA have given prominent status to this concept in their health and development agendas. The experience of "zero preventable deaths" from the USA[4] is another good example of this endeavour.

## The burden of disease

Globally, more than 5 million people die each year due to injuries, accounting for approximately 10% of deaths worldwide[9]. There is considerable variability between countries, with an eightfold difference between Singapore (14/100,000) and the Russian Federation (118/100,000), which have the lowest and highest reported injury-related incidence death rates, respectively[10]. Injuries are the leading cause of death in adolescents and young adults (15-25 years) with very little variation in five of the six World Health Organization (WHO) geographic regions. The exception is Africa, where the number of injury-related deaths is increasing but it is still less than those caused by communicable diseases.

As another example of these differences at country level, for motor vehicle crashes (MVC) in the European Union there are mortality

rates as dissimilar as 2.8/100,000 (Sweden, United Kingdom) and 9.8/100,000 (Bulgaria)[11].

Trauma can result in long term physical and mental health effects in all ages. One important issue that must be considered is that adolescents exhibit higher levels of risk-taking than adults[12]. Recent research has shown that exaggerated risk-taking is related to both biological and environmental

(viz. specific social and psychological) factors which interact with brain maturation during adolescence[13,14]. Thus, prevention may be feasible through early psychological and medical interventions[15,16]. Trauma also has a significant impact among the elderly, and the same type of injury due to trauma results in significantly higher mortality if the victim is aged over 54.

WHO defines intentional injuries, as "interpersonal violence, such as homicide, sexual assault, neglect and abandonment, and other maltreatment, suicides and collective violence (war)". In addition, unintentional injuries are defined as "most road traffic injuries, poisoning, falls, fire and burn injuries, and drowning."[17]. Globally, 72% of total injury-related mortality results from unintentional injuries, with little difference between high income countries (HICs) and low/middle-income countries (LMICs). Most of the remaining total injury-related deaths are the result of violence (suicide and homicide)[9].

## Disparities

There are large disparities in life expectancy between HICs, with only 15% of the global population, and LMICs, with 85%, respectively. In HICs, 60% of individuals will live to 70 years of age, compared with only 30% in LMICs[18]. Furthermore, 90% of road traffic deaths occur in LMICs, even though these countries account for only 53% of the world's registered vehicles. The most recent data indicate a greater decrease in road-traffic deaths in HICs compared to LMICs. Only 28 countries (representing 449 million people or 7% of the world's population) have adequate policies addressing all five road traffic risk factors: speed, drink-driving, helmets, seat-belts and child restraints[19]. If no action is taken, this situation will continue to represent a huge public health problem in the coming years[20,21].

However, trauma resulting from motor vehicle crashes is not always the major cause of death in young people. In LMICs in the Americas, interpersonal violence results in nearly twice as many deaths of 15-29-year-old people than road crashes[22].

Injury distribution disparities across countries are key to understanding the devastating impact of trauma. It is crucial to implement strategic interventions to develop a trauma system methodology, particularly in LMICs. To accomplish this initiative, it is relevant to consider the lack of adequate pre-hospital and hospital emergency care[23-25] and the scarcity of specific trauma training in health teams[26-29]. This situation extends the critical time interval before trauma victims reach the right place at the right time with the right healthcare providers, contributing to increased morbidity and mortality. In such cases, internationally validated guidelines for the development of trauma systems and proper and efficient trauma care are often not followed, diagnostic and imaging facilities are poorly equipped, resources are insufficient, and treatment practices routinely used in HICs are not being implemented.

In addition, the paucity of road safety regulations[30–33] and the inequity in income and access to resources further contribute to the disparities in mortality and morbidity.

## The case for considering trauma as a disease

Since the 1800s and the pioneering work of Robert Koch on infectious diseases, diseases (as in the case of cancer, mentioned above) have been characterized as a defined morbid entity consisting of at least three out of four criteria: (1) known aetiological agent(s); (2) a distinctive pathophysiology; (3) a group of identifiable cellular and organ disruptions; and (4) signs and symptoms[34,35].

Considering acute injury/trauma as a biopsychosocial disease would

ensure that healthcare professionals and hospital leaders are addressing and treating patients exposed to key risks and causes in the same way they do for other broad groups of diseases/illnesses.

This approach would also promote a solid platform for research that focuses on the elements that contribute to the severity of trauma and long-term disabilities (physical, cognitive and behavioural), as well as designing strategies to prevent the disease or decrease the severity of injury.

The failure to scientifically link causes to the magnitude of the consequences has contributed to a confusing social understanding of trauma, precluding the development of a legitimate area for healthcare professionals to prevent and control injuries. An example of this is the widespread misuse of the word 'accident' (an unforeseen and unplanned event, which alters the normal course of events) to define unintentional injuries, as it suggests the actions that led to them are attributable to chance without causal attribution. Similarly, attributing accidents to "chance, fate or destiny" is unscientific and hinders, even inhibits, the implementation of prevention strategies.

Eliminating the term accident to describe injury-related events would lead to them being seen as a consequence of a causal chain of facts and circumstances, allowing for the elaboration and testing of strategies that will not only reduce the events themselves but also the precursor events when they do occur.

Aristotle noted "there is no science of the accident – because all scientific knowledge is related to things that happen always or usually, so (...) having reviewed the nature and cause of the accidental, it is clear that there is no science of it"[36]. Furthermore, Professor Susan Baker, a pioneer in the area of injury prevention at Johns Hopkins', stated: "The word injury comes from Latin words that mean 'not right'. I cannot think of a more fitting term for the number one killer and crippler of children and young people. Surely that is 'not right', especially when it is in our power to change the situation"[1].

Thus, considering trauma as a foreseeable and preventable biopsychosocial disease[37] will allow for the development of more effective prevention, treatment and rehabilitation.

## Why a disease framework is suitable for trauma

Public health policies for communicable[38] and non-communicable[39] diseases cast light on the impact of interventions developed under the disease framework: identify the problem, measure the consequences, find the causative agent, develop treatment strategies and implement a prevention plan all within a measurement and analysis continuum.

To declare trauma as a disease would result in the following continuum and response: once the causes and consequences of this disease have been identified, health authorities must receive the appropriate support to develop an injury prevention and control plan to reduce trauma mortality, as well as improve treatment and rehabilitation. With respect to prevention, a horizontal plan (with integrated programmes, aiming for Health System improvement) is preferable to a vertical one (targeted, disease-specific programmes)[40,41] given that risk construction is determined by different components of the environment. Certain interventions, such as those linked to controlling the five road traffic risk factors, may act like "magic bullets", so a diagonal approach, i.e., a a strategy in which explicit interventions toward specific goals (such as the reduction of driving under the influence of alcohol) could mix with such generic issues as safer roads or the promulgation of helmet and speed limit laws, may also be appropriate[42–44].

This is recognized in the Tampere Declaration of the 12th World Conference on Injury Prevention and Safety Promotion – Safety 2016[45], which states "as the world orients itself to the 2030 Agenda for Sustainable Development, there is a unique opportunity for coordinated engagement from a range of government and nongovernment stakeholders in injury prevention and safety promotion.

Governments are turning their attention to what can be done to achieve the Sustainable Development Goals and targets, and many will find they need to engage civil society groups,

foundations and community-based organizations to reduce the impact of injuries and violence on their nations and communities. Several cross-cutting actions will facilitate scaled-up, effective prevention of injuries and violence".

## Trauma-related costs

Worldwide, fatal and non-fatal trauma is associated with an annual economic cost of approximately US$670 billion in medical care expenses and lost productivity[4]. In the specific case of car crashes, while figures vary between regions, globally 1.2 million people die annually and an additional 20-50 million survive but have mild to serious disabilities. The overall cost of car crashes has been estimated at more than US$160 billion annually[46].

24 of the 25 countries with the greatest disability-adjusted life years (DALY) losses due to traffic injuries are LMICs, while 48% of the 25 countries with the highest economic losses are HICs[46]. This disparity between impact and cost underlines the differences in the availability of resources, but there are few global reports on the cost of injuries, especially for LMICs[47,48]. However, some recent WHO estimates suggest that MVCs cost an average of 3% of a country's gross domestic product (GDP)[49], being roughly 2% in HICs and up to 5% in LMICs. These estimates include direct costs of medical care, vehicle damage and administrative costs, as well as indirect costs related to loss of productivity and treatment of disability. As examples, from an intentional injuries' viewpoint, estimates of the economic costs of homicide and suicide ranged from 4% of GDP in Jamaica to 0.4% in Thailand[7].

## The need for research

At a global level, more decision-makers recognize the need to prevent and control injuries, so it is necessary to develop a better understanding of local variability in order to design, implement and follow up on effective prevention programmes[7].

As neuroimaging research (e.g., functional and structural magnetic resonance imaging)[50] has shown that risk-taking has specific neural underpinnings, it is essential that intensive age-specific research on diagnosis and therapeutic strategies be undertaken with the support of medical agencies in both HICs and LMICs.

The considerable knowledge and resource differences between HICs and LMICs can impact the effectiveness of transferring protocols from the former to the latter. Therefore, it is essential to develop registries relating to all facets of trauma, not only to yield rational interventions, but also to inform policymakers and improve clinical practice as well as for the advancement of knowledge acquisition through research. Such investments would ensure that societies would benefit by treating trauma in the same way they have addressed a myriad of communicable and non-communicable diseases.

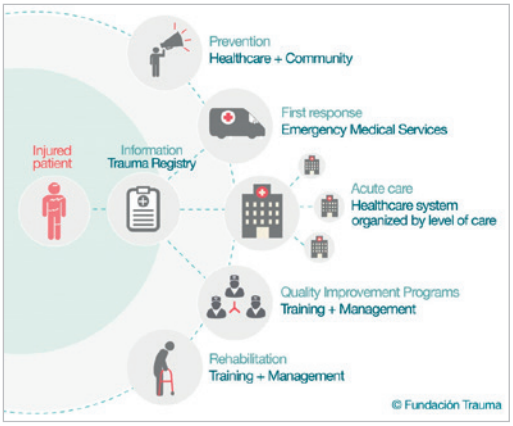
The launch of the Global Alliance for the Care of the Injured (GACI), a global organization linking governments and NGOs from several countries, with the aim of minimizing the trauma burden through the development of trauma systems[51], is an important initiative to achieve these goals.

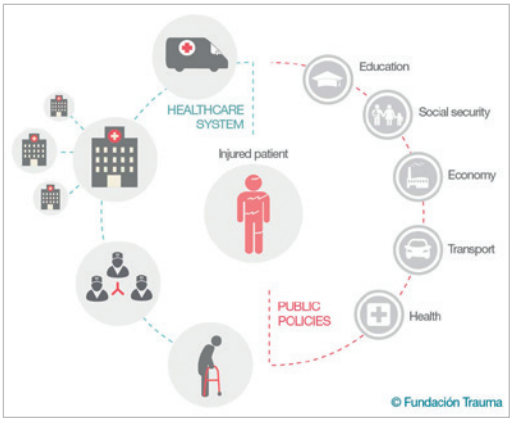
## Recommendations for Academies

IAP for Health member academies should draw attention to the need for a strong paradigm shift to consider acute injury/trauma as a biopsychosocial disease. This will enhance the development of better acute and post-acute care systems, surveillance institutions as well as research organizations in each country. They should also encourage scientific and healthcare communities to join with other regional academies to promote an urgently-needed paradigm shift essential to reduce inequities in healthcare between countries.

**At country level, IAP for Health member academies should:**

1. Engage with public health authorities and other decision-makers to assess current national responses to trauma victims and determine the most effective role they can play to improve the trauma systems that will meet the needs of their country.
2. Support scientific institutions offering trauma and emergency training to ensure that health teams can provide the best possible care according to international standards and local needs.
3. Work with universities to develop curricula for physicians, nurses and technicians, in both graduate and post-graduate courses, where trauma is framed as a disease.
4. Help universities and research institutions to secure funds to develop a disease model approach for the complex problem of trauma and the development of national trauma registries.
5. Encourage the development of systematic trauma prevention strategies based on local evidence using the "three E's" approach of prevention (environment, education and enforcement) with healthcare providers and the whole community.




**At regional level, IAP for Health member academies should help establish regional agreements to:**

1. Reduce well-known risk factors for MVCs. These would include speed limits, drinking and driving laws, the compulsory use of helmets, seat-belts and child restraints, banning the use of cell phones while driving, and promoting violence prevention using the information obtained from trauma registries.
2. Develop collaborative strategies to secure more funds for the necessary research.
3. Establish a common standard for data reporting.

## References:


1. Baker S. Advances and adventures in trauma prevention. J Trauma. 1997; 42(3): 369–373.
2. National Academy of Sciences. National Research Council. Division of Medical Sciences. Accidental Death and Disability: The Neglected Disease of Modern Society. Washington DC; 1966.
3. Kegler SR, Baldwin GT, Rudd RA, Ballesteros MF. Increases in United States life expectancy through reductions in injury-related death. Popul Health Metr. 2017; 15: 32.
4. National Academies of Sciences, Engineering, and Medicine. A national trauma care system: Integrating military and civilian trauma systems to achieve zero preventable deaths after injury. Washington, DC: The National Academies Press; 2016.
5. Norton R, Kobusingye O. Injuries. N Engl J Med. 2013; 368:1723-1730.
6. World Health Organization. International Classification of Diseases. Available at: http: //www.who.int/classifications/icd/en/
7. Baker SP, O'Neill B, Karpf RS. The injury fact book. Lexington, MA, Lexington Books; 1984.
8. Holder Y, Peden M, Krug E et al (Eds). Injury surveillance guidelines. Geneva, World Health Organization; 2001.
9. World Health Organization. Injuries and Violence. The Facts. Geneva: WHO; 2014.
10. Global Health Observatory (GHO) data. Causes of death, by WHO region. Available at: http://www.who.int/gho/mortality_burden_disease/ causes_death/region/en/. Accessed on 07/08/2018.
11. Eurostat. Road safety statistics at regional level. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Road_safety_statistics_at_regional_level
12. Wolf LK, Wright ND, Kilford EJ, Dolan RJ, Blakemore SJ. Developmental changes in effects of risk and valence on adolescent decision-making. Cogn Dev. 2013; 28: 290-299.
13. Foulkes L, Blakemore SJ. Studying individual differences in human adolescent brain development. Nat Neurosci. 2018; 21: 315-323.
14. Tamnes CK, Herting MM, Goddings AL, Meuwese R, Blakemore SJ et al. Development of the Cerebral Cortex across Adolescence: A Multisample Study of Inter-Related Longitudinal Changes in Cortical Volume, Surface Area, and Thickness. J Neurosci. 2017; 37 :3402-3412.
15. Pandey A, Hale D, Goddings AL, Blakemore SJ, Viner R. Systematic review of effectiveness of universal self-regulation-based interventions and their effects on distal health and social outcomes in children and adolescents: review protocol. Syst Rev. 2017; 6: 175.
16. Knoll LJ, Fuhrmann D, Sakhardande AL, Stamp F, Speekenbrink M, Blakemore SJ. A Window of Opportunity for Cognitive Training in Adolescence. Psychol Sci. 2016; 27: 1620-1631.
17. Children's environmental health. Intentional and unintentional injuries. Available at: http: //www.who.int/ceh/risks/cehinjuries2/en/. Accessed on 07/08/2018.
18. World Health Organization. The World Health Report 2003: Shaping the Future. Geneva, Switzerland: World Health Organization; 2003.
19. Global status report on road safety 2013: supporting a decade of action. Geneva: World Health Organization; 2013.
20. Murray CJL, Lopez AD. The Global Burden of Disease: A Comprehensive Assessment of Mortality and Disability from Diseases Injuries, and Risk Factors in 1990 and Projected to 2020. Cambridge, Mass: Harvard University Press; 1996.
21. Murray CJL, Lopez AD. Global Health Statistics: A Compendium of Incidence Prevalence and Mortality Estimates for Over 200 Conditions. Cambridge, Mass: Harvard University Press; 1996
22. World Health Organization. Top 10 causes of death. Available at: http: // www.who.int/gho/mortality_burden_disease/causes_death/top_10/en/
23. Razzak JA, Kellermann AL. Emergency medical care in developing countries: is it worthwhile? Bull World Health Organ. 2002; 80: 900–905.
24. Goosen J, Bowley DM, Degiannis E, Plani F. Trauma care systems in South Africa. Injury. 2003; 34: 704–708.
25. Joshipura MK, Shah HS, Patel PR, Divatia PA, Desai PM. Trauma care systems in India. Injury. 2003; 34: 686–692.
26. Mock C, Arreloa-Risa C, Quansah R. Strengthening care for injured persons in less developed countries: a case study of Ghana and Mexico. Inj Control Safety Promotion. 2003; 10: 45–51.
27. Mock CN, Quansah RE, Addae-Mensah L. Kwame Nkrumah University of Science and Technology continuing medical education course in trauma management. Trauma Q. 1999; 14: 345–348.
28. Quansah RE, Mock CN. Trauma care in Ghana. Trauma Q. 1999; 14: 283–294.
29. Quansah RE. Availability of emergency medical services along major highways. Ghana Med J. 2001; 35: 8–10.
30. Bishai D, Hyder AA, Ghaffar A, Morrow RH, Kobusingye O. Rates of public investment for road safety in developing countries: case studies of Uganda and Pakistan. Health Policy Plann. 2003; 18: 232–235.
31. Sodemann M, Jakobsen MS, Molbak K, Alvarenga IC Jr, Aaby P. High mortality despite good care-seeking behaviour: a community study of childhood deaths in Guinea-Bissau. Bull World Health Organ. 1997; 75: 205–212.
32. Williams AF. Barriers and opportunities in reducing motor vehicle injuries. Inj Prev. 2001; 7: 83–84.
33. Van der Spuy J, Steenkamp M. Ambulance transport of trauma victims: a metropolitan profile. J Trauma Emerg Med. 1996; 13: 9–12.
34. Merriam-Webster Medline Plus Medical Dictionary. Available at http://c.merriam-webster.com/medlineplus/disease. Accessed on 07/08/2018.
35. On-line Stedman's Medical Dictionary. Available at http://stedmansonline.com/. Accessed on 26/05/2018.
36. Aristotle. Metaphysics, VI. II.12–III.3 (p. 305). Availabe at: https://archive.org/stream/in.ernet.dli.2015.185284/2015.185284.Aristotle-The-Metaphysics#page/n337/mode/2up
37. Neira J, Bosque L. The word "accident": no chance, no error, no destiny. Prehosp Disaster Med. 2004; 19: 188-189.
38. The Global Eradication of Smallpox. Final Report of the Global Commission for the Certification of Smallpox Eradication, Geneva, December 1979. WHO: Geneva; 1980.
39. Mendis S. Global progress in prevention of cardiovascular disease. Cardiovasc Diagn Ther. 2017; 7: S32–S38.
40. Henderson DA, Klepac P. Lessons from the eradication of smallpox: an interview with D. A. Henderson. Philos Trans R Soc Lond B Biol Sci. 2013; 368: 20130113.
41. Pedersen D. Vertical trauma focused interventions versus broader horizontal psychosocial interventions. Intervention. 2014; 12: 278-282.
42. ANTH 1310 S01. Vertical vs. Horizontal Approach: the Drawbacks of Each and a Need for a Merging or "Diagonal" Approach. 2015. Available at https://blogs.brown.edu/anth-1310-s01/2015/10/22/vertical-vs-horizontal-approach-the-drawbacks-of-each-and-a-need-for-a-merging-or-diagonal-approach/. Accessed on 07/08/2018.
43. Ooms G, Van Damme W, Baker BK, Zeitz P, Schrecker T. The "diagonal" approach to Global Fund financing: a cure for the broader malaise of health systems? Glob Health. 2008; 4:6.
44. Frenk J. Bridging the Divide: Comprehensive Reform to Improve Health in Mexico. Lecture for WHO Commission on Social Determinants of Health, Nairobi. Available at: http://www.who.int/social_determinants/ resources/frenk.pdf. Accessed on 30/09/2018.
45. Tampere Declaration. 12th World Conference on Injury Prevention and Safety Promotion. Available at: http://www.euro.who.int/en/media-centre/events/events/2016/09/12th-world-conference-on-injury- prevention-and-safety-promotion-safety-2016. Accessed on 07/08/2018.
46. Dalal K, Lin Z, Gifford M, Svanström L. Economics of Global Burden of Road Traffic Injuries and Their Relationship with Health System Variables. Int J Prev Med. 2013; 4: 1442–1450.
47. Wesson HK, Boikhutso N, Bachani AM, Hofman KJ, Hyder AA. The cost of injury and trauma care in low- and middle-income countries: a review of economic evidence. Health Policy Plan. 2014; 29: 795-808.
48. Wesson HKH, Boikhutso N, Hyder AA, Bertram M, Hofman KJ. Informing road traffic intervention choices in South Africa: the role of economic evaluations. Glob Health Action. 2016; 9:30728.
49. 2015 Global Status Report on Road Safety. Geneva: WHO; 2015.
50. Ewing SW, Sakhardande A, Blakemore SJ. The effect of alcohol consumption on the adolescent brain: A systematic review of MRI and fMRI studies of alcohol-using youth. Neuroimage Clin. 2014; 5: 420-437.
51. Global Alliance for Care of the Injured – GACI. Available at: http: //www.who.int/emergencycare/gaci/en/. Accessed on 07/08/2018.

