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From Patient Reported Outcome Measure (PROM) to Environment Related Outcome Measure (EROM): Towards "Green Breast Surgery"

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Abstract. *Climate change is a global issue that has had significant impacts on public health and healthcare policy worldwide. The direct impact of climate change on healthcare has been associated with extreme weather events, resulting in a higher demand for disaster management resources and reduced healthcare access. Moreover, the increase of zoonotic spillover effects has increased the risk of transmission of different diseases, including COVID-19. The healthcare industry alone is responsible for 4.4% of greenhouse gas global emissions. The surgical theatre is a resource-intense healthcare activity and a major carbon emitter, thus surgical processes require rethinking. This article proposes the introduction of environmental-related outcome measures in clinical trials, which will associate highest clinical standards to a reduced impact of care on climate change. Breast cancer care may represent a model disease for the implementation of evidence-based protocols, such as Green Breast Surgery, aiming to optimize the carbon footprint of care without affecting oncological and non-oncological outcomes. Physicians and healthcare workers worldwide should be aware of the importance of addressing environmental issues in healthcare policy, implementing programs to reduce their carbon footprint, and contributing to a more sustainable future.*

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Since the mid-eighteenth century, a steady increase of global temperature has been registered, especially between 1980s and 2020s, with an anomalous increase of nearly 1.00˚C in 2020. Climate change has been associated in the last years with an increase in the number of environmental events and disasters (1). Most scientists argue that the main cause of global warming is the anthropogenic emission of greenhouse gases (GHG) [*e.g.*, carbon dioxide (CO_2), methane (CH4), and nitrous oxide (N_2O)] (Table I). In order to contain GHG emission and avoid global temperature increase >2.0˚, 196 delegates during the 21st United Nations Conference of the Parties on Climate Change COP21 in Paris agreed voluntarily to reduce their greenhouse emission. For instance, the European union aims to reduce its GHG emission by 50% before 2030 and reach carbon neutrality in 2050 (2). The GHG emission reduction is a part of the larger Sustainable Development Goals declared by United Nations (UN) in 2015 in addition to end poverty and enhance human lives (3). Whereas good health and well-being are reported as the third goal of this program, the UN underlined how global warming counteraction should not interfere with health care admission worldwide. To achieve these crucial goals, a tremendous effort must be made by every single citizen of the world.

Climate change has a direct impact on global health care and health policy worldwide, mostly on the marginalized and lower income population. The higher rate of extreme weather events requires higher resources for disaster management, trauma, and mental health care, reducing health care resources assigned to elective and preventive measures (4, 5). Direct economic damage is only a small part of the effect on heath care policy, only in 2021 253 billion US dollars were spent for disaster management especially in low Human Development Index (HDI) countries, where most of these expenses are covered directly by the population, potentially

Table I. *Definition of non-medical terms to understand the green surgery protocol philosophy; the terms are enlisted as they appear in the text.*

Greenhouse gas emission	Greenhouse gas (GHG) enlists anthropic produced gases such as carbon dioxide (CO_2), methane, nitrous oxide, and fluorinated gases, that contribute to heat entrapment in the atmosphere.
Carbon neutrality	According to the definition of the Intergovernmental Panel on Climate Change (IPCC), carbon neutrality, or net zero CO_2 emissions, refers only to carbon dioxide emissions and is a state of balance between the CO_2 emitted into the atmosphere and the CO_2 removed from the atmosphere.
Human development index (HDI)	HDI is a summary measure of average achievement in key dimensions of human development: a long and healthy life, being knowledgeable and having a decent standard of living. The HDI is the geometric mean of normalized indices of each of the three dimensions (50).
Gross domestic product (GDP)	GDP measures the monetary value of final goods and services—that is, those that are bought by the final user – produced in a country in a given period of time (say a quarter or a year).
Carbon dioxide equivalent (CO_2e)	A metric measure used to compare the emissions from various greenhouse gases on the basis of their global-warming potential (GWP), by converting amounts of other gases to the equivalent amount of carbon dioxide with the same global warming potential.
Carbon footprint	Carbon footprint is the total amount of greenhouse gases (including carbon dioxide and methane) that are generated by our actions.

reducing health care access (6, 7). Moreover, heat waves and direct heat exposure have been associated with a potential loss of 470 billion labor hours globally in 2021, equivalent to 0.72% of global economic output, and 5-6% of gross domestic product (GDP) in low HDI countries (6).