## Academies that have endorsed the IAP Statement A call for action to declare trauma as a disease

National Academy of Medicine, Buenos Aires, Argentina
Australian Academy of Science
Bangladesh Academy of Sciences
Brazilian Academy of Sciences
National Academy of Medicine of Brazil
*Academia Chilena de Medicina*
Chinese Academy of Sciences
Chinese Academy of Engineering
Croatian Academy of Medical Sciences
Croatian Academy of Sciences and Arts
Czech Academy of Sciences
Academy of Sciences of Dominican Republic
Academy of Scientific Research and Technology, Egypt
*Academie des Sciences*, France
German National Academy of Sciences *Leopoldina*
Union of the German Academies of Sciences and Humanities
Ghana Academy of Arts and Sciences
Hungarian Academy of Sciences
*Accademia Nazionale dei Lincei*, Italy
Science Council of Japan
Academy of Sciences Malaysia
Mongolian Academy of Sciences
Hassan II Academy of Science and Technology, Morocco
Nepal Academy of Science & Technology
Royal Netherlands Academy of Arts and Sciences
Nigerian Academy of Science
Palestine Academy for Science and Technology
Academia Nacional de Medicina, Peru
National Academy of Science and Technology, Philippines
Polish Academy of Sciences
Korean Academy of Science and Technology
Academy of Medical Sciences of Romania
Slovak Academy of Sciences
Academy of Science of South Africa
Sudanese National Academy of Sciences
Council of Finnish Academies
Royal Swedish Academy of Sciences
Tanzania Academy of Sciences
Thai Academy of Science and Technology
Turkish Academy of Sciences
Uganda National Academy of Sciences
African Academy of Sciences
Caribbean Academy of Sciences
Islamic World Academy of Sciences
The World Academy of Sciences
World Academy of Art and Science

## Working Group

Jorge Neira, co-chair (Argentina)
Ezequiel Monteverde, co-chair (Argentina)
Dario Birolini (Brazil)
Ariana Vorko Jovič (Croatia)
Alan Ivkovic (Croatia)
Karl Zilles (Germany)
Shuvra Dasgupta (Jamaica)
Tatsuhiro Yamanaka (Japan)
Ashok Ratna Bajracharya (Nepal)
Loek Leenen (Netherlands)
Raul Nelson Morales Soto (Peru)
Edward Wang (Philippines)
Dan Mircea Enescu (Romania)
Soraya Seedat (South Africa)
Achala Upendra Jayatilleke (Sri Lanka)
Feza Korkusuz (Turkey)
Stephen W. Hargarten (USA)

This statement is the final academic review of an original manuscript produced by the Argentine Academy of Medicine (Acad. Jorge Neira; Acad. Vicente Gutierrez), *Fundación Trauma Argentina* (Jorge Neira, MD, FCCM; Ezequiel Monteverde, MD; Laura Bosque, PhD) and endorsed by the Argentine Ministry of Health.

April 2019

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from: www.interacademies.org/statement/call-action-declare-trauma-disease

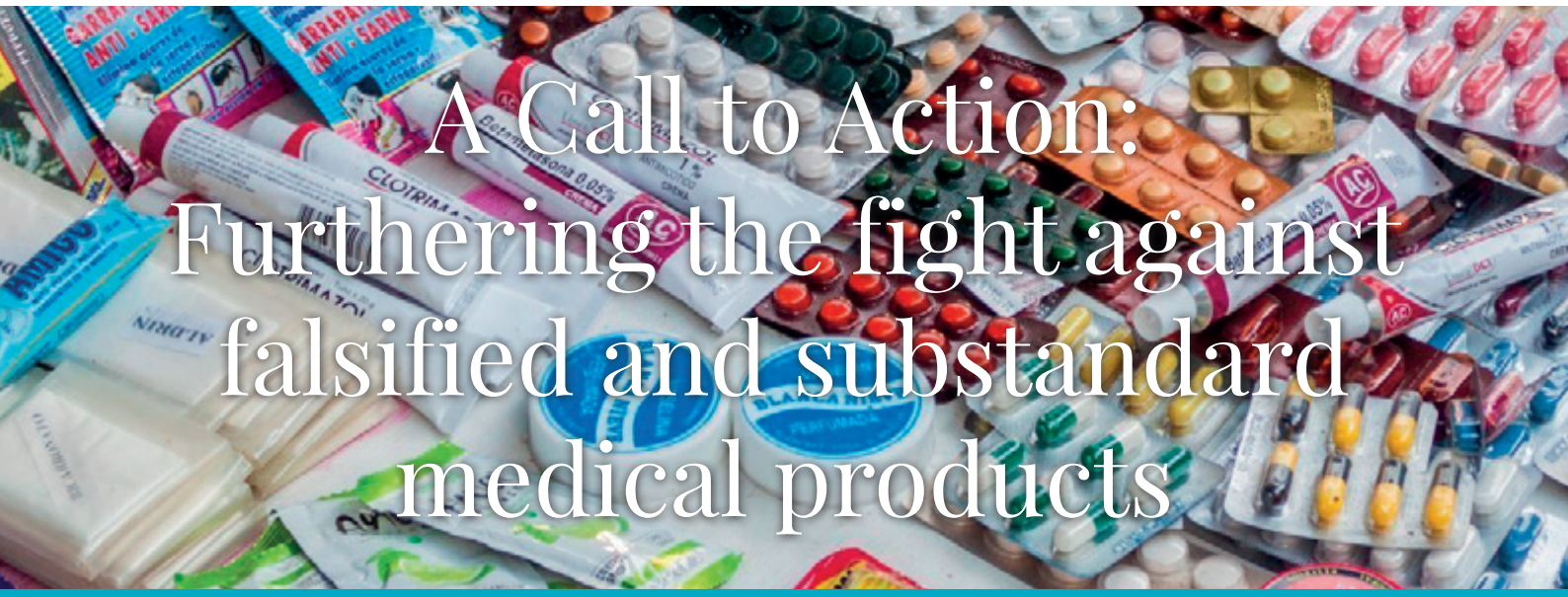
## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership



# A Call to Action: Furthering the fight against falsified and substandard medical products

**Falsified and substandard medical products[1] (including vaccines, medical devices and veterinary products) – products that are 'fake' or of poor quality – are an increasing global scourge that threaten life, health and security in significant ways. Patients receiving these products not only get ineffective treatment but are also often exposed to serious harm. The toll from these products may be as high as a million lives lost per year. In addition, their use increases the risk of drug resistant infections, and expenditure on ineffective or harmful products depletes much-needed healthcare resources. This serious and growing problem has been exacerbated by the increasing complexity of global supply chains, as well as by the inappropriate sale of medical products on the internet or in open markets. Nonetheless, efforts to tackle this issue have been woefully inadequate, reflecting in part the magnitude of the problem but also a lack of sustained political will and commitment to act.**

The Inter Academy Partnership (IAP) deplores this situation and urges political decision-makers at all levels, in concert with regional and international organizations, to work with medical product regulatory authorities, national and international law enforcement agencies, manufacturers, importers, distributors, health professionals and patients to solve this urgent issue.

## Introduction

Falsified and substandard medical products are a global public health threat. Traffic in these products is constantly growing, impacting patients particularly


Counterfeit drugs often look like the real thing
© U.S. Food and Drug Administration.

in low-income countries where resources to help keep such products off the market are limited. These problems have also reached worrying levels in many high-income countries, including in Europe and the USA. Any medical product can be falsified or made in a substandard manner, including both innovator products and generics, whatever their price. Internet and open market sales that bypass national quality control systems and/or regulated channels are worsening the situation[1,2].

Such products harm patients by denying them the benefit of a safe and effective treatment. In many cases, the wrong active ingredient, an incorrect amount of the active ingredient, or no active ingredient at all can be found. As such they can result in serious therapeutic failures, as well as the development of drug resistance, particularly in the fields of antibiotics, anti-malaria or anti-viral products. They can also be dangerous per se, as they may include toxic compounds[3].

Despite these harmful effects it has been difficult to limit the traffic for many reasons including:

- *Detection*: Current manufacturing and printing techniques allow the production of very closely copied, falsified packaging that is difficult for even the trained eye to detect. In addition, poor quality manufacturing leading to substandard products requires rigorous oversight while resources for inspection and compliance are often lacking;
- *Discovery*: At present, the methods for discovery are often medical, such as finding that a treatment is ineffective or discovering unusual side effects. The cause of these effects may not be easy to identify, especially in countries with limited medical and laboratory resources. Routine surveillance or insider reporting are also factors in discovery. However systems for detection and reporting are often inadequate;
- *Danger of internet or open market sales*: On the internet and on the open market, medical products lose the protection of the usual lawful professional distribution chain. Under these circumstances it is very difficult for patients, even if they are aware of the risks, to ensure they are acquiring an appropriate, safe, genuine and effective drug (i.e. to determine which products are legitimate and which are not).

The current means to combat this extensive problem are limited:

- The legal framework is not fit-for-purpose in many countries; internet and other cross-border sales blur jurisdictions and the possibility of legal sanctions;
- The various responsible bodies are often fragmented at national and international levels;
- Detection techniques exist but they are still not adequately developed or effectively implemented. Additionally, approaches differ from one country/region to another;
- The pharmaceutical supply chain may lack full integrity due to limited regulatory oversight and/or capacity, or it may be weakened by deregulation based on economic or trade considerations rather than public health criteria. In addition, in many countries, especially low income countries, it is difficult to control all commercial activities effectively, in particular those of wholesalers and importers.

Not all actors are committed to preventing the sale of falsified and substandard products on their markets. In particular there is often:

- Lack of political engagement at the national level, with lack of support to domestic agencies as well as a lack of national policies to assure access to affordable, quality medical products, which can prompt consumers to seek alternative sources of medications;
- Inadequate oversight and stewardship of pharmaceutical products and practices;
- Lack of consistent and effective legal and judicial frameworks;
- Limited capacity in many countries of certified laboratories able to detect fraudulent products in the supply chain, most particularly of concern in low income countries;
- Health professionals (physicians and pharmacists) are not always aware of risks and are not adequately warned in a timely fashion of the presence of falsified and substandard products on their markets, some of which may be very sophisticated fakes. They are sometimes isolated and not well-trained in this regard. As a result, it is difficult to engage them to confront this scourge;
- In general, the public is unaware of, or not well enough informed about, this problem, particularly the risks of buying these kinds of products on the internet, at open air markets, or otherwise outside of the regular, lawful, quality-assured pharmaceutical supply chain. In these extra-lawful environments, it is nearly impossible for consumers to differentiate legitimate from illegitimate products.

Falsified and substandard medicines are an international issue that threatens people around the world, involving numerous different actors and a diverse set of stakeholders. Solutions to this urgent and complex problem cannot be considered in an isolated way. A shared commitment to the effective coordination and the engagement and mobilization of all players is necessary if we are to succeed.

## Background

Falsified and substandard medicines have been a long-standing concern, yet no comprehensive, well-resourced and sustained international campaign has been organized and waged, despite some limited national and international initiatives. For a long time, one of the impediments to comprehensive international action was a tension between public health considerations and intellectual property debates. For example, the word 'counterfeit' was generally considered to refer to products that infringe on the patents in a market where such patents are in force. As several countries perceived this as potentially blocking cheaper legitimate generic copies of these products, they were unable to support early drafts of resolutions and actions proposed by the World Health Organization (WHO). To try to clarify the situation, it was decided to use the acronym SSFFC (Substandard, Spurious, Falsely labelled, Falsified, Counterfeit)[4]. This was an effort to try to differentiate the public health problem

of falsified and substandard products from the intellectual property issues. More recently, in an attempt to further clarify the public health problem caused by these products, the WHO Member States Mechanism proposed the terms 'substandard and falsified medicines' to designate the products that are the focus of these activities. This terminology was adopted by the May 2017 World Health Assembly (WHA). The definition adopted for 'falsified products' is: "Medical products that deliberately/fraudulently misrepresent their identity, composition or source". The agreed definition for 'substandard products' is: "Authorized medical products that fail to meet either their quality standards or their specifications or both". These definitions are clear progress in clarifying the meaning of the terms, as well as the focus of efforts to confront this public health challenge[5].

Customs officers seize $663K in unmarked Viagra pills © U.S. Food and Drug Administration.

In addressing the problem of falsified and substandard medical products two distinct, though related, avenues of concern arise:

- Penetration of such medical products into the legal, regulated supply chain;
- Direct to the public licit or illicit marketing of medical products (e.g. via the internet or in open markets).

Given the seriousness of the issue, it is troubling that there are not better sources of data about the magnitude and scope of the problem. New efforts are underway to address this shortcoming. At present, however, it is difficult to give precise numbers but it appears that in many low-income countries a large proportion of the medical products available are falsified or substandard. Estimates of 20-30% in some African and Asian countries seem realistic[6].

Authentic and counterfeit drugs being screened by CD-3, a small portable device invented by FDA scientists © U.S. Food and Drug Administration.

Some estimates for particular products are even higher, including an extremely worrisome 30-50% for anti-malarial drugs in south-east Asia[7]. Of note, some 50% of all reports of substandard and falsified medicines received by the WHO Global Alert system are from sub-Saharan Africa, and 80% of these are for essential medicines like anti-malarials and antibiotics[8].

High-income countries are also impacted. For example, in the United States, several instances of falsified dugs are detected each year. The US Food and Drug Administration (FDA) has launched an alert system, publishing these cases to warn the public[9]. In Europe, a link has been established between an unregulated distribution chains and the number of falsifications detected[10]. Some 50% of the products proposed for sale on the internet are also believed to be falsified[11].

There have been a range of efforts to combat falsified and substandard medical products, many organized at a national level, as well as a few specific international operations such as Jacques Chirac's 'Call of Cotonou[12]. The International Medical Products Anti-counterfeiting Taskforce (IMPACT) represented an earlier more international effort launched by WHO (2006-2010), but it was put on hold due to conflicts among Member States based on disagreements over counterfeit drugs definition, the enforcement of patents and the public health impacts described above. The recent Member State mechanism framework and activities offer new opportunities for collaboration and action, including the 2017 World Health Assembly resolutions on this topic[13].

It is also necessary to recognize the efforts that have been made internationally to address the problem. At the inter-governmental level these include the important Council of Europe's (CoE) MEDICRIME Convention[14], open also to countries that are not members of the CoE; the European Union's Falsified Medicines Directive 2011/62/EU which has introduced regulatory constraints to all stakeholders; as well as the successful international cooperation which has been achieved in Operation Pangea initiatives against online sales of falsified and substandard medicines. Importantly, the WHO has significantly increased its surveillance, monitoring and programmes in this area. Despite very limited resources, WHO currently hosts a database recording the different cases reported and working with over 150 Member States to develop better means of detection, reporting and collaboration to improve identification of such products and their removal from national and international commerce.

## Previous work by academies

In 2011, the US Institute of Medicine (now called the National Academy of Medicine) undertook a major study of this issue, assembling a diverse, international expert committee. Their report and recommendations were

released in February 2013 in a document entitled 'Countering the Problem of Falsified and Substandard Drugs'[15].

The French Academy of Medicine, in collaboration with the French Academy of Pharmacy and the Veterinary Academy of France, undertook an effort in 2015 to prepare a report describing the facts, analysing the different aspects and factors impacting the problem, and proposing some recommended actions. This report was presented at the Academy of Medicine's plenary session in December 2015[16] with a public manifesto signed by the three French academies as well as by the presidents of the three health professional chambers[16].

These important efforts have underscored the fact that falsified and substandard drugs represent an international problem requiring international cooperation. They also underscore the urgency of meaningful and sustainable action.

## Recommendations from IAP

IAP for Health seeks to draw attention to the necessary fight against the global trafficking of falsified and substandard medical products, and supports the call for a comprehensive, well-resourced, international effort to address this devastating problem. IAP for Health member academies consist of national and international leaders of the academic and scientific communities with important access to policy makers, key stakeholders and the public. They must use their unique position to actively promote this fight around the world to benefit public health and foster better healthcare for all.

IAP for Health and its member academies, recognizing the increasing trafficking of these products throughout the world, and the almost total impunity of the perpetrators, despite the risk to the life and health of patients, denounce the gravity of these criminal practices. They call for the launch at an international level of a strong, comprehensive, well-resourced policy and programme of prevention in the fight against this scourge. This must include the development and implementation of informed policies; the adequate funding of regulatory oversight systems; strengthened, coordinated enforcement mechanisms; the development and utilization of easy to use and affordable detection equipment; and the education of the public and healthcare providers.

IAP recommends that the terms 'falsified' and 'substandard' medicines and their definitions as recently adopted by WHO and the World Health Assembly be used worldwide, and that this issue be entirely separated from discussions about intellectual property rights.

IAP underlines that the right of people to health is unalienable. Manufacturing, carrying, stocking and selling falsified and substandard medical products, including drugs, vaccines, medical devices, and other medical products are crimes. Due to their severe consequences on public health and individual healthcare, these crimes must be prosecuted and punished to the fullest extent possible.

Given that this activity affects every country in the world, IAP emphasizes that governments, regulatory authorities and industry must oversee and regulate the supply chain effectively in order that the security and the continuity of the supplies of medical products are guaranteed, especially in countries most burdened by the problem of falsified and substandard drugs. This can be achieved through robust oversight of good manufacturing processes, the use of comprehensive and cost-effective technologies, wholesaling transparency, and traceability of products from manufacturing to market, including the financial flows. This also requires a renewed attention to quality control and assuring that regulatory authorities and law enforcement and judicial authorities are adequately resourced, trained and empowered.

IAP strongly affirms the importance of warning the public about the risk of buying prescription medicines over the internet and of advising online purchase only through certified internet pharmacies. In this regard, groups such as the Alliance for Safe Online Pharmacies (ASOP)[17] represent valuable assets. In many countries, similar efforts must be undertaken to educate and warn the public about the risks of purchases in open marketplaces.

IAP decries the delays and the insufficient resources invested in this fight. Specific one-off operations, even if locally efficacious, are not sufficient. It is necessary that global intergovernmental and intersectoral actions are agreed on, coordinated and sustained.

IAP underscores the fact that the prevention of this threat requires improved access to legitimate, quality medical products, including equitable pricing policies and better healthcare coverage.

IAP recommends strong consideration of a substantive, comprehensive and well-resourced policy and programme to address this scourge as a priority action of national authorities and international organizations in charge of public health, including the extension of the MEDICRIME Convention.

Lastly, IAP agrees that WHO is uniquely situated, through its membership and global remit, to provide leadership and coordination to combat this pressing problem. We therefore call on our national governments to support WHO in this effort and to hold them accountable for progress. We request that WHO sponsor a resolution at the next World Health Assembly that will call upon the WHO to coordinate and implement a major, comprehensive and sustained effort in this regard. Further, we call upon our national governments to assure that WHO has adequate financial and technical resources specifically to implement any such World Health Assembly resolution.

600,000+ pills found with no markings
© U.S. Food and Drug Administration.

The fight against falsified and substandard medicines is a global threat that must be addressed through global cooperation and collaboration. All stakeholders – at international, regional and national levels – should join forces to implement these recommendations to help improve public health worldwide.

## References:


1. Mackey, T., *et al.* (2015). Counterfeit penetration into global legitimate medicine supply chains: A global assessment. *The American Journal of Tropical Medicine and Hygiene*, 92, pp.59-67.
2. Traverriti-Fortier, C., *et al.* (2015). Trafic de faux médicaments: panorama 2014. *Thérapie*, 70, pp. 455-464.
3. WHO. Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit (SSFFC) medical products [online]. Available at https://www.who.int/medicines/regulation/ssffc/en/ [Accessed 15 August 2020].
4. OMS/WHO. Médicaments de qualité inférieure et contrefaits, January 2018. [online] Available at https://www.who.int/fr/news-room/fact-sheets/detail/substandard-and-falsified-medical-products https://www.who.int/medicines/regulation/ssffc/en/ [Accessed 15 August 2020].
5. WHO Report by the Director General, Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, March 2017 [online]. Available at http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_23-en.pdf [Accessed 15 August 2020].
6. Deats, M. (2013). 'The effects of falsified and substandard drugs' in Buckley G.J., Gostin L.O. (eds.) Countering the problem of falsified and substandard drugs. Washington (DC): National Academies Press (US). pp.1-16. Available at https://www.ncbi.nlm.nih.gov/books/NBK202526/ [Accessed 15 August 2020].
7. McGivering, J. (2007). Tracking the fake malaria drug threat [online]. Available at https://news.bbc.co.uk/2/hi/asia-pacific/6692431.stm [Accessed 15 August 2020].
8. WHO Global Surveillance and Monitoring System for substandard and falsified medical products report, 2017. Available at https://www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1 [Accessed 15 August 2020].
9. Food & Drug Administration (FDA) Counterfeit alert network (2019). Available at https://www.fda.gov/drugs/drug-safety-and-availability/counterfeit-alert-network [Accessed 15 August 2020].
10. Almuzaini, T. Sammons, H. Choonara, I. (2013). Substandard and falsified medicines in the UK: a retrospective review of drug alerts (2001-2011). *British Medical Journal open*, 3:e002924 doi:10.1136.
11. WHO. A study on the public health and socioeconomic impact of substandard and falsified medical products, 2017 [online]. Available at https://www.who.int/medicines/regulation/ssffc/publications/SE_Study_EN.pdf [ Accessed 15 August 2020].
12. Chirac, J. (2019). Appel de Cotonou contre les faux médicaments, Available at https://www.fondationpierrefabre.org/wp-content/uploads/sites/2/2019/02/appel-de-cotonou-signe.pdf [Accessed 15 August 2020].
13. WHO, Definitions of Substandard and Falsified (SF) Medical Products (2017), Available at https://www.who.int/medicines/regulation/ssffc/definitions/en/ [Accessed 15 August 2020].
14. WHO Member State Mechanism on Substandard/spurious/falsely-labelled/falsified/counterfeit (Ssffc) Medical Products. Available at https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1 [Accessed 15 August 2020].
15. Convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique, Entrée en vigueur: 2016. Available at https://www.coe.int/fr/web/conventions/full-list/-/conventions/treaty/211 [Accessed 15 August 2020].
16. Institute of Medicine (2013). In Buckley G.J., Gostin L.O. (ed) Countering the Problem of Falsified and Substandard Drugs. Washington (DC): The National Academies Press (US). Available at https://www.nap.edu/read/18272/chapter/1 [Accessed 15 August 2020].
17. Gentilini, M., Juillet, Y. (2015). Falsified Medicines. More than a Scandal, a Crime. *Bulletin de l'Académie Nationale de Médecine*, 199 (8-9), pp.1433-1448. Available at http://www.academie-medecine.fr/wp-content/uploads/2015/12/Rapport-ANM-Med-Fals-3.pdf [Accessed 15 August 2020].
18. Alliance for Safe Online Pharmacies (ASOP), Available at https://buysaferx.pharmacy/about-asop-global/ [Accessed 15 August 2020].07/08/2018.