Besides economic side effects, a robust body of evidence demonstrates how GHG rising, heat waves, wildfires or other natural disaster may also affect public health by increasing the rate of cardiovascular diseases, respiratory disorders, allergies, and oncological diseases (8). While respiratory disorders (as asthma or Chronic obstructive pulmonary disease) may be easily associated with the inhalation of air pollutants, multiple cardiovascular effects have been recorded after exposure to air pollutants (9). Short-term exposure has been associated with hypertension, stroke, myocardial infarctions, and heart insufficiency, coronary atherosclerosis, ventricular hypertrophy are reported to occur in humans after long-time exposure to pollutants (10-12). Inflammation and long-term pollutant exposure have been related to psychosocial, neurological and skin disorders (13, 14).

Moreover, a relationship has been reported between oncological diagnosis and climate change. An increased exposure to several carcinogenic agents has been associated with climate change (air pollution, chemical toxicants, ultraviolet radiation). Moreover, health behavior including the diet, physical activity, and sun protection may be impaired or modified by different consequences of climate change such as air pollution, chemical toxicants, ultraviolet radiation, food supply, and infections (15).

Additionally, the increase of zoonotic spillover effects is a well-documented consequence of the climate change. In fact, deforestation, urbanization, and width of the arid tropical edge plays a pivotal role in the expansion of the arthropod vector range for emerging diseases (16, 17). For instance, health care policy is currently facing an increase of Vibrio pathogen transmission due to coastal water rising temperature worldwide, an increase of 31.3% of months suitable for Malaria spread in America, and an increase of dengue transmission by 12% in the same period (6). The climate change pressure to the health system due to zoonotic and emerging diseases is expected to rise also because of the coexistence of pandemics by different pathogens (*e.g.*, COVID-19 and Dengue fever) in regions of South America, Asia, and Africa.

Under this perspective, COVID-19 pandemic represents the most famous example of zoonotic spillover (5, 18). Declared pandemic in march 2020, COVID-19 had a strong effect on elective surgery and health care policy worldwide (19, 20). Frail population, most of them requiring surgical or medical treatments, avoided hospital due to fear of cross infections and the higher perceived risk of mortality (21, 22). For instance, during the pandemic a mean reduction of 48.4% in admissions for acute myocardial failure was reported in Italy when compared with the previous year and up to 40% of breast oncological surgery were not performed during the highest peak of COVID-19 transmission (23). As an unexpected stressor for health care facilities, COVID-19 required urgent publication of temporary guidelines and fast change in clinical daily practice (20, 24, 25). Most of the countries adopted lockdown measures that required physicians to embrace innovative solutions such as telehealth applications and fast track protocols to sustain non-COVID-19 pathology treatments with limited resources, reducing the time spent in hospital (26-28). However, despite of economic, social, and health shock, COVID-19 seems to have a positive effect on the environment, through improvement in air quality, reduction in GHG emission, and mitigation of other pollutants due to the reduced human mobility (29). Even the health care industry was not immune to this effect; a monocentric study demonstrated how strong telehealth application in postoperative setting may