## Academies that have endorsed the IAP Statement A Call to Action: Furthering the fight against falsified and substandard medical products

Albanian Academy of Sciences
*Academia Nacional de Ciencias Exactas, Físicas y Naturales*, Argentina
*Academia Nacional de Medicina*, Argentina
Austrian Academy of Sciences
Bangladesh Academy of Sciences
*Koninklije Academie voor Geneeskunde van Belgie*
*Académie Royale de Médecine de Belgique*
*Académie Nationale des Sciences, Arts et Lettres du Bénin*
Academy of Sciences and Arts of Bosnia and Herzegovina
*Academia Nacional de Medicina*, Brazil
Brazilian Academy of Sciences
National Academy of Sciences Burkina Faso
Cameroon Academy of Sciences
Royal Society of Canada
Canadian Academy of Health Sciences
*Academia Chilena de Ciencias*
Chinese Academy of Engineering
Colombian Academy of Exact, Physical & Natural Sciences
Croatian Academy of Arts and Sciences
Croatian Academy of Medical Sciences
Czech Academy of Sciences
Royal Danish Academy of Sciences and Letters
*Academia de Ciencias de la República Dominicana*
Academy of Scientific Research and Technology, Egypt
Estonian Academy of Sciences
Ethiopian Academy of Sciences
Council of Finnish Academies
*Académie des sciences, Institut de France*
*Académie Nationale de Médecine, France*
Georgian National Academy of Sciences
Georgian Academy of Medical Sciences
Union of German Academies of Sciences and Humanities
German National Academy of Sciences, Leopoldina
Ghana Academy of Arts and Sciences
Academy of Athens, Greece
*Academia de Ciencias Médicas, Físicas y Naturales, Guatemala*
Hungarian Academy of Sciences
India National Science Academy
Royal Irish Academy
*Accademia Nazionale dei Lincei*, Italy
*Accademia Nazionale di Medicina*, Italy
Science Council of Japan
Royal Scientific Society of Jordan
National Academy of Sciences, Republic of Korea
Lithuanian Academy of Sciences
*Akademi Sains Malaysia*
Mauritius Academy of Science and Technology
*Academia Mexicana de Ciencias*
Mongolian Academy of Sciences
Hassan II Academy of Science and Technology, Morocco
Royal Netherlands Academy of Arts and Sciences
Nigerian Academy of Science
Pakistan Academy of Sciences
Palestine Academy for Science and Technology
National Academy of Medicine Peru
National Academy of Science and Technology, Philippines
Polish Academy of Sciences
Academy of Medical Sciences of Romania
Academy of Science of South Africa
National Academy of Sciences, Sri Lanka
Sudanese National Academy of Sciences
Royal Swedish Academy of Sciences
Swiss Academies of Arts and Sciences
Tanzania Academy of Sciences
Turkish Academy of Sciences
Uganda National Academy of Sciences
Royal Society, UK
Academy of Medical Sciences, UK
Zambia Academy of Sciences
Zimbabwe Academy of Sciences
African Academy of Sciences
European Academy of Sciences and Arts
Federation of European Academies of Medicine
Global Young Academy
Islamic World Academy of Sciences
Latin American Academy of Sciences
The World Academy of Sciences

## Working Group

Yves Juillet, France (chair)
Lal G. Chandrasena, Sri Lanka
Mario Collado, Dominican Republic
Josip Culig, Croatia
Abdallah Daar, Canada
Richard Day, Australia
Antonio R. de los Santos, Argentina
Dan Mircea Enescu, Romania
Zbignew Fijatek, Poland
Margaret Hamburg, US
Shaohong Jin, China
Jean-Michel Kauffmann, Belgium
Sami A. Khalid, Sudan
Monet M. Louquias, Philippines
Patience O. Sadebe, Nigeria
Arthur Commey Sackeyfio, Ghana
Tsetsegmas Sanjjav, Mongolia
Otmar Schober, Germany
Jacob Thiessen, Canada
Kenton Linton Woods, UK



September 2020

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from: www.interacademies.org/medical_products

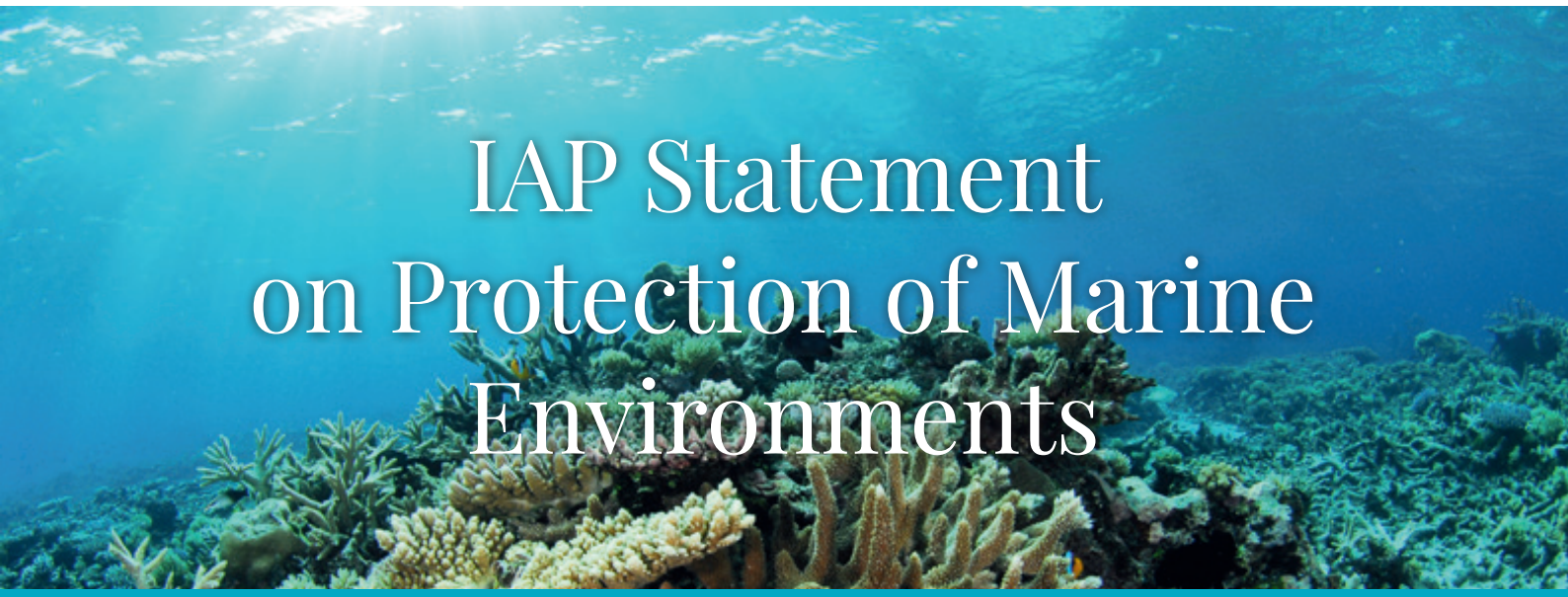
## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership



# IAP Statement on Protection of Marine Environments

**The ocean, connected over approximately 71% of the Earth's surface, supports humankind. Human well-being and our economy have benefited from the ocean for oxygen to breathe, fish and seafood to eat, leisure and healing places to visit, seaways for transportation, and the many jobs associated with ocean activities. However, unregulated and excessive human activities and recent climate change are causing the deterioration of the marine environment, reducing biodiversity and threatening its ecosystem services. Key areas of concern include:**

- **A healthy ocean** is indispensable to human well-being and vitality and to the homeostasis of life on Earth. **Ocean health** is threatened by excessive human activities and has already been compromised on many levels. Facilitation of holistic ocean sciences and cooperation of diverse stakeholders are needed to understand complex processes in the marine environment and to implement solutions to protect and restore ocean health.
- The world's oceans are experiencing extensive **habitat destruction** due to both direct impacts (e.g. coastal development) and indirect impacts (e.g. climate change, invasive species, pollution). In particular, coastal areas, including coral reefs, kelp forests, mangroves, seagrass beds and intertidal mudflats, have suffered from massive habitat degradation and loss. This destruction increasingly extends to the deep sea. Multiple anthropogenic stressors damage ecosystem structure and function, as well as the capacity for marine habitats to provide ecosystem services. Most of these sensitive habitats are in need of immediate measures for protection, conservation and rehabilitation.
- Anthropogenic **environmental contaminants** continue to disrupt marine ecosystems. Accumulation of excessive nutrients, toxic chemicals, heavy metals, and marine debris including macro-, micro- and nano-plastics, destabilizes ecological processes, degrades natural resources and inflicts major economic losses. Strict controls for the management of environmental contaminants should be implemented immediately.

© Korea Institute of Ocean Science and Technology (KIOST)

- The ocean regulates the Earth's climate and provides a buffer to **climate change**. In return, the marine environment is subject to adverse effects of climate change. Ocean warming causes sea level rise, loss of dissolved oxygen, redistribution and alteration of marine life, and intensification of heatwaves and tropical cyclones. Excessive carbon dioxide emissions also cause ocean acidification. Interdisciplinary research on the ocean and the atmosphere and development of new management strategies will help mitigate and adapt to climate change.
- Marine fisheries are important contributors to human food and nutritional security. **Over-exploitation** of world fisheries is causing a rapid decline of fisheries resources. To meet current and future food requirements of the growing human population the recovery of depleted fish stocks through the implementation of extensive no take zones together with sustainable aquaculture production are needed.

## 1. Ocean health

Exploitative approaches to marine resources have led to declining ocean integrity. Consequently, a shared appreciation of ocean conservation is highly recommended. We have little time to nurture the ocean's resilience, remove threats and eliminate disruptions, especially because climate change has an increasing impact on ocean health. The recovery and protection of the ocean is contingent on the development of inclusive and integrated marine sciences, with public access to scientific data, information and knowledge.
A holistic approach to the ocean requires universal recognition of our common interest in and dependence on the status of the ocean. Marine interventions can have substantial ecological benefits. For example, Marine Protected Areas are accepted worldwide as an economically viable means of enhancing biodiversity, and maintaining and replenishing fish and shellfish stocks.

The UNESCO philosophy of Ocean Literacy for All seeks appreciation of the ocean at all levels throughout all cultures (UNESCO, 2020a). The objective is a large-scale behavioural transformation toward a global constituency that fully grasps the completeness of our reliance on the ocean and subscribes to the sustainable management and use of marine resources. Dynamic cooperation among interdisciplinary ocean-related sciences is essential.

## 2. Habitat destruction

Coastal areas have long been threatened by habitat destruction due to development (e.g. land reclamation, intensified agriculture and urban expansion) and human population growth. In addition to direct habitat loss, many sensitive ecosystems have been damaged by pollution, invasive species and climate change. Accordingly, critically important coastal habitats such as estuaries, seagrass beds, coral reefs, oyster reefs, tidal wetlands, and kelp and mangrove forests, have suffered ecologically with associated socioeconomic consequences. These impacts also threaten pelagic and deep-sea habitats. Coastal habitats contribute substantially to the maintenance of biodiversity and to the succession of generations of marine organisms (IPBES, 2019). Nursery areas in particular are substantial determinants of ocean health and biodiversity. Environmental integrity in these marine habitats must be protected and, in many cases, rehabilitated.

## 3. Environmental contaminants

Excess loading of nutrients and organic matters from terrestrial human activities and coastal aquaculture (eutrophication) causes algal blooms leading to the expansion of dead-zones, with mass mortality of fish and other marine life. Some algal species also produce toxins that may even lead to human casualties.

Photo: Unhyuk Yim

Biomagnification of toxic substances in mid-to-higher trophic levels can suppress the growth of marine organisms and inhibit their reproduction. Persistence and long-range transportation of chemical contaminants is problematic globally. Furthermore, bioaccumulation of persistent and toxic substances, including toxic metals, in commercial seafood threatens human health and causes economic loss in fisheries.

Poor solid waste management results in the accumulation of marine debris, including over 8 million tonnes of plastics in the ocean annually. Plastics, which account for up to 80% of marine debris, cause ecological impacts by

entanglement and ingestion by marine organisms, dispersion of pathogens and non-indigenous species, and compromised benthic habitats. In addition, marine plastic debris can result in economic losses due to decline of tourism, damage to fishing gear and boats, and obstruction of nautical propellers and cooling systems. Micro- and nano-plastics are everywhere in the marine environment, including marine food webs, and even in the human diet.

© National Institute of Fisheries Science, Korea/ Photo: Hyun Woo Kim

## 4. Climate change

The continuous increase in atmospheric greenhouse gases is recognized as a global threat that needs ambitious goals and international collaboration to combat the resulting climate change. The ocean has absorbed 30% of total anthropogenic CO2 emissions since the 1980s with enormous global impacts (IPCC, 2019). Climate change alters ocean circulation and mixing, biogeochemistry and ecosystems. These changes could interfere with the ocean's capacity for ecosystem services such as food supply, carbon storage, oxygen generation and climate stability. Global warming leads to melting of glaciers and polar ice caps as well as thermal seawater expansion. In turn, these processes lead to worldwide sea level rise that is threatening for the many people living in coastal areas. Ocean acidification threatens carbonate shell synthesis, respiration, reproduction, early development, and the growth and survival of innumerable marine animals. Expanding oxygen-depleted dead-zones are uninhabitable by aerobic organisms. The IPCC Special Report (2019) highlights the extreme urgency of prioritizing timely, ambitious and coordinated action to address unprecedented and enduring changes in the ocean. One obvious priority measure is the protection of seagrass beds, salt marshes and kelp and mangrove forests, which utilize excess nutrients, generate oxygen, and sequester carbon in the form of organic matter through photosynthesis, thereby moderating global warming.

## 5. Overexploitation

Most fisheries stocks are fully exploited: more than 90% of marine stocks are either overfished (34.2%) or fished at maximum sustainable levels (59.6%; FAO, 2020). Additional disruptions result from illegal, unreported and unregulated (IUU) fishing, habitat degradation, pollution and gear abandonment.

Capture fisheries yields plateaued in the late 1980s and are unlikely to increase. Maintaining even current yields (84.4 million tonnes in 2018) will require rethinking our husbandry of ocean ecosystems. The focused removal of organisms at one trophic level can destabilize marine ecosystems. For example, harvests of higher-value predatory species cause the loss of biodiversity and disruptive imbalances in marine communities. In addition, heavy harvests of young and otherwise unmarketable fish for agricultural and aquaculture feeds exert additional pressure on already-distressed marine ecosystems. IUU fishing is thought to be responsible for annual catches of up to 25.9 million tonnes (FAO, 2016) and has undermined sustainable fisheries management, threatening 4.3 billion people who depend on fisheries for nutrition (FAO, 2020).

Aquaculture production in aquatic environments (including fish, invertebrates and aquatic plants) reached 114.5 million tonnes in 2018, expanding at 5-6% annually (FAO, 2020). Aquaculture is already delivering 50% of the seafood we consume, and is expected to meet an increasing proportion of humanity's nutritional requirements. Refinement of culture practices toward sustainability and conservation-sensitivity is necessary to relieve pressure on wild, overexploited marine stocks.

## 6. Conclusions and Recommendations

Excessive exploitation of marine resources and products, the cumulative impacts of multiple stressors, and chronic disregard for marine ecosystems have left our oceans more in need of consideration than ever before. The ocean is subject to complex, poorly-understood problems, many of which interact with one-another, collectively threatening the integrity and continuity of life on Earth. Earlier misconceptions of the ocean as an immense realm with unlimited resilience are no longer valid. The fundamental challenge that policy-makers must address is how to achieve a sustainable use of the oceans (EASAC, 2016). This situation urgently calls for a comprehensive and pervasive new approach, and fresh commitments of current and future generations and nationalities to the health of the ocean.

The United Nations has urged cooperation among global communities to solve threats to the ocean by proclaiming the UN Decade of Ocean

© National Institute of Fisheries Science, Korea/ Photo: Cheol Beom Kim

Science for Sustainable Development (2021-2030; UNESCO, 2020b). Advancement of 'ocean literacy' will raise consciousness about the vital importance of the ocean to humanity and the essential contributions of the ocean's ecosystem services.

Other international initiatives such as the Convention on Biological Diversity (CBD), the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), and Biodiversity Beyond National Jurisdiction (BBNJ) also seek the conservation of marine environments and biodiversity, while Sustainable Development Goal (SDG) #14 of the UN 2030 Agenda refers to 'Life Below Water' with seven specific targets.

Through this Statement, the InterAcademy Partnership calls on governments, NGOs and IAP member academies to:

- Share scientific information and data, build comprehensive understanding of the ocean, and develop an international ocean knowledge database that is equitably accessible, for devising solutions and making policies and decisions.
- Coordinate actions to protect and restore ocean health with expansion of research capacity development, ocean literacy and mechanisms to promote the exchange of information at the science-policy interface.
- Implement inclusive protection measures for coastal and other sensitive marine habitats.
- Assess sources of environmental contaminants, address their distributions, fates and impacts on ocean health, and develop means to eliminate entry of land-based contaminants into the ocean and to reduce their marine impacts.
- Mitigate and adapt to the impacts of greenhouse gases and climate change on the ocean ecosystem in acidification, deoxygenation and redistribution and change of marine life, thereby avoiding failure in the livelihoods of people who depend on the ocean.

Photo: Deokbae Park

- Ensure improved scientific management of capture fisheries, strengthen enforcement against IUU fisheries, and promote environmentally sensitive marine aquaculture.
- Increase ocean literacy, encouraging the global society to understand its intricate connection to the oceans and to respect the role of the oceans in maintaining Earth's biodiversity and habitability.

© KIOST/Photo: Joon-Yeon Chung

Photo: Wonjoon Shim

## References:


EASAC, 2016. Marine Sustainability in an Age of Changing Oceans and Seas. Reports and Statements, European Academies' Science Advisory Council (EASAC). Available online; retrieved 24 May 2020. https://easac.eu/publications/details/marine-sustainability-in-an-age-of-changing-oceans-and-seas/

FAO, 2016. The FAO Agreement on Port State Measures (PSMA) to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing. Available online; retrieved 24 May 2020: Rome: FAO. http://www.fao.org/port-state-measures/en

FAO, 2020. The State of World Fisheries and Aquaculture 2020. Sustainability in action. Rome. Available online; retrieved 9 June 2020: https://doi.org/10.4060/ca9229en

IPBES, 2019. Summary for Policymakers of the Global Assessment Report on Biodiversity and Ecosystem Services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. S. Díaz, J. Settele, E. S. Brondízio E.S., H. T. Ngo, M. Guèze, J. Agard, A. Arneth, P. Balvanera, K. A. Brauman, S. H. M. Butchart, K. M. A. Chan, L. A. Garibaldi, K. Ichii, J. Liu, S. M. Subramanian, G. F. Midgley, P. Miloslavich, Z. Molnár, D. Obura, A. Pfaff, S. Polasky, A. Purvis, J. Razzaque, B. Reyers, R. Roy Chowdhury, Y. J. Shin, I. J. Visseren-Hamakers, K. J. Willis, and C. N. Zayas (eds.). IPBES secretariat, Bonn, Germany. 56 pages.



IPCC, 2019: IPCC Special Report on the Ocean and Cryosphere in a Changing Climate [H.O. Pörtner, D.C. Roberts, V. Masson-Delmotte, P. Zhai, M. Tignor, E. Poloczanska, K. Mintenbeck, M. Nicolai, A. Okem, J. Petzold, B. Rama, N.W Weyer (eds.)].

UNESCO, 2020a. Ocean Literacy Portal. Available online; retrieved 16 May 2020: https://oceanliteracy.unesco.org

UNESCO, 2020b. United Nations Decade of Ocean Science for Sustainable Development (2021-2030). Available online; accessed 24 May 2020: https://en.unesco.org/ocean-decade


Photos: IAP/Peter McGrath

## Academies that have endorsed the IAP Statement on Protection of Marine Environments

Albanian Academy of Sciences
Algerian Academy of Sciences and Technology
*Academia Nacional de Ciencias Exactas, Fiscas y Naturales de la Republica Argentina*
*Academia Nacional de Medicina de Buenos Aires*, Argentina
National Academy of Sciences of Cordoba, Argentina
Australian Academy of Science
Bangladesh Academy of Sciences
*Academie Nationale de Sciences, Arts et Lettres du Benin*
Academy of Sciences and Arts of Bosnia and Herzegovina
Brazilian Academy of Sciences
*Academia Nacionale de Medicina*, Brazil
Bulgarian Academy of Sciences
Bulgarian Academy of Sciences and Arts
Cameroon Academy of Sciences
Royal Society of Canada
Chilean Academy of Sciences
Chinese Academy of Sciences
Chinese Academy of Engineering
Colombian Academy of Exact, Physical & Natural Sciences
*Academia Nacional de Medicina de Colombia*
Croatian Academy of Arts and Sciences
Cuban Academy of Sciences
Czech Academy of Sciences
Royal Danish Academy of Sciences and Letters
Academia de Ciencias de la Republica Dominicana
Academy of Scientific Research and Technology, Egypt
Ethiopian Academy of Sciences
Council of Finnish Academies
*Academie des Sciences*, France
*Academie Nationale de Medecine*, France
Union of German Academies of Sciences and Humanities
German National Academy of Sciences, *Leopoldina*
Ghana Academy of Arts and Sciences
*Academia de Ciencias Medicas, Fisicas y Naturales de Guatemala*
Hungarian Academy of Sciences
Academy of Sciences of the Islamic Republic of Iran
Royal Irish Academy
Israel Academy of Sciences and Humanities
*Accademia Nazionale dei Lincei*, Italy
Science Council of Japan
Kenya National Academy of Sciences
National Academy of Sciences, Republic of Korea
Korean Academy of Science and Technology
Lebanese Academy of Sciences
Lithuanian Academy of Sciences
*Akademi Sains Malaysia*
Mauritius Academy of Science and Technology
Mexican Academy of Sciences
Mongolian Academy of Sciences
Royal Netherlands Academy of Arts and Sciences
Nicaraguan Academy of Sciences
Pakistan Academy of Sciences
Palestine Academy for Science and Technology
National Academy of Science and Technology, Philippines
Polish Academy of Sciences
Macedonian Academy of Sciences and Arts
Romanian Academy
Russian Academy of Sciences, Siberian Branch
Rwanda Academy of Sciences
Serbian Academy of Sciences and Arts
Academy of Science of South Africa
National Academy of Sciences, Sri Lanka
Sudanese National Academy of Sciences
Royal Swedish Academy of Sciences
Tunisian Academy of Sciences, Letters and Arts *Beit al Hikma*
Turkish Academy of Sciences
Uganda National Academy of Sciences
Royal Society, UK
National Academy of Sciences of Uruguay
The National Academy of Sciences (NAS)
Caribbean Academy of Sciences
Islamic World Academy of Sciences
Global Young Academy
The World Academy of Sciences (TWAS)
World Academy of Art and Science

## Working Group

Suam Kim (Republic of Korea, chair)
Leif Anderson (Sweden)
Antje Boetius (Germany)
Jaime Ricardo Cantera Kintz (Colombia)
Luiz Drude de Lacerda (Brazil)
Alaa Eldin Abdel-Mouty Mohamed Eissa (Egypt)
Judith Gobin (Trinidad & Tobago)
Sung Yun Hong (Republic of Korea)
Jeffrey A. Hutchings (Canada)
Lekelia Jenkins (USA)
Monika Kedra (Poland)
Youn-Ho Lee (Republic of Korea)
Syed Wajih Ahmad Naqvi (India)
Japhet Micheni Ntiba (Kenya)
Hugh Possingham (Australia)
Yoshihisa Shirayama (Japan)
Richard Thompson (UK)
Jaehyoung Lee (Republic of Korea, KAST project manager)

IAP appreciates the initial contribution of the Zero Draft Committee members (C. Brown, S. Kang, J.S. Khim, S. Kim, Y-H. Lee and W. Shim) assigned by KAST



June 2021

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from: www.interacademies.org/statement/protection-marine-environments

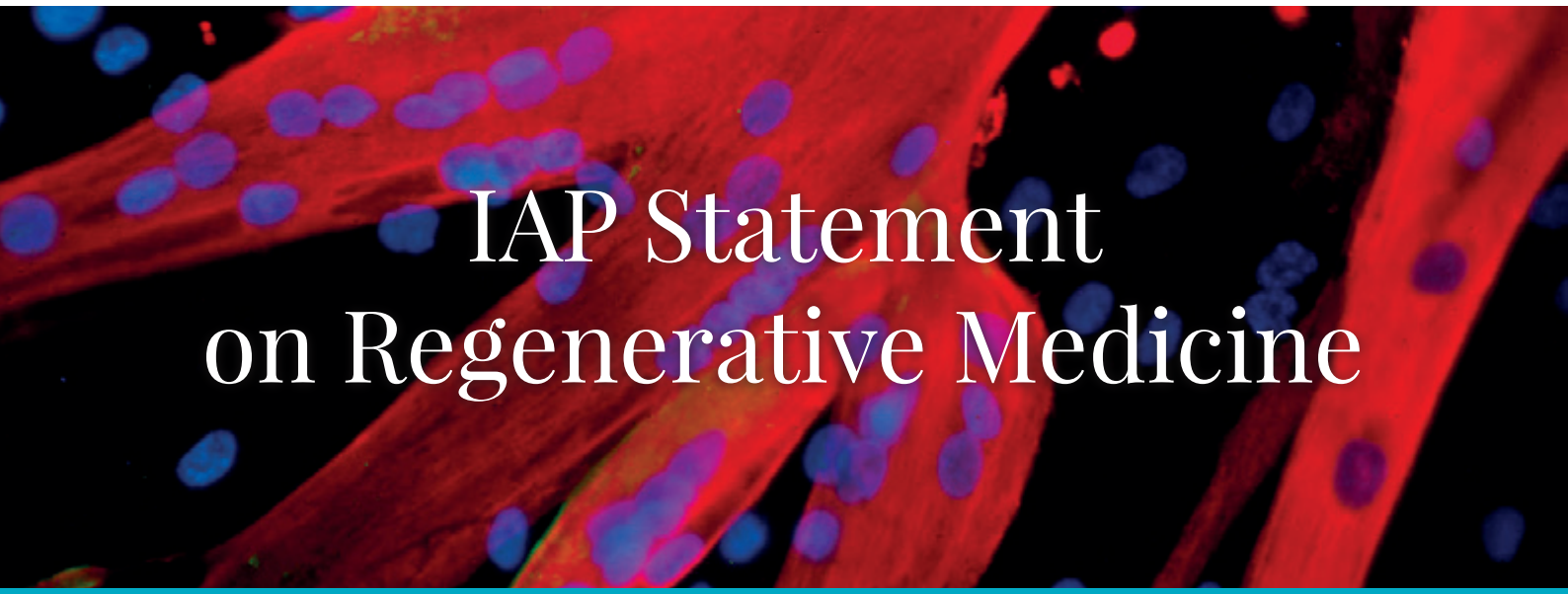
## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership



# IAP Statement on Regenerative Medicine

**Regenerative medicine has great potential for tissue regeneration and repair, comprising various novel interdisciplinary approaches including the use of cell and gene therapies, and tissue engineering. The pace of advance in the science is exciting and the medical opportunities in addressing the causes of disease rather than the symptoms may be transformative, but concerns about the misuse of regenerative medicine technologies also grow.**


## Summary

*In this consensus Statement the InterAcademy Partnership (IAP) seeks to raise awareness of two main priorities:*

- *To use advances in research and development as rapidly as possible, safely and equitably, to provide new routes to patient benefit.*
- *To support medical claims by robust and replicable evidence so that patients and the public are not misled.*

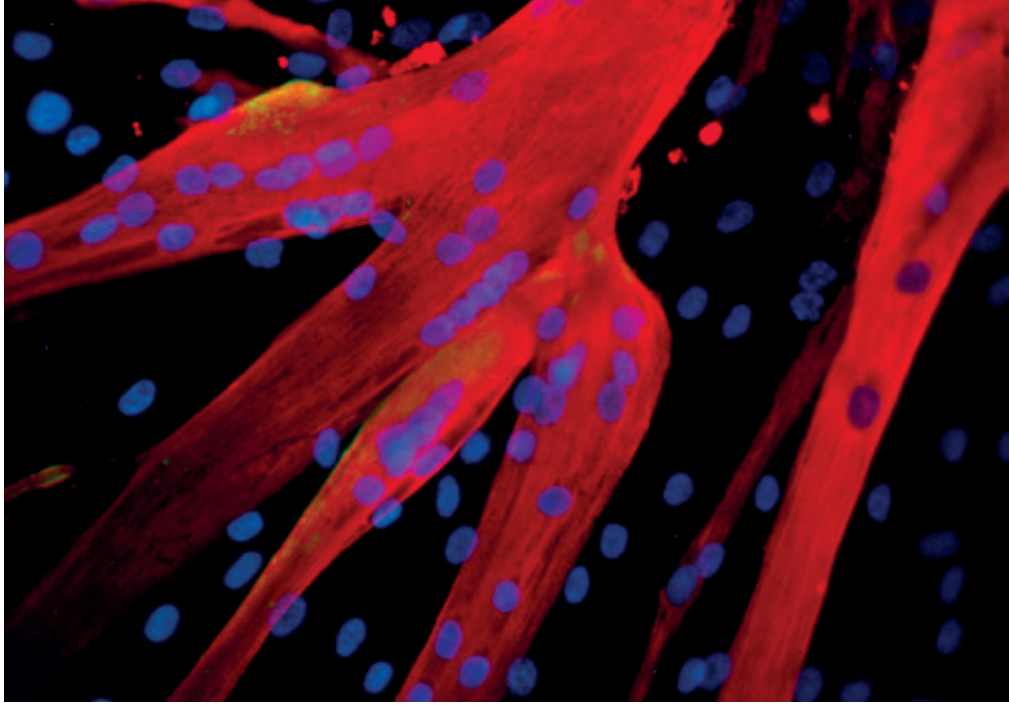
*The focus of this IAP Statement is on unmet medical needs: stem cells are described as a case study with many of our conclusions relevant more broadly for regenerative medicine. Although stem cell therapy is well-established in only a limited number of clinical indications, there is active research and development in many more. However, enthusiasm about the clinical potential has led to a disconnect between expectations and the realities of translating advances in technology into clinical practice. In many countries, there are two main problems. First, unscrupulous private clinics offer unregulated therapies promising much, but using poorly characterised products with little scientific basis or evidence for efficacy, with safety concerns unresolved. Second, premature regulatory authority approval and commercialisation based on some, but insufficient, scientific rationale and clinical evidence. Accelerated access is a vital tool for patient benefit but researchers must not cut corners.*

*In order to strengthen the frameworks for research and innovation and patient protection, IAP has identified priority actions for: engaging with patients, the public and policy makers; ethical assessment; pre-clinical and clinical research procedures; regulatory authorisation and options for facilitating access to new medicines; and noted the particular relevance of these actions also in the response to COVID-19.*

*IAP concludes that:*

- *For the present, regenerative medicine should concentrate on serious medical conditions and be judged by rigorous consideration of the potential risks versus the benefits.*
- *For many potential applications, more evidence is needed on product quality, safety and efficacy.*
- *Good science must be promoted at every step, from fundamental research through to clinical trials and the translation to practice.*
- *Proportionate and harmonised regulatory authority actions should be based on robust and replicable science, ethically informed by science across the disciplines. Unregulated provision of unproven regenerative medicine must be deterred.*
- *Researchers must follow guidelines on responsible science, and teaching on regenerative medicine should be part of the curriculum for health professionals. Clinicians must be bound by both professional guidelines and community standards of medical practice.*
- *In putting patient interests first, the scientific and medical communities have a responsibility to provide reliable information and ensure that decisions are evidence-based.*

*Therefore, to deliver clinical benefits equitably, a coordinated strategy must encompass better science, better funding, better governance and better public and patient engagement.*



Muscle cells differentiated from human stem cells in culture, from ongoing research by Professor Giulio Cossu, University of Manchester, UK, on stem-cell therapy for muscular dystrophy.

## Introduction

Regenerative medicine comprises various novel interdisciplinary approaches to healthcare, aimed at tissue regeneration, repair, restoration and reorganisation (Box 1). Regenerative medicine strategies depend upon harnessing, stimulating, guiding or replacing endogenous development and repair processes.

## Purpose of this IAP Statement

The InterAcademy Partnership (IAP), the global network of more than 140 academies of science, engineering and medicine, is publishing this consensus Statement to build on the interest in regenerative medicine, and related issues for responsible science, expressed by members of academies and regional academy networks and to raise awareness of two main priorities for the field:

- To ensure that advances in science and innovation are used as rapidly as possible, safely and equitably, in providing new routes to patient benefit, potentially addressing the causes of disease rather than their symptoms.
- To ensure that medical claims are based on robust, replicable evidence and that patients and the public are not misled, either deliberately or inadvertently.

The focus is on unmet medical needs. We address stem cells as a particular case study because of the urgent and complex challenges, but our conclusions can in most respects be generalised to other forms of regenerative medicine. We recognise that many other assessments have been made of this field but as the science is advancing rapidly and the commercial environment also changing rapidly it is timely and relevant now to provide global recommendations from the academies. We discuss principles rather than prescribe specific legislative actions and this IAP Statement is intended to inform and stimulate discussion with policy makers and regulatory authorities, our member academies and others in the scientific and medical communities more broadly. Some other international sources of information and analysis are listed in Box 2.

**Box 1: The scope of regenerative medicine includes:**

- Cell transplantation, where cells originate from human embryonic stem cells, perinatal stem cells, induced pluripotent stem cells or tissue specific (adult) stem cells or other forms of cell therapy
- Gene therapy, both *in vivo* and *ex vivo*, the latter being a form of cell therapy
- Tissue engineering, typically using 3D scaffolds formed from either natural biomaterials or artificial, biocompatible biomaterials produced from a variety of fabrication processes
- Organoids, from adult and pluripotent stem cells
- Small-molecule drugs
- Subcellular bodies (e.g. mitochondria, vesicles)
- Artificial cells (currently prokaryotic only) and other synthetic biology approaches

## Identifying therapeutic opportunities and challenges

As noted in Box 1, regenerative medicine covers a wide range of approaches; even within the category of stem cells differing objectives are sought. Stem cell transplantation has a principal aim of replacing lost cells, requiring that the transplanted cells are committed to a specific fate and, once differentiated, are functionally integrated in the tissue. Alternatively, stem cells may provide

support for recipient cellular growth or differentiation via secreted products, mediate immunomodulation, or promote plasticity. Cell and gene therapies also have important roles in cancer treatment (e.g. chimeric antigen receptor T-cells) but here the main goal is to eliminate cancer rather than regenerate diseased tissue.

Regenerative medicine offers significant promise to tackle intractable diseases. Stem cell therapies are well established for bone marrow or epidermis transplantation, in congenital immunodeficiency, and lysosomal storage disease. In addition to the therapeutic applications, the methodologies of regenerative medicine, e.g. development of organoid models, are being used increasingly for *in vitro* assessment of biological function, evaluation of disease mechanisms and screening of novel pharmacological agents (Rowe and Daley, 2019).

Although stem cell therapy has proven itself, so far, in the treatment of only a limited number of approved clinical indications there is active research and development underway for many others, including neurological, hepatic, cardiovascular, retinal and musculoskeletal disorders[1]. However, enthusiasm about the broad potential of regenerative medicine applications has led to a disconnect between expectations and the realities of translating technologies into clinical practice. To address this gap requires tackling multiple issues, for poor quality science, inconsistent ethical and regulatory policies, unclear funding models, unrealistic hopes and unscrupulous private clinics (Cossu *et al.*, 2018)[2], as outlined in the following sections. The consequences of not doing this would be to waste investment, researcher activity and aspirations to cure, as well as to undermine patient protection.

**Box 2: International sources of information**

Professional Societies: International Society for Stem Cell Research (ISSCR, www.isscr.org) and International Society for Cell & Gene Therapy (ISCGT, http://isctglobal.org) particularly for guidelines on research and development, and information for patients and other stakeholders. The ISCGT website provides recent updates on research for COVID-19 and on mesenchymal stromal cells and immune-mediated therapeutics. The ISSCR website provides recent support for enforced regulation of clinics offering unproven/unapproved interventions. TERMIS (www.termis.org), supporting the advancement of tissue engineering and regenerative medicine worldwide also provides much useful information as part of its remit to generate knowledge and improve patient outcomes.

EASAC and FEAM report (2020) for broad overview in Europe. See also *Lancet* Commission on Regenerative Medicine for discussion of opportunities and challenges (Cossu *et al.*, 2018) and NASEM (2019) for broad perspective on regenerative engineering products and their clinical translation. Other national academy work is described subsequently in the text (e.g. Ardaillou et al., 2017).

European Medicines Agency (www.ema.europa.eu), providing various documents on advanced therapy medicinal products; concerns on unregulated products; accelerated access initiatives; good clinical practice. See also Hines et al. (2019) for future strategy. Many other national regulators provide relevant guidelines, e.g. in Japan (www.pmda.go.jp) the Pharmaceuticals and Medical Devices Act (2014), with conditional approval instituted for regenerative medicine in 2017, emphasises a focus on patient safety. The US Food and Drug Administration (www.fda.gov), provides guidance and warnings about unregulated products and initiatives on legal proceedings against providers. See also Marks and Gottlieb, 2018.

Alliance for Regenerative Medicine (https://alliancerm.org) particularly for information on products in development and issues for regulatory harmonisation.

## Issues for supporting research and innovation while protecting patients

The pace of advance in regenerative medicine science is exciting and the medical opportunities are considerable, but the concerns also grow. We emphasise two major problems.

First, in many countries commercial clinics offer unregulated products and services promising a wide range of benefits using poorly characterised treatments with little or no evidence of efficacy, safety concerns, misleading scientific rationale, and with the primary intention of financial profit. What principles and guidance should be available to inform patients contemplating such offerings?[3] An informed patient should only consent to receiving stem cells (even if autologous) if the cell population is well-characterised, if clinical evidence on efficacy and side effects is well-documented, and if the number of patients treated previously with the same procedure is clearly disclosed. There is a crucial criterion for patients in deciding whether to consent: they should not be expected to pay to participate in clinical

1 Recent scientific reviews of the current status of stem cells include De Luca *et al.*, 2019; Ntege *et al.*, 2020; and other sources cited by EASAC and FEAM, 2020. A recent update on industry developments is by Ilic and Liovic, 2020. Gene therapy is also a very active area of clinical research, mainly in cancer (melanoma, glioma) but approximately 10% of gene therapy trials focus on monogenic disease, see e.g. Mullard, 2019; Shahryari *et al.*, 2019. Future developments in regenerative medicine more broadly have been reviewed extensively elsewhere, e.g. Clarke *et al.*, 2018, NASEM, 2019.

2 The opportunities and challenges for cell-based therapies are exemplified by a recent statement by the American Society of Bone and Mineral Research-Orthopaedic Research Society joint Task Force report (O'Keefe *et al.*, 2020), describing the potential to treat a range of disorders of the musculoskeletal system but also the possibility of misuse and misrepresentation for the efficacy of such treatment.

3 A recent account from the field of neurology in the USA observes that many neurologists are unprepared to discuss the issues surrounding stem cell therapies with their patients who seek advice about unproven offerings even though there are an alarming number of hitherto unreported complications from these unregulated procedures (Julian *et al.*, 2020). A standard for informed consent for stem cell-based interventions outside of clinical trials was published in 2019 by ISSCR, www.isscr.org/docs/default-source/policy-documents/isscr-informed-consent-standards-for-stem-cell-based-interventions.pdf.

research on regenerative medicine until it becomes an approved and consolidated treatment that may be reimbursed according to the specific procedures of each country health system, whether public or private.

Second, an evidence crisis occasioned by premature marketing approval and commercialisation of expensive approaches based on some, but insufficient, scientific rationale and clinical evidence, facilitated by regulatory authority initiatives for accelerated access. It is difficult to generalise because of a wide variation in researcher practices (EASAC and FEAM, 2020) but in some cases, the cells may be well characterised, protocols are registered with regulatory authorities, early results are published in reputable journals (that favour newsworthiness), yet the application for marketing approval is premature and based on inadequate evidence. Accelerated regulatory approval is an essential tool in bringing novel therapies to patients as fast as possible but it should not be abused by cutting corners in research and development. The problem persists despite the availability of international guidelines, e.g. from ISSCR.

In an era of increasing pressure for international competitiveness, where some regulatory frameworks become increasingly permissive (Sleeboom-Faulkner, 2019), it is essential that countries do not lower their regulatory threshold without fully considering the consequences for patient safety, healthcare budgets and public trust in science, and without ensuring that commitments on post-marketing studies are adhered to. Undesirable practices inherent in stem cell tourism are a consequence of the relative laxity in some national regulatory frameworks.

Academies have a continuing role to advise on priorities for research and innovation and can help to catalyse progress and monitor consistency of developments worldwide. These priorities include the following areas:

**Ethical assessment**

National regulatory conditions and clinical research frameworks are dependent on ethical considerations. Ethical issues must be addressed at various levels – including in health professional training and other education and as part of the approval and supervision of clinical trials, and should be based on interdisciplinary perspectives, that is from social sciences as well as medicine, to take account of different expectations of medicines within and between different societies.

In addition to questions pertaining to safety and efficacy, the following ethical issues need to be addressed: patient expectations (is uncertainty about benefits outweighed for the patient by their lack of other options?); patient consent (can the patient understand the risk and benefit, is the intervention experimental, should the family be involved?); information (where can reliable advice be found?); professional responsibilities (might there be conflicts of interest?); and equity and fairness (do all patients have equal access and might limited health resources be diverted from other care?). However, regenerative medicine may not be within the competence of local ethical committees and then a case can be made for a national ethical committee.

Other ethical controversies in regenerative medicine have surrounded the provenance of donated biological samples and whether consent has been obtained, and the use of embryonic stem cells, although this latter concern is diminishing with the advent of induced pluripotency (where adult cells are de-differentiated to an embryonic stem cell-like state, although there will still be safety concerns if contaminated with undifferentiated cells which could develop into teratomas and tumours).

**Clinical trial procedures and other research**

As in other clinical areas, regenerative medicine trials should be performed according to an approved design, e.g. paying attention to expected recruitment numbers (recruiting the calculated minimum number, who may be exposed to unknown risks, necessary to obtain statistically significant results), standardised dosages, management of adverse effects, transparency in data collection, and criteria for premature termination of the trial. The clinical protocol should have been reviewed and approved by the host research organisation and by an ethics committee. There should be follow-up to collect data of failed as well as successful trials.

The implications of the orphan nature of some of the rarer clinical applications must be acknowledged in terms of designing clinical trials with an acceptable level of evidence for safety and efficacy. If patient groups are small, it is difficult to conceive large, standard phase III placebo-controlled trials and there is more to be done internationally to facilitate a framework for robust evidence collection in these circumstances. One option for research capacity building globally is to focus on those initiatives, e.g. with haematopoietic stem cells, which may be relatively easier to establish in Low- and Middle-Income Countries (LMICs). However, adopting improved clinical trial procedures for other indications and other regenerative medicine approaches has significant implications for research infrastructure and for sharing skills worldwide.

Clinical research should be preceded by research *in vitro* and in animal models sufficient to provide a robust scientific foundation. This requires ensuring consistency in the composition and viability of the novel agent as it moves through successive stages of research and development. There are challenges in the scale-up from laboratory-level production to clinical and commercial scale and there must be attention to product quality throughout research and in the transition to industrial scale production (as recommended by a joint report from the French Academy of Medicine and Academy of Technologies, Ardaillou *et al.*, 2017).

More generally, there is a crucial role for investment in basic science and bioengineering to provide the resource for identifying next generation novel approaches and to inform scenario development. There is need for research in the social sciences on the ethical, legal and other societal consequences to support these longer-term considerations and to inform engagement with patient groups and others in civil society.

**Regulatory authorisation and access to new medicines**

Regulatory procedures need to become robust, transparent and evidence-based globally, without also becoming a heavy burden in terms of time and costs. Proportionate and consistent regulatory activities, including approval on the start of human studies, oversight of clinical trials, authorisation for marketing, post-marketing surveillance, and enforcement against fraudulent claims, must be based on replicable science. Unregulated provision of unproven regenerative medicine interventions must be deterred. The ethical issues and regulatory challenges need to be addressed in a rigorous, consistent and constructive way that includes the international development of standards[4] as a step towards the necessary greater regional[5] and global regulatory coordination (Qiu *et al.*, 2020). Harmonisation is important in making best use of the evidence base, but it does not solve the practical problem of unregulated, unscrupulous private clinics. A globally consistent framework might also introduce training and certification for practitioners of regenerative medicine and licensing of permitted clinics once regulators authorise products.

Policy makers face difficult choices. The present systems of governance procedures are complex and there is variation in codes of conduct and other frameworks for regulating clinical research and development. Governments and intermediaries (such as universities) may have a vested interest in promoting regenerative medicine (McKelvey *et al.*, 2018). How should governance mechanisms be (re)designed to encourage enough risk-taking (experimentation) to develop radically new knowledge and innovation while at the same time protecting the safety of patients and protecting the population against misconduct and fraud? These are difficult challenges at the national level and even more difficult for international coordination.

Encouraging innovation while putting patients first requires action throughout research and development. For example, increasing investment in basic and clinical research must be accompanied by attempts to solve the problem of how expensive therapies can be reimbursed[6] otherwise pipelines will be filled with innovation that cannot be afforded. Health technology assessments and cost-benefit discussions, between the public and private sectors and with regulatory authorities, need to occur earlier in product development. Expensive therapies appear inequitable and equity is important for LMICs, indeed for all countries facing the very high prices that might be requested. However, it is necessary to take a long-term health economics approach: advanced technologies may bring sustained and substantial cost savings for an agent that initially appears cost-ineffective. If successful, a new therapy in regenerative medicine would eliminate costs of poorly efficacious existing therapies as well as the cost of assisting the patient, often for decades.

**Engaging with patients, policy makers and the public**

Notwithstanding the excellent work of professional scientific societies (Box 2), there is more to be done to create and share platforms to describe the difference between evidence-based practices and unproven, erroneous and illegitimate practices. As with other emerging technologies, better regulation and an informed public depend on education at all levels. Regulatory authorities and their advisers worldwide must have access to the latest biosciences/interdisciplinary experience. Education must encompass undergraduate and graduate programmes for health professionals and communication efforts with lay audiences and policy makers. Engagement worldwide should be sensitive to socio-economic context, literacy, religious and cultural beliefs.

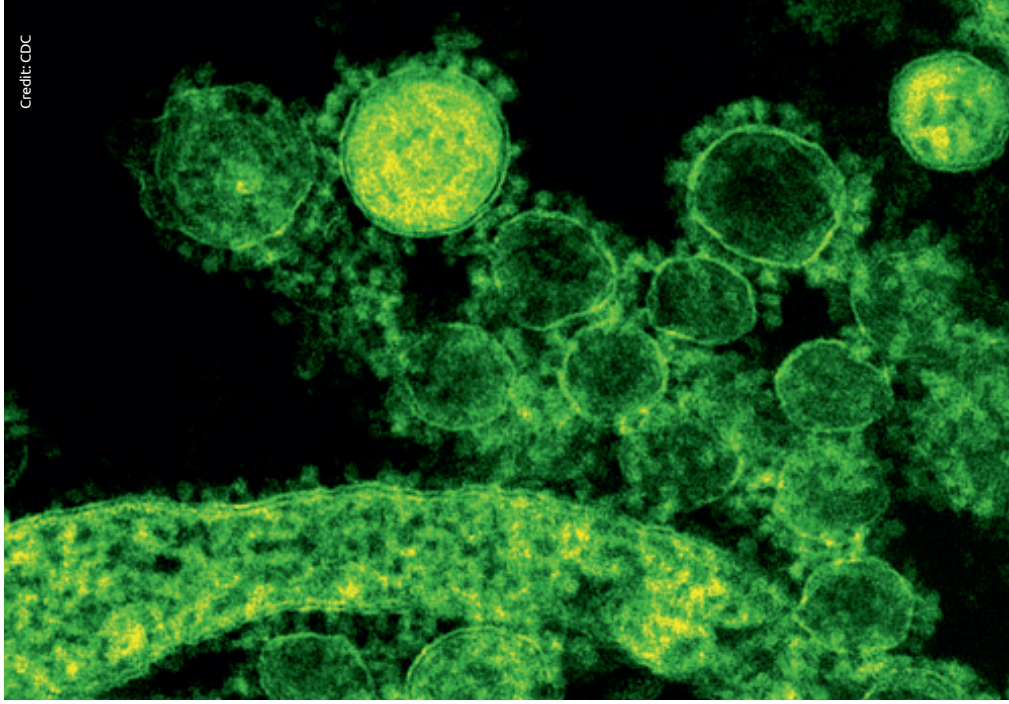
IAP encourages its member academies and regional networks to become involved in the formulation of guidelines for research and practice; in discussion of the evidence base for claims of efficacy and safety; and in helping policy makers

4 For example, WHO (2020) describes ongoing work on the development of standards of cellular and gene therapy products to facilitate global convergence among regulators from both high-income countries and LMICs with regard to quality, safety, efficacy and post-market surveillance. The first proposed reference reagents are for pluripotent stem cell identity and mesenchymal stromal cell identity. See also Lee *et al.* (2017) for a discussion of possible additional WHO roles. While several international organisations are pursuing global standardisation, especially concerning cell banking, there is less harmonisation on assays for critical quality characteristics such as safety and potency (Karanu *et al.*, 2020).

5 An example of the measures involved in regional harmonisation that includes regenerative medicine is provided by the Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia (Executive Committee on Global Health and Human Security, 2020).

6 It is important for pricing negotiations to be more transparent and to be more clearly linked to costs of research and development and manufacturing: WHO discussions on transparency of health product markets (e.g. at the 72nd World Health Assembly in 2019) may help to stimulate action.

to decide on priority medical conditions (at a time when the boundary between medicine and biological enhancement may be increasingly diffuse, e.g. in preventing/retarding the effects of ageing). The focus in this IAP Statement on serious medical conditions is intended to cover a range of concerns that threaten health and interfere with the tasks of daily living as well as life-threatening conditions. The challenges in doing all this – with substantial implications for allocation of research and health care resources – are not, of course, confined to regenerative medicine, and have been explored in other IAP work[7].


Credit: CDC

**COVID-19**

The points discussed above apply also to the proposed use of stem cells to tackle COVID-19. Any such use must be based on rigorous evidence of safety and efficacy, following strict research protocols that consider the ethical issues and characterise the stem cells used, focusing on a defined stage of the disease and in the hands of a team with capacity and validity to undertake the intervention.

Unfortunately, as the FDA observes, some of the same clinics in the USA that have been offering unproven regenerative medicine therapies for diverse conditions are now offering unproven treatments for the treatment of complications of COVID-19 (Marks and Hahn, 2020). There are other examples worldwide. While some research is in progress, e.g. on mesenchymal stromal cells, the preliminary studies are insufficient to support commercialisation. There is a further concern regarding these unproven treatments for COVID-19: fraudulent claims of efficacy may encourage purchasers to abstain from taking other steps, e.g. social distancing, to protect themselves and others from COVID-19.

**IAP consensus recommendations**

Regenerative medicine has transformative potential, but action is required from the scientific and policy communities to sustain responsible research and innovation worldwide, develop new forms of partnership, and build health services readiness while also engaging with patients and the public to counter misinformation and deter the provision of unregulated interventions. Our key messages are:

- Regenerative medicine is designed to treat serious medical conditions with unmet needs, judged by rigorous consideration of the potential risks versus the benefits. Other applications are inappropriate for the time being.
- We are now at the threshold of being able to offer treatments for major genetic and other diseases – but for many, more evidence is needed on their likely benefit or efficacy, especially for the more complex polygenic and acquired degenerative diseases, and on safety, especially long-term safety.
- It is vital to promote good biomedical science – from fundamental research and its translation to clinical trials. This has implications for public sector commitment to funding of well-planned first-in-human trials with reliable, shared and objective end-points determined with input from supporting expert networks and patients. There are also implications for novel forms of partnership between academia and industry and with regulatory agencies.
- Proportionate and consistent regulatory activities must be based on robust and replicable science, ethically informed by science across the disciplines, and accompanied by efforts for international harmonisation. Unregulated provision of unproven regenerative medicine procedures must be deterred.
- Researchers must follow professional guidelines on responsible research (both in pre-clinical and clinical phases) and standard-setting, in pursuit of good practice. Clinicians must be bound by both professional guidelines and community standards of medical practice.
- Teaching on regenerative medicine should be part of the curriculum for health professionals.
- Scientific and medical communities have a responsibility to provide reliable sources of information and ensure that discussions and decisions are evidence-based. The risks created by misinformation go deeper than the possible harms to individuals. There is also potential to harm the credibility of research and scientific integrity.
- Patient interests must be put first. There must be a validated scientific basis for the clinical intervention and for the end-points selected for measurement of efficacy and safety, as well as a commitment to share good practice internationally.

In summary, in order to deliver sustainable, clinically significant and equitable benefits from regenerative medicine, a coordinated strategy needs to encompass better science, better funding, better governance and better public and patient engagement. Academies worldwide are ready to play their part at the national, regional and global levels.

7 For example. IAP with UK Academy of Medical Sciences 2019, 'Achieving universal health coverage in LMICs: the role of quality of care research'; IAP co-signatory in open letter to the UN, 2020 'Health inequity during the pandemic: a cry for ethical global leadership.'

## References


Ardaillou R, Jarry B and Stoltz J-F (2017). Transition to an industrial scale of human stem cell production for therapeutic use. *Bull. Acad. Natle. Med.* **201**, 983-1018.

Clarke G, Harley P, Hubber E-L *et al.* (2018). Bench to bedside: current advances in regenerative medicine. *Current Opinion in Cell Biology* **55**, 59-66.

Cossu G, Birchall M, Brown T et al. (2018). *Lancet* Commission: stem cells and regenerative medicine. *Lancet* **391**, 883-910.

De Luca M, Aiuti A, Cossu G *et al.* (2019). Advances in stem cell research and therapeutic development. *Nature Cell Biology* **21**, 801-811.

EASAC and FEAM (2020). Challenges and potential in regenerative medicine. https://www.interacademies.org/publication/challenges-and-potential-regenerative-medicine

Executive Committee on Global Health and Human Security, Japan Center for International Exchange (2020). A UHC approach to harmonizing Asian pharmaceutical and medical device regulations.

Hines PA, Guy RH, Humphreys AJ and Papaluca-Amati M (2019). The European Medicines Agency's goals for regulatory science to 2025. *Nature Reviews Drug Discovery* **18**, 403-404.

Ilic D and Liovic M (2020). Industry updates from the field of stem cell research and regenerative medicine in February 2020. *Regenerative Medicine* **15**, https://doi.org/10.2217/rme-2020-0033.

Julian K, Yuhasz N, Rai W, Salerno J and Imitola J (2020). Complications from "stem cell tourism" in neurology. *Annals of Neurology* **88**, 661-668.

Karanu F, Ott L, Webster DA and Stehno-Bittel L (2020). Improved harmonization of critical characterization assays across cell therapies. *Regenerative Medicine* **15**, https://doi.org/10.2217/rme-2020-0003.

Lee T-L, Lysaght T, Lipworth W et al. (2017). Regulating the stem cell industry: needs and responsibilities. *Bulletin of the World Health Organization* **95**, 663-664.

Marks P and Gottlieb S (2018). Balancing safety and innovation for cell-based regenerative medicine. *New England Journal of Medicine* **378**, 954-959.

Marks PW and Hahn S (2020). Identifying the risks of unproven regenerative medicine therapies. *JAMA* **324**, 241-242.

McKelvey M, Saemundsson RJ and Zaring O (2018). A recent crisis in regenerative medicine: analyzing governance in order to identify public policy issues. *Science and Public Policy* **45**, 608-620.

Mullard A (2019). Gene therapy boom continues. *Nature Reviews Drug Discovery* **18**, 737.

NASEM (2019). Exploring sources of variability related to the clinical translation of regenerative engineering products. Washington DC: National Academies Press. https://www.nap.edu/catalog/25371/exploring-sources-of-variability-related-to-the-clinical-translation-of-regenerative-engineering-products

Ntege EH, Sunami H and Shimizu Y (2020). Advances in regenerative therapy: a review of the literature and future directions. *Regenerative Therapy* **14**, 136-153.

O' Keefe RJ, Tuan RS, Lane NE *et al.* (2019). American Society for Bone and Mineral Research-Orthopaedic Research Society Joint Task Force Report on Cell-Based Therapies. *Journal of Bone and Mineral Research* **35**, https://doi.org/10.1002/jbmr.3839.

Qiu T, Hanna E, Dabbous M, Borislav B and Toumi M (2020). Regenerative medicine regulatory policies: a systematic review and international comparison. *Health Policy* **124**, 701-713.

Rowe BG and Daley GQ (2019). Induced pluripotent stem cells in disease modelling and drug discovery. *Nature Reviews Genetics* **20**, 377-388.

Shahryari A, Jazi MS, Mohammadi S et al. (2019). Development and clinical translation of approved gene therapy products for genetic disorders. Frontiers in Genetics https://doi.org/10.3389/fgene.2019.00868.

Sleeboom-Faulkner M (2019). Regulatory brokerage: competitive advantage and regulation in the field of regenerative medicine. *Social Studies of Science* **49**, 355-380.

WHO Expert Committee on Biological Standardization (2020). WHO Technical Report Series no. 1024.


## Academies that have endorsed the Statement on Regenerative Medicine (July 2021)

Albanian Academy of Sciences
Algerian Academy of Sciences and Technology
*Academia Nacional de Medicina de Buenos Aires*, Argentina
*Academia Nacional de Ciencias*, Argentina
Australian Academy of Science
Bangladesh Academy of Sciences
*Academie Royale de Medecine de Belgique*
*Academie Nationale de Sciences, Arts et Lettres du Benin*
Academy of Sciences and Arts of Bosnia and Herzegovina
Brazilian Academy of Sciences
*Academia Nacionale de Medicina*, Brazil
Cameroon Academy of Sciences
Royal Society of Canada
*Academia Chilena de Ciencias*
Chinese Academy of Sciences
Chinese Academy of Engineering
Croatian Academy of Arts and Sciences
Cuban Academy of Sciences
Czech Academy of Sciences
*Academia de Ciencias de la Republica Dominicana*
Academy of Sciences of Ecuador
Academy of Scientific Research and Technology, Egypt
Ethiopian Academy of Sciences
Council of Finnish Academies
*Academie Nationale de Medecine*, France
Union of German Academies of Sciences and Humanities
German National Academy of Sciences, *Leopoldina*
Ghana Academy of Arts and Sciences
Academy of Athens, Greece
*Academia de Ciencias Medicas, Fisicas y Naturales de Guatemala*
National Academy of Sciences of Honduras
Hungarian Academy of Sciences
Indian National Science Academy
Royal Irish Academy
*Accademia Nazionale dei Lincei*, Italy
*Accademia Nazionale di Medicina*, Italy
Science Council of Japan
Kenya National Academy of Sciences
African Academy of Sciences
National Academy of Sciences, Republic of Korea
Korean Academy of Science and Technology
Lithuanian Academy of Sciences
*Akademi Sains Malaysia*
Mauritius Academy of Science and Technology
*Academia Mexicana de Ciencias*
Mongolian Academy of Sciences
Hassan II Academy of Science and Technology, Morocco
Royal Netherlands Academy of Arts and Sciences
Royal Society of New Zealand
Nicaraguan Academy of Sciences
Nigerian Academy of Science
Norwegian Academy of Sciences and Letters
Palestine Academy for Science and Technology
National Academy of Science and Technology, Philippines
Polish Academy of Sciences
Macedonian Academy of Sciences and Arts
Romanian Academy
Serbian Academy of Sciences and Arts
Academy of Science of South Africa
National Academy of Sciences, Sri Lanka
Sudanese National Academy of Sciences
Royal Swedish Academy of Sciences
Swiss Academies of Arts and Sciences
Academia Sinica, Taiwan, China
Tanzania Academy of Sciences
Tunisian Academy of Sciences, Letters and Arts Beit al Hikma
Turkish Academy of Sciences
Uganda National Academy of Sciences
Royal Society, UK
Academy of Medical Sciences, UK
European Academy of Sciences and Arts
Global Young Academy
The World Academy of Sciences (TWAS) for the advancement of science in developing countries
Islamic World Academy of Sciences
World Academy of Art and Science

## Working Group

Volker ter Meulen (Germany, chair)
Consuelo Milagro Macías Abraham (Cuba)
Hidenori Akutsu (Japan)
Lara Theresa Alentajan-Aleta (Philippines)
Mamun Al Mahtab (Bangladesh)
Andrés Caicedo (Ecuador)
Antonio Carlos Campos de Carvalho (Brazil)
Miodrag Čolić (Serbia)
Jillian Cornish (New Zealand)
Patrice Debré (France)
Geoffrey Dierckxsens (Czech Republic)
Nagwa El-Badri (Egypt)
Patrick Ching-Ho Hsieh (Taiwan, China)
Maneesha S Inamdar (India)
Pradeep Kumar (South Africa)
Romaldas Mačiulaitis (Lithuania)
Fergal O'Brien (Ireland)
Michael Sean Pepper (South Africa)
Robin Fears (UK, secretariat)
In discussion with:
Giulio Cossu (UK/Italy)
George Griffin (UK)

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from:
www.interacademies.org/statement/iap-statement-regenerative-medicine

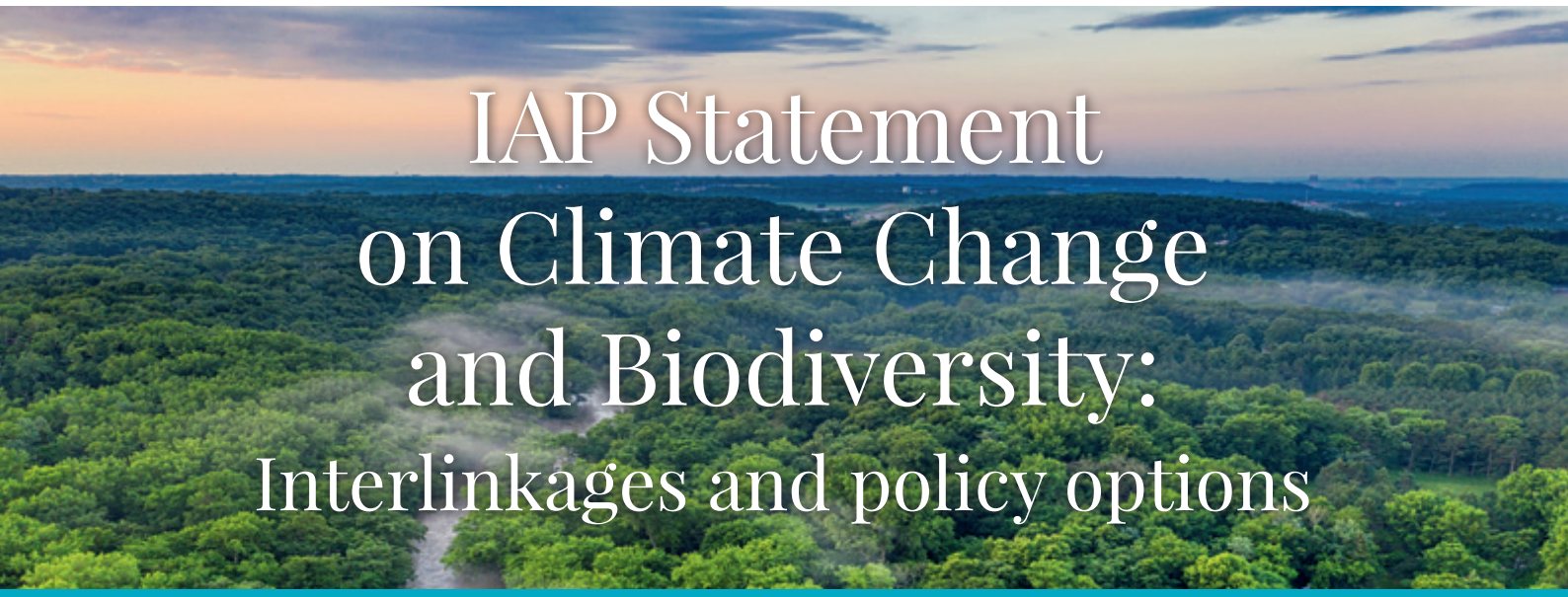
## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership



# IAP Statement on Climate Change and Biodiversity:

## Interlinkages and policy options

**Climate change and biodiversity decline are major challenges of our time. Both are predominantly caused by human activities, with profound consequences for people and the ecosystems on which we depend. In 2021 and 2022, major United Nations conferences on biodiversity (COP15) and on climate change (COP26) will be held, providing an opportunity for governments to focus international attention on the interconnectedness and interdependence of climate change and biodiversity. Some policy measures are beneficial in both areas, helping to mitigate and adapt to climate change as well as to conserve and restore biodiversity. However, this is not guaranteed, and some climate actions can undermine biodiversity goals. This IAP Statement examines interconnections between biodiversity and climate change and outlines how measures that benefit biodiversity have the potential to support climate action, and how some aspects of climate action can support biodiversity. It also discusses instances where addressing climate change can undermine efforts to enhance biodiversity.**

## Key policy recommendations and principles for action

**Policy recommendations:**

- Build a sustainable food system with climate- and biodiversity-friendly agricultural practices, responsible food trade, and equitable food distribution.
- Reduce rates of natural ecosystem loss and degradation, protect, restore and expand natural ecosystems, and increase landscape connectivity.
- Ensure that expansion of renewable energy systems has positive biodiversity benefits built into its design.
- Recognise, respect and safeguard the rights and livelihoods of local and traditional users of ecosystems when implementing biodiversity and climate change actions.
- Discourage ecosystem-based approaches to climate mitigation that have negative outcomes for biodiversity, such as tree planting in inappropriate ecosystems, monocultures, and unsustainable energy crops.

**Principles underpinning biodiversity and climate action:**

- **Transformation.** Mitigation at the scale needed to keep the rise in global temperatures to 1.5°C, or to reverse global biodiversity decline, requires a transformative change in the way our societies consume and produce resources.
- **Collaboration.** Governments alone cannot achieve the transformations needed – coordinated climate and biodiversity actions from multiple stakeholders, including the private sector and civil society, are essential.
- **Integration.** Greater understanding of the biodiversity-climate relationship should help to end the separation between the national and international policy frameworks that currently address climate change and biodiversity decline.
- **Additionality.** Where Nature-based Solutions are implemented to help mitigate climate change, they should not delay or lower any ambition to reduce carbon dioxide emissions from fossil fuels or reduce energy use through more energy efficient technologies.
- **Best practice.** The success or failure of Nature-based Solutions and of other responses to climate change and biodiversity issues is dependent on the adoption of best practice and should be evidence-based and tailored to the location.
- **Equity**. The diversity of environmental and climate policies, from protected areas to payments for ecosystem services, should acknowledge the different dimensions of equity to ensure a sustainable and equitable future that leaves no one behind.

# SECTION A. Understanding the interlinkages between climate change and biodiversity

## A1. How climate change, biodiversity and ecosystems affect each other

**What is biodiversity and why is it important?**

Biodiversity is the variety and variability of life on Earth, from genes to ecosystems, and the interactions between species, together with the ecological and evolutionary processes that sustain it.

Countless interactions between organisms sustain human life on the planet, providing physical, cultural, recreational and spiritual benefits to society, often referred to as 'ecosystem services' or 'nature's contributions to people'. The loss of biodiversity can threaten these key benefits, including some as essential as supplies of food and clean water, or regulation of the climate. Biodiversity loss may also cause outbreaks of pests and pathogens.

**How does climate change affect biodiversity?**

Aspects of climate change, such as rising temperatures, changing rain and snowfall patterns and extreme weather events, have a range of impacts on biodiversity.

In marine environments, climate change is causing intensified marine heatwaves, loss of oxygen and sea level rise, which lead to already observed changes in biodiversity, ecosystem functioning and livelihoods such as fishing, particularly for coastal ecosystems[1]. The impacts of climate change are compounded by ocean acidification, which is also caused by increased carbon dioxide concentrations. Many terrestrial, freshwater and marine species have shifted their geographic ranges, seasonal activities, migration patterns, abundances and the ways in which they interact with other species in response to ongoing climate change[2].

The rapid pace of climate change in the 21st century, with a temperature rise in excess of 3°C possible within this century[3], could mean that many species fail to adapt or migrate at sufficient speed, particularly in more fragmented landscapes and for rare or specialist species. Some plant and animal species may become extinct[4] and certain populations will decline whilst others will increase, affecting species interactions such as predation, competition and the spread of diseases.

**How do ecosystems affect the climate?**

Ecosystems affect the climate in several ways, and their biodiversity

secures climate-regulating functions. Ecosystems influence the climate by altering the properties of the land surface and the flows of energy and matter in the oceans and on land. Vegetation increases the rate of water cycling to the atmosphere, which lowers surface temperatures, increases atmospheric humidity and affects local cloud formation and, in some cases, also the rate or intensity of rainfall. At a larger scale, these features affect atmospheric circulation and, hence, regional and global climate patterns.

Ecosystems, through vegetation, animals, microbes and soils, are major reservoirs of carbon. The total amount of carbon stored in the terrestrial biosphere is three times that found in the atmosphere as carbon dioxide[5]. Changes in these carbon reservoirs, caused by

human activity and climate change, can significantly affect the Earth's climate.

The biodiversity within ecosystems makes them more resilient to varying and shifting climates and other disturbances.

### A2. How is biodiversity changing and what role is climate change playing?

Wildlife worldwide has been negatively impacted by human activities causing a decline in abundance of many species in the last half-century[6,7,8]. Around one million animal and plant species are now estimated to be threatened with extinction as a result of human activity[4]. On average, local species richness, the number of different species in an ecosystem, is estimated to have fallen by around 14% due to human activity, but by more than 75% in the worst affected habitats[9].

The main driver of biodiversity decline in the past 50 years has been change in land and sea use (especially the expansion and intensification of agriculture, including tropical deforestation as the largest single cause of biodiversity loss), followed by direct exploitation of organisms, such as fisheries; climate change; pollution; and the invasion of species, especially on islands[4].

While climate change has yet to cause major species decline in some ecosystems, in others it has already resulted in severe reductions in population size, changes in composition, and extinction. For example, warming-induced coral bleaching has caused declines of up to 90% in coral populations in some regions, leading to shifts to alternative types of organisms such as macroalgae, or broad-scale transformations in coral species composition[10,11]. A 2°C warming is expected to cause a decline of greater than 99% of coral reefs[23]. On land, the impacts of climate change on the diversity of plants and vertebrates are predicted to exceed those of land use by 2050[12,13]. For mountain-top species, these changes could be particularly dramatic in the long term as they won't be able to migrate to higher elevations and are likely to face competition from species migrating from lower altitudes[14].

Species decline and other impacts of global warming would be significantly reduced by limiting warming to 1.5°C. A recent study suggests that whereas 4% of vertebrates, 8% of plants and 6% of insects have been projected to lose over half of their climate-determined geographic range at 1.5°C of warming, this will rise dramatically under 3°C warming to 26% of vertebrates, 44% of plants, and 49% of all insects. Under 3°C of warming, there may also be critical declines in some whole habitats, such as alpine, mountain and high-latitude ecosystems and some tropical forests[15,17].

### A3. How can biodiversity support climate change adaptation and mitigation efforts?

Biodiversity and the ecosystem functions associated with it can support climate action in many ways, particularly through well-designed and implemented 'Nature-based Solutions' (NbS)[16].

These actions are intended to protect, sustainably manage and restore ecosystems that address societal challenges such as climate change, while providing human well-being and biodiversity benefits. These are reasonably well understood and available for deployment in terrestrial systems, but less advanced in marine systems[17].

NbS that support both climate change mitigation and adaptation include protecting and restoring ecosystems such as peatlands and seagrass meadows, and reforesting woodland and mangroves, thus enhancing soil and biomass carbon sequestration whilst increasing resilience to climate change impacts[14]. Scaling up nature-based

actions to their maximum possible extent has been estimated to result in a potential net absorption of around 11 billion tonnes of $CO_2$-equivalent per year until the mid-century at least, equivalent to around 27% of current fossil-fuel $CO_2$ emissions, through enhanced sinks and reduced sources of greenhouse gas (GHG) emissions[18,19]. However, NbS will allow us to meet climate targets only in tandem with strict and rapid decarbonisation of the economy; the carbon-holding capacity of the biosphere is limited compared to current and potential fossil fuel emissions.

While some NbS, such as improving soil carbon sequestration, can be applied without changing land use, a key consideration for others is how much land conversion is required and what potential trade-offs may emerge against existing uses and biodiversity.

## SECTION B. Action plan – integrated policy options for climate change and biodiversity

How to develop a coordinated effort to combat both climate change and biodiversity decline? First, this section sets the scene by looking at the current international climate and biodiversity policy context. Second, it proposes six principles to guide a joined-up climate and biodiversity policy response. Third, it explores available options for better integrating global climate and biodiversity policymaking at a governance level. The final section provides guidance on which climate measures should be encouraged or discouraged based on their impacts on biodiversity.

### B1. International policy context

In 1992, at the Rio de Janeiro 'Earth Summit', the international community established structures to address climate and biodiversity issues in the form of the UN Framework Convention on Climate Change (UNFCCC) and the Convention on Biological Diversity (CBD), respectively.

The year 2021 should be a historic turning point for the global environment as it marks the start of the *decade of action* towards the Sustainable Development Goals (SDGs), which integrate climate change and biodiversity with other socio-environmental targets to be achieved by 2030. Also, in 2021

and 2022, both the UNFCCC and CBD are due to hold their COP26 and COP15 conferences, respectively. In prospect are new targets to cut emissions, new goals for biodiversity, new forms of collaboration between the conventions, and a new ambition for progress and social justice as part of the hoped-for global recovery from COVID-19. This convergence of events presents a unique opportunity to build on previous academy work[20] and to make a major difference towards achieving a more sustainable and fairer future for people and nature. For example, were the post-2020 biodiversity targets to integrate climate change, they would result in more realistic targets which could also contribute to the mitigation and adaptation of climate change[21].

### B2. Six principles to guide a joined-up climate and biodiversity policy response

Here we introduce six principles that should be considered to enable a joined-up climate and biodiversity policy response.

**Transformation.** Modelling and scenario analyses demonstrate that mitigation at the scale needed to keep the rise in global temperatures to 1.5°C, or to reverse global biodiversity decline, requires a transformative change in the way our societies consume and produce resources[22]. Such change would include rapid and far-reaching transitions in consumption supply chains, energy production and use, land use, infrastructure, and lifestyle[4,23,24]. The 2021 Dasgupta Review and recent international climate change and biodiversity assessments have highlighted the need to transform the economic system. Examples of ways to do this include: (i) complementing GDP (Gross Domestic Product) with measures that include multiple values for nature by reducing and redirecting some of the subsidies for, and financial investment in, fossil fuel, agriculture, fisheries, forestry, transportation and mining towards sustainable policies and practices; (ii) internalising environmental and social externalities (according to the International Monetary Fund these amount to about US$5 trillion in 2017[25]); and (iii) embracing a circular economy[2,5,26,27].

**Collaboration.** Governments alone cannot achieve the transformations needed – coordinated climate and biodiversity actions from multiple stakeholders, including the private sector and civil society are essential. Collaborations should be made at all

levels from sub-national (municipality, province/state) to national and international levels. Just as the Paris Agreement, based on governmental collaboration, has become a cornerstone to mitigate climate change, a global treaty for biodiversity could be decisive in providing an overall framework and goal to conserve the diversity of life on Earth[28].

**Integration.** Greater understanding of the biodiversity-climate relationship would help ending the separation between the national and international policy frameworks that currently address climate change and biodiversity decline. It is important for policymakers to look at impacts in both areas when considering any intervention.

**Additionality.** Where NbS are implemented to help mitigate climate change, they should not delay or lower ambition to reduce carbon dioxide emissions from fossil fuels or reduce energy use through more energy efficient technologies[29]. Early projections indicate that even ambitious deployment of NbS worldwide can provide only 0.1-0.3°C of lowered global peak temperatures, a significant contribution but not a solution to climate change in the absence of ambitious fossil fuel emissions reductions[30].

**Best practice.** The success or failure of NbS and of other responses to climate change and biodiversity issues is dependent on the adoption of best practice. In many cases, best practice will involve place-specific NbS: the appropriate solution for a specific location and context. The spread of best practice requires a well-defined framework for NbS that includes evidence-based standards and guidelines[31,32] to ensure that they avoid unintended or maladaptive outcomes[33,34] and that facilitates their monitoring.

**Equity**. The strong linkages between environmental policies and society make equity a key component of environmental governance[35]. The diversity of environmental and climate policies, from protected areas to payments for ecosystem services, should acknowledge the different dimensions of equity to ensure a sustainable and equitable future that leaves no one behind[36,37]. Early engagement with stakeholders who would be affected by environmental policies is fundamental to ensure equitable outcomes.

### B3. Integration of global policymaking in both areas

The current separation in global governance frameworks means that scientific advice and policymaking for the deeply interwoven issues of climate change and biodiversity decline are handled by separate administrative and scientific organisations and by different intergovernmental conventions who have historically had limited interaction. If the two issues are to be managed holistically, links between the two governance systems need to be strengthened. In particular, scientists need to engage with policymakers to ensure that NbS achieve their potential to tackle both the climate and biodiversity crises while also contributing to sustainable development. This will require systemic change in the way we conduct research and run institutions[9].

Practical steps to do this could include:

- promoting holistic sustainability frameworks, such as the SDGs;
- aligning climate and biodiversity goals and targets at various scales;
- ensuring the new global biodiversity goals to be adopted by the CBD for the next decade are holistic and ambitious[38];
- increasing liaison between the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) and the Intergovernmental Panel on Climate Change (IPCC), through initiatives such as their joint workshop in December 2020;
- strengthening the role of the Joint Liaison Group on the Rio Conventions[1]; and
- exploring funding for NbS, particularly via the UNFCCC's planned forum on 'Finance for nature-based solutions'[39].

## B4. Guidance on policy measures

This section sets out which land-based and sea-based climate policies are beneficial for biodiversity and should therefore be encouraged, and which are not and should therefore be discouraged.

### Policy measures to encourage:

**Building a sustainable food system.** One third of crops are fed to livestock rather than humans[40], and a third of food globally is lost or wasted[41]. Animal agriculture is a major contributor to global biodiversity loss[42]. A reduction in meat and dairy consumption and a significant reduction in food loss and waste would not only significantly reduce GHG emissions[43,44], which itself benefits biodiversity through limiting climate change, it would also reduce pressure for deforestation with associated biodiversity loss and free land and resources for biodiversity recovery and the wider use of NbS[23]. As such, dietary shifts for people who can choose what they eat and reduction in food loss and waste create the enabling conditions that make other actions outlined below more feasible[44].

A revolutionary change in farming is essential to meeting the goals of the Paris Agreement and reducing biodiversity decline. To achieve that aim, further research on agriculture, which is underfunded compared to other key human activities, should be a priority. Moreover, farmers should be offered financial and other incentives to support climate and biodiversity friendly activities, such as agro-ecological practices[45].

**Sustainable and responsible food trade, and equitable food distribution.** Since the price of food and other products does not incorporate environmental externalities, too often, many countries benefit from cheap products that are grown unsustainably in other countries, with the latter having to bear the burden of environmental degradation without benefiting from the food. Avoiding importing food that has been produced unsustainably elsewhere, and instead supporting sustainable production modes and distributing available food fairly amongst those who need it is a critical part of a sustainable and responsible food system.

**Reducing rates of natural habitat loss and degradation, particularly of forests.** Deforestation, currently mainly in the tropics and subtropics, is the major contemporary cause of terrestrial biodiversity loss and local climate change, and has contributed 5.7 $GtCO_2$ annual emissions over the last decade, 14% of global $CO_2$ emissions[46]. Reducing deforestation and degradation rates can be achieved through both supporting *in situ* conservation, resourcing alternative development pathways and reducing international demand for products of deforestation[47]. Reducing deforestation would have the health co-benefit of lowering the risk of disease outbreaks caused by pathogens present in these areas passing from wildlife to humans[2].

**Natural ecosystem restoration and expansion.** Expansion of native ecosystems, through restoration and rehabilitation, in a network that facilitates connectivity and species migration, will enhance biodiversity and carbon storage in ecosystems. Natural forests have been calculated to be 40 times better than plantations at storing carbon[48]. A global forest restoration effort could absorb 2 $GtCO_2$/year. Ecologically appropriate restoration of non-forest ecosystems, such as savannas and grasslands, can increase carbon stocks in soils and maintain biodiversity.

**Peatland preservation and restoration.** Peatlands have been estimated to store more than 600 Gt or 20% of the global

1 The mandate of the Joint Liaison Group, which comprises the Executive Secretaries of the CBD, the United Nations Convention to Combat Desertification (UNCCD) and the UNFCCC, is to enhance coordination among the three Rio Conventions and explore options for further cooperation.

2 Although considerations of human health are not a primary focus of this Statement, such considerations are of critical importance in understanding the benefits of retaining biodiversity and tackling climate change, and thus are being addressed in an ongoing IAP project on climate change and health: www.interacademies.org/project/climate-change-and-health.

stock of soil carbon, twice as much as the world's forests[49], on only 3% of its land. Peatland preservation and restoration has multiple benefits for amenity, water resources, flood protection, biodiversity and the climate. For example, restored peatlands show renewed growth of *Sphagnum* moss species and attract invertebrates and birds[50]. Existing drained peatlands globally are expected to cumulatively release the equivalent of nearly 2 $GtCO_2$ that could be saved by restoration[51].

**Extension and enforcement of Marine Protected Areas (MPAs).** As well as restoring and protecting biodiversity, and helping it to be resilient to climate change, many MPAs support climate resilience, either by protecting the coastline from severe weather events, for example through coral reefs or mangroves, or by absorbing carbon dioxide in seagrasses, salt water reedbeds and muddy habitats[52,53]. To be effective, MPAs should be extended with new investment in their management and enforcement of protection rules.

**Biodiversity friendly renewables.** Upscaling of renewable energy production should avoid negative impacts on biodiversity where possible. For example, engineers can design offshore wind farms to be biodiversity friendly and attract species under water[54]. Techniques include structures on which new reefs can grow along with fish habitats and sea grass settlements. Overall, marine sites where renewable energy technologies are being deployed should be managed to optimise potentially positive effects, by adopting exclusion zones from other destructive activities such as bottom trawling and dredging and support the colocation of other industries such as mariculture that support wider benefits from nature[55]. On land, solar farms should avoid fragmenting habitats or becoming barriers to the movement of animals[56]. It is also important to source raw materials for renewables in a way that ensures minimal damage to biodiversity.

**Increased landscape connectivity.** Creating corridors (for example restoring river corridors planting and connecting conservation efforts) and increased coverage of semi-natural ecosystems in intensively used landscapes will assist species migration and support ecosystem

resilience in a changing climate. Increasing green spaces in cities is vital for adaptation as they have a cooling effect and support biodiversity and its connectivity. They contribute to climate change mitigation through carbon storage, and enable many biodiversity-associated mental and cultural welfare benefits to urban people[57,58].

### Policy measures to discourage:

**Tree planting in inappropriate ecosystems.** Expanding tree cover in ecosystems that do not naturally support expansive tree cover (e.g. grasslands, grassland savannas, temperate peatlands) has negative consequences for biodiversity[59] and ecosystem functioning. In the case of peatlands, planting

trees can also have negative climate consequences by resulting in drainage and consequent release of soil carbon reserves.

**Monocultures.** Planting trees, either for bioenergy or as long-term carbon sinks, should focus on restoring and expanding native woodlands, as well as avoid creating large monoculture plantations that do not support high levels of biodiversity. Simple targets such as 'numbers of trees planted' ignore biodiversity considerations, such as long-term survival of trees or stewardship, and can be misleading, potentially contributing to policy failure and misuse of carbon offsets[32].

**Unsustainable energy crops.** The modelled benefits of Bioenergy with Carbon Capture and Storage (for example, the use of crops to generate power and fuel while capturing $CO_2$) to mitigate climate change are significant. However, the scale of some modelled deployments would either take up large amounts of land now used for food production or have negative effects on the amount of land available for preservation or restoration of natural ecosystems[60]. Policy should also limit use of fuelwood pellets and other feedstocks for bioenergy where it might intensify pressure on semi-natural ecosystems.

**Disempowerment of indigenous and local communities:** Biodiversity and climate change actions should recognise, respect and safeguard the rights and livelihoods of local and traditional users of ecosystems[61].

## Conclusion

Climate change and biodiversity are inherently connected and addressing them is central to achieving the SDGs. While a warming planet leads to biodiversity decline, NbS can contribute to both climate change mitigation and adaptation. However, climate change and biodiversity are governed separately at the international and often at national levels, hindering solutions that could address both issues.

By better integrating climate and biodiversity policies at international and national levels, the full potential of biodiversity to support climate action could be leveraged, whilst at the same time helping to reverse the ongoing decline in biodiversity[62].

Research shows that, although some degree of climate change and biodiversity loss are unfortunately now unavoidable, we still have time to limit profound consequences for people and the ecosystems on which we depend. The year 2021 could be one of the turning points in history, in which the international community collaborated to make a long-lasting difference by streamlining and integrating climate change and biodiversity policies and embarking on a pathway towards a stable climate and a vibrant biosphere.

## References:


1 IPCC. Summary for Policymakers. In: IPCC Special Report on the Ocean and Cryosphere in a Changing Climate. 2019. Available from: https://www.ipcc.ch/srocc/chapter/summary-for-policymakers/

2 IPCC. Special Report: Global Warming of 1.5°C. 2018. Available from: https://www.ipcc.ch/sr15/

3 UNEP. Emissions Gap Report. 2020. Available from: https://www.unep.org/emissions-gap-report-2020

4 Román-Palacios, C., & Wiens, J. J. (2020). Recent responses to climate change reveal the drivers of species extinction and survival. Proceedings of the National Academy of Sciences, 117(8), 4211-4217. www.pnas.org/cgi/doi/10.1073/pnas.1913007117

5 Ciais P, Sabine C, Bala G. Carbon and Other Biogeochemical Cycles. In: *Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change*. Cambridge University Press. Cambridge.

6 WWF. Living Planet Report. 2020. Available from: https://livingplanet.panda.org/en-us/

7 IPBES. Global assessment report on biodiversity and ecosystem services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services. 2019. Available from: https://www.ipbes.net/global-assessment

8 Díaz S, Settele J, Brondízio ES, Ngo HT, Agard J, Arneth A, et al. Pervasive human-driven decline of life on Earth points to the need for transformative change. *Science*. 2019 Dec 12;366(6471):eaax3100. Available from: http://dx.doi.org/10.1126/science.aax3100

9 Newbold T, Hudson LN, Hill SLL, Contu S, Lysenko I, Senior RA, et al. Global effects of land use on local terrestrial biodiversity. Nature. 2015 Apr;520(7545):45–50. Available from: http://dx.doi.org/10.1038/nature14324

10 Graham NAJ, Jennings S, MacNeil MA, Mouillot D, and Wilson, SK, Predicting climate-driven regime shifts versus rebound potential in coral reefs. *Nature* 2015. 518: 94-97. https://www.nature.com/articles/nature14140

11 Hughes TP, Kerry JT, Baird AH, Connolly SR, Dietzel A, Eakin CM, et al. Global warming transforms coral reef assemblages. Nature, 2018 556: 492-496. http://dx.doi.org/10.1038/s41586-018-0041-2

12 Di Marco M, Harwood TD, Hoskins AJ, Ware C, Hill SLL, Ferrier S. Projecting impacts of global climate and land-use scenarios on plant biodiversity using compositional-turnover modelling. *Glob Change Biol*. 2019 Jun;25(8):2763–78. Available from: http://dx.doi.org/10.1111/gcb.14663

13 Newbold T. Future effects of climate and land-use change on terrestrial vertebrate community diversity under different scenarios. *Proc R Soc B*. 2018 Jun 20;285(1881):20180792. Available from: http://dx.doi.org/10.1098/rspb.2018.0792

14 Dullinger S, Gattringer A, Thuiller W, Moser D, Zimmermann NE, Guisan A, et al. Extinction debt of high-mountain plants under twenty-first-century climate change. *Nature climate change*, 2012 2(8), 619-622. https://doi.org/10.1038/nclimate1514.

15 Warren R, Price J, Graham E, Forstenhaeusler N, VanDerWal J. The projected effect on insects, vertebrates, and plants of limiting global warming to 1.5°C rather than 2°C.

*Science*. 2018 May 17;360(6390):791–5. Available from: http://dx.doi.org/10.1126/science.aar3646

16 Seddon N, Chausson A, Berry P, Girardin CAJ, Smith A, Turner B. Understanding the value and limits of nature-based solutions to climate change and other global challenges. *Phil Trans R Soc B*. 2020 Jan 27;375(1794):20190120. Available from: http://dx.doi.org/10.1098/rstb.2019.0120

17 Solan M, Bennett EM, Mumby PJ, Leyland J, Godbold JA. Benthic-based contributions to climate change mitigation and adaptation. *Phil Trans R Soc B*. 2020 Jan 27;375(1794):20190107. Available from: http://dx.doi.org/10.1098/rstb.2019.0107

18 Griscom BW, Adams J, Ellis PW, Houghton RA, Lomax G, Miteva DA, et al. Natural climate solutions. *Proc Natl Acad Sci USA*. 2017 Oct 16;114(44):11645–50. Available from: http://dx.doi.org/10.1073/pnas.1710465114

19 Griscom BW, Busch J, Cook-Patton SC, Ellis PW, Funk J, Leavitt SM, et al. National mitigation potential from natural climate solutions in the tropics. *Phil Trans R Soc*. 2020 Jan 27;375(1794):20190126. Available from: http://dx.doi.org/10.1098/rstb.2019.0126


20 EASAC. EASAC Commentary: Key messages from European Science Academies for UNFCCC COP26 and CBD COP15 (2021; forthcoming)

21 Arneth, A., Shin, Y. J., Leadley, P., Rondinini, C., Bukvareva, E., Kolb, *et al.* Post-2020 biodiversity targets need to embrace climate change. *Proceedings of the National Academy of Sciences*, 2020 *117*(49), 30882-30891. https://doi.org/10.1073/pnas.2009584117

22 Leclère D, Obersteiner M, Barrett M, Butchart SHM, Chaudhary A, De Palma A, et al. Bending the curve of terrestrial biodiversity needs an integrated strategy. *Nature.* 2020 Sep 10; Available from: http://dx.doi.org/10.1038/s41586-020-2705-y

23 IPCC. Special Report: Global Warming of 1.5°C. 2018. Available from: https://www.ipcc.ch/sr15/

24 IPCC. Special Report: Climate Change and Land. 2019. Available from: https://www.ipcc.ch/srccl/

25 Coady, D., Parry, I., Piotr-Nghia L., Shang, B. 2019. Global Fossil Fuel Subsidies Remain Large: An Update Based on Country-Level Estimates. International Monetary Fund. Available from: https://www.imf.org/en/Publications/WP/Issues/2019/05/02/Global-Fossil-Fuel-Subsidies-Remain-Large-An-Update-Based-on-Country-Level-Estimates-46509

26 Dasgupta, P. The Economics of Biodiversity: The Dasgupta Review. London. HM Treasury. 2021. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962785/The_Economics_of_Biodiversity_The_Dasgupta_Review_Full_Report.pdf

27 United Nations Environment Programme. Making Peace with Nature: A scientific blueprint to tackle the climate, biodiversity and pollution emergencies. 2021. Available from: https://www.unep.org/resources/making-peace-nature

28 Rounsevell MD, Harfoot M, Harrison PA, Newbold T, Gregory RD, and Mace, GM. A biodiversity target based on species extinctions. *Science*, 2020 368(6496), 1193-1195. DOI: 10.1126/science.aba6592

29 Anderson CM, DeFries RS, Litterman R, Matson PA, Nepstad DC, Pacala S, et al. Natural climate solutions are not enough. Science. 2019 Feb 28;363(6430):933–4. Available from: http://dx.doi.org/10.1126/science.aaw2741

30 Girardin CAJ, Jenkins S, Seddon N, Allen M, Lewis SL, Wheeler CE, et al. "Nature-based solutions can help cool the planet—if we act now." 2021: 191-194. https://doi.org/10.1038/d41586-021-01241-2.

31 Cohen-Shacham E, Andrade A, Dalton J, Dudley N, Jones M, Kumar C, et al. Core principles for successfully implementing and upscaling Nature-based Solutions. *Environmental Science & Policy*. 2019 Aug;98:20–9. Available from: http://dx.doi.org/10.1016/j.envsci.2019.04.014

32 NbS Guidelines. Nature-based solution to climate change: key messages for decision makers in 2020 and beyond. [updated 13 Feb 2020; cited Feb 2021]. Available from: www.nbsguidelines.info

33 Nesshöver C, Assmuth T, Irvine KN, Rusch GM, Waylen KA, Delbaere B, et al. The science, policy and practice of nature-based solutions: An interdisciplinary perspective. *Science of The Total Environment.* 2017 Feb;579:1215–27. Available from: http://dx.doi.org/10.1016/j.scitotenv.2016.11.106

34 Seddon N, Smith A, Smith P, Key I, Chausson A, Girardin C, et al. Getting the message right on nature-based solutions to climate change. *Glob Change Biol.* 2021 Feb;27(8):1518–46. Available from: http://dx.doi.org/10.1111/gcb.15513

35 Halpern, B. S., Klein, C. J., Brown, C. J., Beger, M., Grantham, H. S., Mangubhai, S., et al. Achieving the triple bottom line in the face of inherent trade-offs among social equity, economic return, and conservation. *Proceedings of the National Academy of Sciences*, 2013 110(15), 6229-6234.

36 Palomo I, Dujardin Y, Midler E, Robin M, Sanz MJ, Pascual U. Modeling trade-offs across carbon sequestration, biodiversity conservation, and equity in the distribution of global REDD+ funds. *Proceedings of the National Academy of Sciences*, 2019 116(45), 22645-22650. Available from: http://dx.doi.org/10.1073/pnas.1908683116

37 Pascual, U., Phelps, J., Garmendia, E., Brown, K., Corbera, E., Martin, A., et al. Social equity matters in payments for ecosystem services. Bioscience, 2014 64(11), 1027-1036.

38 Díaz S, Zafra-Calvo N, Purvis A, Verburg PH, Obura D, Leadley P, et al. Set ambitious goals for biodiversity and sustainability. *Science.* 2020. Available from: http://dx.doi.org/10.1126/science.abe1530



39 UNCC. The next SCF forum – Finance for Nature-based Solutions. 2020. Available from: https://unfccc.int/topics/climate-finance/events-meetings/scf-forum/the-next-scf-forum-financing-nature-based-solutions

40 Mottet A, de Haan C, Falcucci A, Tempio G, Opio C, Gerber P. Livestock: On our plates or eating at our table? A new analysis of the feed/food debate. *Global Food Security*. 2017 Sep;14:1–8. Available from: http://dx.doi.org/10.1016/j.gfs.2017.01.001

41 FAO. Global food losses and food waste – Extent, causes and prevention. 2011. Available from: http://www.fao.org/3/a-i2697e.pdf

42 Crist E, Mora C, Engelman R. The interaction of human population, food production, and biodiversity protection. *Science*. 2017 Apr 20;356(6335):260–4. Available from: http://dx.doi.org/10.1126/science.aal2011

43 Roe S, Streck C, Obersteiner M, Frank S, Griscom B, Drouet L, et al. Contribution of the land sector to a 1.5 °C world. *Nat Clim Chang*. 2019 Oct 21;9(11):817–28. Available from: http://dx.doi.org/10.1038/s41558-019-0591-9

44 InterAcademy Partnership. Opportunities for future research and innovation on food and nutrition security and agriculture. 2018. Available from: https://www.interacademies.org/publication/opportunities-future-research-and-innovation-food-and-nutrition-security-and

45 Wezel A, Herren BG, Kerr RB, Barrios E, Gonçalves ALR, Sinclair F. Agroecological principles and elements and their implications for transitioning to sustainable food systems. A review. *Agron Sustain Dev*. 2020 Oct 27;40(6). Available from: http://dx.doi.org/10.1007/s13593-020-00646-z

46 Friedlingstein P, O'Sullivan M, Jones MW, Andrew RM, Hauck J, Olsen A, et al. Global Carbon Budget 2020. *Earth Syst Sci Data*. 2020 Dec 11;12(4):3269–340. Available from: http://dx.doi.org/10.5194/essd-12-3269-2020

47 InterAcademy Partnership. Communique on Tropical Forests from the InterAcademy Partnership. 2019. Available from: https://www.interacademies.org/publication/iap-communique-tropical-forests

48 Lewis SL, Wheeler CE, Mitchard ETA, Koch A. Restoring natural forests is the best way to remove atmospheric carbon. *Nature*. 2019 Apr;568(7750):25–8. Available from: http://dx.doi.org/10.1038/d41586-019-01026-8

49 UNEP. Peatlands store twice as much carbon as all the world's forests. 2019. Available from: https://www.unenvironment.org/news-and-stories/story/peatlands-store-twice-much-carbon-all-worlds-forests

50 Bain, C.G., Bonn, A., Stoneman, R., Chapman, S., Coupar, A., Evans, M., Gearey, B., et al. F. 2011. IUCN UK Commission of Inquiry on Peatlands. IUCN UK Peatland Programme, Edinburgh. Available from: https://repository.uel.ac.uk/item/86047

51 Leifeld J, Menichetti L. 2018. The underappreciated potential of peatlands in global climate change mitigation strategies. *Nat Commun*. 14;9(1). Available from: http://dx.doi.org/10.1038/s41467-018-03406-6

52 Gov.uk. Climate benefits of Marine Protected Areas revealed. 2020. Available from: https://www.gov.uk/government/news/climate-benefits-of-marine-protected-areas-revealed

53 InterAcademy Partnership. IAP Statement on Protection of Marine Environments. 2021. Available from: https://www.interacademies.org/statement/protection-marine-environments

54 Wind Europe. Offshore wind and fisheries: a win-win relationship is essential for the energy transition. 2020. Available from: https://windeurope.org/newsroom/news/offshore-wind-and-fisheries-a-win-win-relationship-is-essential-for-the-energy-transition/

55 Rees SE, Sheehan EV, Stewart BD, Clark R, Appleby T, Attrill MJ, et al. Emerging themes to support ambitious UK marine biodiversity conservation. *Marine Policy*. 2020 Jul;117:103864. Available from: http://dx.doi.org/10.1016/j.marpol.2020.103864

56 Gasparatos A, Doll CNH, Esteban M, Ahmed A, Olang TA. Renewable energy and biodiversity: Implications for transitioning to a Green Economy. *Renewable and Sustainable Energy Reviews*. 2017 Apr;70:161–84. Available from: http://dx.doi.org/10.1016/j.rser.2016.08.030

57 Wilkes P, Disney M, Vicari MB, Calders K, Burt A. Estimating urban above ground biomass with multi-scale LiDAR. *Carbon Balance Manage*. 2018 Jun 26;13(1). Available from: http://dx.doi.org/10.1186/s13021-018-0098-0

58 Bratman GN, Anderson CB, Berman MG, Cochran B, de Vries S, Flanders J, et al.. Nature and mental health: An ecosystem service perspective. *Science advances* 2019 5, no. 7 eaax0903. Available from: http://dx.doi.org/10.1126/sciadv.aax0903

59 Veldman JW, Overbeck GE, Negreiros D, Mahy G, Le Stradic S, Fernandes GW, et al. Where Tree Planting and Forest Expansion are Bad for Biodiversity and Ecosystem Services. *BioScience*. 2015 Sep 9;65(10):1011–8. Available from: http://dx.doi.org/10.1093/biosci/biv118

60 EASAC. The current status of biofuels in the European Union, their environmental impacts and future prospects. 2012. Available from: https://easac.eu/publications/details/the-current-status-of-biofuels-in-the-european-union-their-environmental-impacts-and-future-prospects/

61 Garnett, S. T., Burgess, N. D., Fa, J. E., Fernández-Llamazares, Á., Molnár, Z., Robinson, C. J., et al.. A spatial overview of the global importance of Indigenous lands for conservation. *Nature Sustainability*, 2018 1(7), 369-374. https://doi.org/10.1038/s41893-018-0100-6

62 InterAcademy Partnership. IAP Communique: Global Green Recovery after COVID-19: Using scientific advice to ensure social equity, planetary and human health, and economic benefits. 2021. Available from: https://www.interacademies.org/greenrecovery

## Academies that have endorsed the Statement on Climate Change and Biodiversity (October 2021)

Afghanistan Sciences Academy
Academy of Sciences of Albania
*Academia Nacional de Ciencias de Argentina*
*Academia Nacional de Medicina*, Buenos Aires
Bangladesh Academy of Sciences
*Académie Nationale des Sciences, Arts et Lettres du Bénin*
*Academia Nacional de Ciencias de Bolivia*
*Academia Nacional de Medicina*, Brazil
Brazilian Academy of Sciences
Cameroon Academy of Sciences
Royal Society of Canada
*Academia di Medicina*, Chile
Chilean Academy of Sciences
Chinese Academy of Sciences
Croatian Academy of Sciences and Arts
Cuban Academy of Sciences
Czech Academy of Sciences
Royal Danish Academy of Sciences and Letters
*Academia de Ciencias del Ecuador*
Academy of Scientific Research and Technology, Egypt
Ethiopian Academy of Sciences
Council of Finnish Academies
*Académie des Sciences*, France
*Académie Nationale de Médecine de France*
Georgian Academy of Medical Sciences
German National Academy of Science *Leopoldina*
Union of the German Academies of Sciences and Humanities
Ghana Academy of Arts and Sciences
Academy of Athens, Greece
Academy of Medical, Physical and Natural Sciences of Guatemala
National Academy of Sciences of Honduras
Hungarian Academy of Sciences
Indian National Science Academy
Indonesian Academy of Sciences
Academy of Sciences of IR Iran
*Accademia Nazionale dei Lincei*, Italy
Science Council of Japan
Royal Society of Jordan
Korean Academy of Science and Technology
National Academy of Sciences, Republic of Korea
*Académie des Sciences du Liban*
Macedonian Academy of Sciences and Arts
Mexican Academy of Sciences
Academy of Sciences of Moldova
Royal Netherlands Academy of Arts and Sciences
Royal Society *Te Apārangi*, New Zealand
Academy of Sciences of Nicaragua
Nigerian Academy of Science
Norwegian Academy of Science and Letters
*Academia Nacional de Ciencias del Peru*
National Academy of Science and Technology Philippines
Polish Academy of Sciences
*Academia das Ciencias de Lisboa*
Romanian Academy
Romanian Academy of Medical Science
Rwanda Academy of Sciences
Serbian Academy of Sciences and Arts
Singapore National Academy of Science
Slovak Academy of Sciences
Slovenian Academy of Sciences and Arts
Academy of Science of South Africa
National Academy of Sciences of Sri Lanka
Sudanese National Academy of Sciences
Royal Swedish Academy of Sciences
Swiss Academies of Arts and Sciences
Thai Academy of Science and Technology
Turkish Academy of Sciences
Uganda National Academy of Sciences
Academy of Medical Sciences, UK
Royal Irish Academy
Royal Society, UK
National Academy of Sciences, USA
*Academia de Ciencias Físicas, Matematicas y Naturales de Venezuela*
Zambia Academy of Sciences
Zimbabwe Academy of Sciences
African Academy of Sciences
European Academy of Sciences and Arts
Caribbean Academy of Sciences
Global Young Academy
Islamic World Academy of Sciences
The World Academy of Sciences
World Academy of Arts and Sciences

## Working Group

Yadvinder Malhi (chair)
Olusegun Adedayo Yerokun
Ruba Ajjour
Yvonne Buckley
Mercedes Maria da Cunha Bustamante
Marcelo Ruben Cabido
Suchana Chavanich
Gensuo JIA
Beth A. Kaplin
Szabolcs Lengyel
David Lindenmayer
Rene Pablo Capote Lopez
Ignazio Musu
Ignacio Palomo
Maria João Santos
Hashimoto Shizuka

IAP appreciates the initial contribution of the Zero Draft Committee members Yadvinder Malhi (chair), Sebsebe Demissew, Sandra Diaz, Nick Graham, Dame Georgina Mace, Isla Myers-Smith, Colin Prentice, Nathalie Seddon, Pete Smith and Martin Solan.



October 2021

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from: www.interacademies.org/statement/climate-change-and-biodiversity-interlinkages-and-policy-options

## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership

# IAP Statement on Implications of Urbanization in Low- and Middle-Income Countries

**In recent years, urban development in low-and middle-income countries (LMICs) has been the subject of serious discussion at the international level. In 2015, UN Member States adopted 17 Sustainable Development Goals (SDGs) among which SDG#11 was specifically about the sustainability of cities. In the following year, the outcome of the UN's Habitat III conference on a 'New Urban Agenda' was endorsed in its entirety by the UN General Assembly. Those two international events bind all countries globally to be cognizant of and to promote these recommendations. Even earlier, in 2012, population growth coupled with unplanned urbanization was recognized as being among the most serious concerns worldwide by the InterAcademy Partnership (IAP, 2012).**

The word 'urbanization' can have different interpretations. The interpretation here relates mainly to the migration of rural residents to urban areas and the growth of urban populations relative to that of rural populations in any particular country. Urbanization was associated with industrialization in 19th Century Europe and often resulted in economic growth experienced by those countries. Later, the mechanization of agriculture provided a further impetus towards urbanization. Thus, in the popular understanding of urbanization within LMICs, economic growth has come to be closely associated with urbanization. However, the economic conditions that spurred urbanization in the Western World are not the same as those causing urbanization in most LMICs today. A significant conclusion in an earlier IAP Statement (IAP, 1996) is that: "*As urban populations multiply, older technologies and practices – previously appropriate to settlement development – will not necessarily be the best solutions to these problems...*".

## The Urbanization Process in LMICs

Today, urbanization is happening almost exclusively in the LMICs. It can bring about significant positive dividends in terms of access to clean water, sanitation, more education and health opportunities (especially for women) and longer lifespans for all, but these dividends are not guaranteed. When the process is mismanaged as often happens, it results in serious inequity, social unrest and the rapid growth of informal settlements. Thus, policies dealing with urbanization along with appropriate planning instruments, processes and stronger urban management, are all deemed to be necessary to reduce the socioeconomic gaps that have steadily increased in LMICs. Framing relevant policies for LMICs requires a clear understanding of the origins, development and intricacies of the urbanization process currently being experienced.

A reliable prediction is that by 2035 all ten of the fastest growing cities in the world will be in sub-Saharan Africa (Uganda National Academy of Sciences, 2018). A relevant statistical study in an Asian LMIC (Datta, 2006) concludes that urbanization:

- induces growth of the largest cities;
- occurs often without industrialization;
- is mainly a consequence of demographic explosion and poverty-induced rural-urban migration;
- encourages the growth of informal settlements; and
- occurs more because of 'rural push' than 'urban pull'.

This interminable 'distress migration' directed often towards 'Primate Cities'[1], which have inordinately large populations, causes severe strains on the access to urban services and results in diminishing the quality of life for all urban residents in those cities. Other causes such as the exploitation of available natural resources have also encouraged urbanization in some countries. This has led to urbanization impacting new urban areas in proximity to such sites[2]. Land rent speculation

associated with colonial and post-colonial land management regimes have also led to uneven urbanization with negative outcomes for the poor. Today, urbanization is taking place in many ways in a number of LMICs[3]. Most of these increases in urban populations are centered in overcrowded and underserved informal settlements. These residents are in effect part of an 'informal city', which functions independently from and in parallel with the formal city (Roy, 2005). Even two decades ago, it was estimated that one billion people, or one in three urban dwellers, lived in these informal settlements (UN Habitat, 2003).

From the spatial point of view, many LMICs, especially the smaller agrarian countries, have some startlingly common characteristics. One is a skewed distribution pattern of towns referred to as 'dendritic distortion'. Another is 'primacy' where one city very substantially predominates over all other urban places in that country. The third is the presence of extreme poverty in some of their geographic regions. These latter are different from 'lagging regions' found in some industrialized countries. These impoverished regions often had resources but were not of interest to the respective colonial economies. Thus, colonial investments and built infrastructure were focused elsewhere. The prolonged neglect of such areas within these LMICs caused their extreme poverty.

The key similarities common to the LMICs in their dense urban contexts may be summarized as:

- inequality of access to social and other infrastructure, services and to housing;
- strong residential segregation, deepened by deficient public transportation systems;
- the existence of several forms of informal and often illegal systems of land occupation associated with housing scarcity;
- inadequate land-use management; and
- the inability of most urban local authorities to deal with these complex issues.

Also, there are some LMICs that also have other concerns in their urban areas which need to be recognized. These include:

- intense national population growth, including but not limited to urban areas;
- very high population densities within such urban areas;
- unsatisfactory housing units often

1 A 'primate city' is one that is disproportionately larger than the next city in rank in that country.

2 Apartheid South Africa, colonial Rhodesia (North & South) and Nyasaland had restrictions imposed on family members residing in rural areas on joining their spouses working in the cities. 'Independence' and removal of these restrictions saw a marked increased urbanization in these countries.

3 Between 1950 and 2018 the urban populations of: Africa increased from 33 million to 548 million; Asia increased from 246 million to 2.3 billion; and Latin America and the Caribbean increased from 70 million to 526 million (UN/DESA, 2019).

with poor sanitary facilities and waste disposal systems;
- authoritarian political processes and inadequate social participation in planning decisions;
- large primate cities and weak urban networks; and
- limited autonomy, power and resources within urban local authorities and also poor vertical coordination on relevant national issues and policies.

## Planning Approaches and Theories

A planning approach developed to guide rapid urban expansion in Britain more than a century ago (Howard, 1985) persists as a model still used in some former British colonies, although there is no evidence of its effectiveness in diminishing the current adversities of urbanization. The consequent inexorable expansion of informal settlements and the unsustainable growth of car-dominated low-density and expansive developments have become the urban realities in most LMICs. The application of exogenous development models is discouraged by knowledgeable planners and scholars in India (Shaw, 1985), Pakistan (Kugelman, 2014), Africa (Pieterse, 2014; Myers, 2011) and Latin America (Rojas, 2003; Díaz-Márquez, 2019). Important inadequacies in urban planning as practiced in LMICs have been thoroughly discussed elsewhere (Belsky *et al*, 2013).

An important study based on the continuing current trend of horizontal urban expansion through urbanization, predicts the tripling of urban land cover worldwide within the next three decades and the consequent adverse impact upon biodiversity. It also states that the main biodiversity 'hotspots' being affected by this trend are in the LMICs (Seto *et al*, 2012). A more recent study on cities in LMICs of over one million population shows that the majority of these cities are expanding outwards and not densifying (Mahtta *et al*, 2019). The main conclusion from these studies could even be that urbanization trends should be arrested and that cities must become denser through infilling, and not continue to spread outwards. LMICs need to preserve their agricultural land and habitats through compact and sustainable urban development. Furthermore, there is evidence that the more compact cities are correlated

with lower greenhouse gas emissions and higher productivity. Therefore the management of urbanization should best be undertaken by professionals working closely with the impacted communities and political authorities who all recognize their responsibility to promote the 'New Urban Agenda' and actively seek to achieve the United Nation's Sustainable Development Goal (SDG) #11: 'Sustainable Cities and Communities'.

There are now many scholars who have understood that:
- skewed national urban systems left behind as colonial legacies in the LMICs are of little use for national development;
- market forces alone cannot be expected to alter such distorted systems;
- urban local authorities must be

empowered with adequate resources and technical capacities;
- effective citizen participation and engagement are necessary to promote and achieve better living conditions in rapidly urbanizing LMICs; and
- community-based organizations (CBOs) and non-governmental organizations (NGOs) can play beneficial roles to support the urban poor.

Intervention at the national policy level is invariably needed to free an LMIC from such structural constraints, which would otherwise encourage ongoing unplanned urbanization. Multi-level governance is also essential, where national and sub-national policies are aligned with local strategies. Local efforts can be seriously constrained without such alignment.

An important observation by IAP (1996) is that: "*the potential for science to ameliorate or solve the problems of the world's multiplying cities has not been realized*". A review of spatial planning literature reveals much scholarship that could influence urban policy intervention. Science and technology can and should inform decision-making. The need also clearly exists for investment in research to improve spatial science and related technologies such as GIS, modelling, remote sensing, etc. Planning decisions should be taken in the light of the best available science and technology, while paying heed to traditional local knowledge, where relevant, for informed and inclusive decision-making.

Another important focus of notable planners and scholars is on the role of small and mid-sized towns in the promotion of the social and economic development of LMICs (Anon., 2018). Some researchers (Rondinelli, 1991) have even concluded that:

- colonial planning and economic policies, reinforced by post-colonial economic growth strategies of the 1950s and 1960s, were major causes of the rapid and extensive growth of some cities in many LMICs;
- urban development was generally prioritized over rural development;
- emphasis was frequently on modernizing the metropolitan economy while rural regions were often neglected and left impoverished; and
- in countries with dominant primate cities, few secondary mid-sized cities could grow large enough and have sufficiently diversified economies to attract rural migrants, stimulate agriculture and promote regional development.

Recognizing the importance of urban-rural linkages needed to achieve balanced regional development has been noted in respect of sub-Saharan Africa (Ugandan National Academy of Sciences, 2018) as well as in many other LMICs.

## Policy Needs and Options

More than 100 reviews of empirical studies across the LMICs and a large number of national programmes for small and mid-sized towns demonstrate that spatial programmes: "*can be a crucial component in attaining social and economic objectives such as increasing*

*the populations reached by basic services; increasing and diversifying agricultural production; and increasing the influence of citizens living in sub-national and sub-regional political and administration units*" (Hardoy and Satterthwaite, 1988).

In discussing small and mid-sized towns, one researcher (Kundu, 2019) states that: "*The declining government investment in infrastructure and basic amenities in these towns over the years contributed to increasing socio-economic disparities within the settlement structure.*" In mid-sized cities and large urban agglomerations investments should be made in infrastructure to improve mobility by public transport and accessibility to services. Urban planning programmes need to be integrated with land use policies to liberate land at low prices and reduce spatial and social segregation. Schemes of social zoning may be used to mitigate difficulties of land prices. This work should utilize as far as possible local knowledge and engage all stakeholders. This engagement is also useful for deciding on the type and nature of needed interventions.

Even where small towns with some infrastructure facilities exist, inadequate urban governance and poor management prevent the much needed extension of those services to their rural hinterlands (Bhagat, 2019). A United Nations publication (UN/ESCAP, 1979) states that: urban-rural inequality is a major problem in Asia; and that more attention should be paid to rural development to achieve a more balanced spatial growth between rural and urban areas and a more equitable distribution of the benefits of economic growth. These inequalities are also found in most LMICs in other continents. United Nations Member States agreed to support both the SDGs and the New Urban Agenda, calling for new inclusive approaches and synergies between urban and rural communities and space for integrated urban and territorial planning and development. The investment necessary for tackling the challenges in cities in many LMICs depends on the engagement of their national governments both in unitary and federalist countries, but also on the consideration of local specificities and demands. Furthermore, there should always be encouragement and space for social participation and democratic governance on decisions to be made by urban local authorities.

The relocation of such settlements and/or their vulnerable populations may be the safest available options.

Even assuming a committed approach to rural development, out-migration from rural areas for non-farm occupations is likely to continue in several world regions. In addition, climate change is increasingly impacting upon migration into cities. Rather than have these rural migrants target the larger cities, the more manageable scenario would be a gradual process whereby at least some migrants move to the mid-sized towns first. Then, movements to the large cities could be confined to the more urbanized migrants from mid-sized towns. This pattern of internal migration is referred to by some scholars as 'decentralized urbanization' (Sharma, 2019).

It is important to note that urban-based services in small and mid-sized towns not only require built infrastructure but also that people with urban-type skills are resident. As such skills are not readily available in the rural regions of most LMICs, urban settlement programmes designed to provide these skills from major urban areas to the small and mid-sized towns are a clear need (Gunaratna, 2000).

There is also an urgent need to recognize the vulnerability of human habitats due to the adversities of climate change. Of particular importance are:

- the many coastal towns and conurbations affected by sea level rise;
- landslide-prone areas in hilly terrains; and
- other urban areas that are exposed to frequent floods and also heat waves.

Public health should also be of special concern in urban planning (Abdullah, 2019). There is the need to counter the danger of the easy spread of epidemics in dense human settlements, a danger accentuated by urbanization. Low-income urban dwellers consequently and inevitably face the twin burden of communicable and non-communicable diseases.

Finally, cities being planned under all these identified initiatives, regardless of their size, must also be consciously and firmly guided by the United Nations' recommendation for a New Urban Agenda and SDG#11. Such planning would ensure that the results are sustainable and to the benefit of all, including dwellers in informal urban settlements who otherwise are all too often excluded from the many benefits of urban life.

## Recommendations

In the light of the foregoing discussions, findings and arguments, key recommendations relating to intervention by national policies on urbanization in the LMICs include the need for:

I. Greater reliance upon science-based approaches in urban and regional planning;
II. Extensive investment in research focused on the varied problems of the urbanization phenomenon as is manifest in LMICs;
III. Planned urbanization as opposed to ad hoc planning;
IV. Planned investment in all types of urban infrastructure including physical, social and economic;
V. A concurrent focus on agriculture and rural development to ensure that urbanization will be an equitable process at the national and sub-national regional levels;
VI. Planned spatial and economic development of small towns with efficient urban governance to provide access to social and economic infrastructure for their residents and also, importantly, for their respective rural hinterlands;
VII. Planned spatial and economic development of mid-sized towns with efficient urban governance to function *inter alia* as ready target locations for rural migrants as alternatives to the largest cities;
VIII. Planned development of cities that ensure densification rather than allowing the ecologically damaging horizontal spread into rural land;
IX. Planned development of cities to include the fostering of healthy lifestyles *inter alia* through the provision of safe access to outdoor physical exercise and to green spaces;
X. Recognizing the serious health hazards that are inherent and difficult to combat within dense informal settlements in large cities;
XI. Providing substantial investment in affordable and social housing including the development of informal settlements;
XII. Monitoring land uses in large metropolises to make them more compact;
XIII. Development of sustainable and efficient public transportation systems accessible to and affordable by all citizens;
XIV. Public programmes for the *in situ* upgrading of informal settlements to provide basic infrastructure and also prevent displacement or their resettlement elsewhere;
XV. Empowering urban local authorities for decision-making and to be coordinated vertically to national urban policies in both Unitary and Federalist countries; and
XVI. Positive action by agencies at all levels in respect of the political commitments made on the UN's 'New Urban Agenda' and the SDGs, with special attention to SDG#11.

## References:


Abdullah, K.A. bin (2019). 'Urbanization and emerging infectious diseases' Workshop Report, 'Managing Urbanization in Asia', National Academy of Sciences Sri Lanka. https://www.interacademies.org/news/managing-urbanisation-asia

Belsky, E. et al. (2013). Advancing inclusive and sustainable urban development: Correcting planning failures and connecting communities to capital. Cambridge, MA, USA. https://www.jchs.harvard.edu/research-areas/reports/advancing-inclusive-and-sustainable-urban-development-correcting-planning

Bhagat, R.B. (2019). 'Nature of urbanisation and urban policies in India'. Workshop Report, 'Managing Urbanization in Asia', National Academy of Sciences Sri Lanka. https://www.interacademies.org/news/managing-urbanisation-asia

Datta P. (2006). 'Urbanisation in India'. European Population Conference, Liverpool (UK), 21-24 June 2006. http://160592857366.free.fr/joe/ebooks/ShareData/Urbanisation+in+India.pdf

Díaz-Márquez, A. (2019). Revisión bibliográficasobre la circulación de ideas urbanasen. América Latina y el caribe. *Revista De Estudios Urbano Regionales*, 45(134). Santiago de Chile.

Gunaratna, L.K. (2000). 'Accelerating regional development'. In: Indraratna A.D.V.de S. (ed) 'A quarter century of Mahaweli: Retrospect and prospect'. National Academy of Sciences Sri Lanka, Colombo, pp. 266-268.

Hardoy, J.E. and Satterthwaite, D. (1988). Small and intermediate urban centres in the Third World: What role for government?' *Third World Planning Review*, J. Liverpool, UK, p 8. http://www.eure.cl/index.php/eure/article/view/2656/1169

Howard, E. (1985) 'Garden Cities of Tomorrow' (revised edition) Attic Books, Eastbourne (UK). First published as 'A Peaceful Path to Real Reform' London, 1898.

IAP (2012). IAP Statement on Population and Consumption. https://www.interacademies.org/statement/iap-statement-population-and-consumption

IAP (1996). IAP Statement on Urban Development. https://www.interacademies.org/index.php/statement/iap-statement-urban-development

Kugelman, M. (2014). M. Kugelman (ed) 'Pakistan's runaway urbanization: What can be done?' Woodrow Wilson International Center for Scholars, Washington DC, 2014.

Kundu, A. (2019). 'Urbanization and industrialization in Asian countries: The spectre of premature deindustrialisation'. Workshop Report, 'Managing Urbanization in Asia', National Academy of Sciences Sri Lanka. https://www.interacademies.org/news/managing-urbanisation-asia

Mahtta, R., Mahendra, A., Seto, K.C. (2019). Building up or spreading out? Typologies of urban growth across 478 cities of 1 million+, *Environmental Research Letters*, 14:124077. https://iopscience.iop.org/article/10.1088/1748-9326/ab59bf/meta

Myers, G.A. (2011). African Cities: Alternative Visions of Urban Theory and Practice. Zed Books, London/New York.

Pieterse, E. (2014). Filling the void: an agenda for tackling African urbanization. In: E. Pieterse and S. Parnell (eds). Africa's Urban Revolution. pp: 200-220. Zed Books, London/New York.

Rojas, E. (2003). Las regiones metropolitanas de América Latina. Problemas de gobierno y desarrollo. In 'Gobernar las Metrópolis', pp. 35-62. Interamerican Development Bank, Washington DC. http://www.economia.unam.mx/cedrus/pdf/Gobernar_las_metropolis.pdf#page=37

Rondinelli, D.A. (1991). Asian urban development policies in the 1990s: From growth control to urban diffusion, *World Development J.*, 19(7): 791-803.

Roy A. (2005), Urban Informality: Toward an Epistemology of Planning. *Journal of the American Planning Association*, 71(2): 147-158.

Seto, K.C. *et al* (2012) Global forecasts of urban expansion to 2030 and direct impacts on biodiversity and carbon pools. *Proceedings of the National Academy of Sciences* http://www.pnas.org/content/early/2012/09/11/1211658109

Sharma, P. (2019). 'Population Monograph of Nepal'. Workshop Report, 'Managing Urbanization in Asia', National Academy of Sciences Sri Lanka. https://www.interacademies.org/news/managing-urbanisation-asia

Shaw, A. (1995). Satellite town development in Asia: The case of new Bombay, India. *Urban Geography J.* 16(3): 254-271.

Uganda National Academy of Sciences (2018). Owning Our Urban Future: Enabling Healthy Cities in Eastern Africa Academies of Ethiopia and Uganda, and the African Centre for Global Health and Social Transformation. https://www.researchgate.net/blication/332672228_Owning_our_Urban_Future_Urban-Rural_Linkages_for_Balanced_Regional_Development_in_Africa

United Nations, Department of Economic and Social Affairs, Population Division (2019). World Urbanization Prospects: The 2018 Revision (ST/ESA/SER.A/420). New York: United Nations.

UN/ESCAP (1979). Guidelines for Rural Centre Planning. UN, New York, pp. 87-89.

UN Habitat (2003). In 'The Challenge of Slums: Global report on human settlements 2003. https://unhabitat.org/the-challenge-of-slums-global-report-on-human-settlements-2003

Anon (2018). Republished Kathmandu seminar (1978) proceedings, Group II report: 'South Asian Seminar on Small and Medium Sized Towns in Regional Development'. See Annex A in K.L. Gunaratna, 'Towards Equitable Progress: Essays from a South Asian perspective', Springer, Singapore 2018. https://link.springer.com/content/pdf/bbm%3A978-981-10-8923-7%2F1


## Academies that have endorsed the Statement on Implications of Urbanization in Low- and Middle-Income Countries (September 2022)

Afghanistan sciences academy
Algerian Academy of Science and Technology
National Academy of Medicine, Buenos Aires
National Academy of Sciences of Argentina
National Academy of Sciences or the Republic of Armenia
Bangladesh Academy of Sciences
*Académie royale de Médecine de Belgique*
*Academia de Ciencias de Bolivia*
Brazilian Academy of Sciences
Cameroon Academy of Sciences
Chilean Academy of Sciences
Chinese Academy of Engineering
Chinese Academy of Sciences
Colombian Academy of Exact, Physical and Natural Sciences
*Academia de Ciencias de Cuba*
Czech Academy of Sciences
Royal Danish Academy of Sciences and Letters
Academy of Sciences of Ecuador
Academy of Scientific Research and Technology, Egypt
Estonian Academy of Sciences
Council of Finnish Academies
*Académie Nationale de Médecine*, France
German Academy of Science, *Leopoldina*
Union of the German Academies of Sciences and Humanities
Georgian Academy of Medical Sciences
Ghana Academy of Arts and Sciences
*Academia de Ciencias Medicas, Fisicas y Naturales de Guatemala*
National Academy of Sciences of Honduras
Indian National Science Academy
Indonesian Academy of Sciences
Academy of Sciences of the Islamic Republic of Iran
Royal Irish Academy
*Accademia Nazionale dei Lincei*, Italy
Science Council of Japan
Kenya National Academy of Sciences
Korean Academy of Science and Technology
National Academy of Sciences, Republic of Korea
Latvian Academy of Sciences
*Académie des Sciences du Liban*
Academy of Sciences Malaysia
Mexican Academy of Sciences
Mongolian Academy of Sciences
Nepal Academy of Science and Technology
Royal Netherlands Academy of Arts and Sciences
Academy of Sciences of Nicaragua
Nigerian Academy of Science
Palestine Academy for Science and Technology
Pakistan Academy of Sciences
National Academy of Science and Technology Philippines
Polish Academy of Sciences
Academy of Medical Sciences of Romania
Romanian Academy
Rwanda Academy of Sciences
Academy of Science of South Africa
Serbian Academy of Sciences and Arts
Singapore National Academy of Science
National Academy of Sciences of Sri Lanka
Sudanese National Academy of Sciences
Royal Swedish Academy of Sciences
Tanzania Academy of Sciences
*Académie tunisienne des sciences, des lettres et des arts "Beït al-Hikma"*
Uganda National Academy of Sciences
Academy of Medical Sciences, UK
Royal Society, UK
*Academia Nacional de Medicina del Uruguay*
National Academy of Sciences of Uruguay
US National Academy of Medicine
US National Academy of Sciences
Zambia Academy of Sciences
Caribbean Academy of Sciences
Islamic World Academy of Sciences
The World Academy of Sciences for the advancement of science in developing countries (UNESCO-TWAS)
World Academy of Art and Science

## Working Group

K. Locana Gunaratna, Sri Lanka (Chair)
Eduardo Cesar Leão Marques, Brazil
Yansui Liu, China
Franco Angela, Colombia
Diaz Angela, Ecuador
Tiit Tammaru, Estonia
Jacob Songsore, Ghana
Liana Ricci, Ireland
Okabe Akiko, Japan
Robert Obudho, Kenya
Madeline Berma, Malaysia
Kumar Karna Suman, Nepal
Qasim Jan, Pakistan
Philip Harrison, South Africa
Brij Maharaj, South Africa
Caroline Knowles, UK
Galea Sandro, USA
Karen C. Seto, USA
Francis M. Ndilila, Zambia



September 2022

iap SCIENCE HEALTH POLICY
the interacademy partnership

## The InteracAdemy Partnership

Under the umbrella of the InterAcademy Partnership (IAP), more than 140 national, regional and global member academies work together to support the vital role of science in seeking evidence-based solutions to the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals. Statements such as this one are prepared by a working group comprising experts nominated by member academies, and are released once they have been endorsed by more than half the member academies of the network.



Additional copies of this statement can be downloaded from: www.interacademies.org/statement/iap-statement-implications-urbanization-low-and-middle-income-countries

## Contacts

iap@twas.org

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**

iap SCIENCE HEALTH POLICY
the interacademy partnership

**IAP Science and IAP Health**
The World Academy of Sciences (TWAS)
ICTP campus • Strada Costiera 11 • 34151 Trieste, Italy
***iap@twas.org***

**IAP Policy**
The US National Academies of Sciences, Engineering and Medicine
500 Fifth Street, NW • Washington, DC, 20001, USA
***secretariat@iapartnership.org***

@IAPartnership
www.linkedin.com/company/interacademypartnership
https://tinyurl.com/IAPyoutube

**www.interacademies.org**