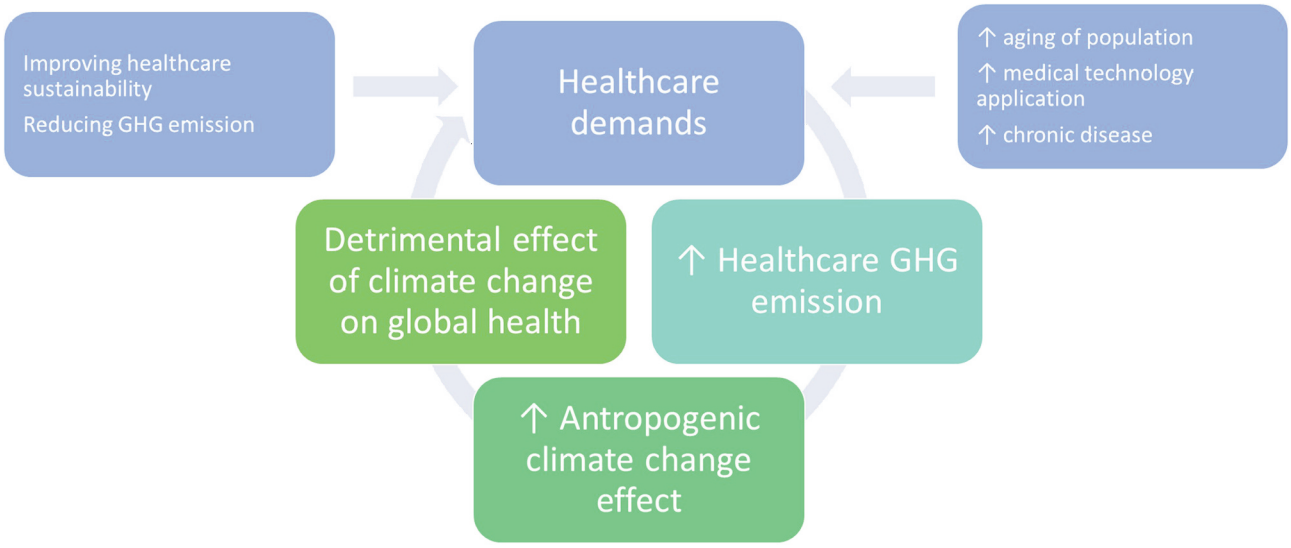

Figure 1. *Relationship between healthcare demands, climate change, and the role of improving sustainability.*

reduce GHG emission due to reduction in patient transportation without a higher postoperative complication rate, but with a high patient satisfaction (30).

In fact, the healthcare industry is the most important anthropic pollutant, and is responsible for 4.4.% of GHG global emission, 10% in US, and 25% in UK (31, 32). If assumed as a single country, all the health care processes were classified as the fifth larger world emitter (33). Every year, over 1.7 million tons of plastic waste are produced by US healthcare industries and this value is likely to rise up due to the increase in single-use plastics (33). Among different specialties, surgery, surgical treatment, and surgical theatre are intense health care activities, requiring expensive equipment, sterilization, and a complex supply chain (32). It has been estimated that up to 70% of GHG from health care industries are produced in surgery rooms and that a single operation may produce between 6 kg and 814 kg carbon dioxide equivalent (CO_2e), the same amount of CO_2e produced by an average petrol car traveling 2,273 miles. Anesthetic gases, consumable supply chain, and electricity usage are the major carbon emitters, requiring to rethink the surgical daily process (34, 35).

Human health and environment health are strongly interdependent, but if the direct effect of climate change on public healthcare has been largely described in the text, physicians should be aware that the same connection may be found between health care policy and climate change (34). As displayed in Figure 1, aging of the population, innovation in health care, and rise of chronic diseases are expected to increase health care demands especially in low HDI countries in the future, increasing the healthcare GHG emission and having detrimental effects on the environment and therefore global health. Under this perspective, health care providers must be aware than every single action during their daily clinical practice may have a long-lasting effect on climate change and future health care policy. Starting from this new sensibility, several authors began to explore several strategies to reduce the carbon footprint of care in various clinical settings (31, 33-38). For instance, regarding surgical procedure, while waste reduction, recycling, and segregation are well-known simple and easy applicable measures, the balance between single-use and reusable materials need to be further investigated (35). Moreover, modern anesthetic gas management is a neglected cause of GHG emission in the atmosphere, which can determine a small, but significative impact on yearly GHG emission (39). Finally, smart controlled surgery rooms may increase hospital efficiency in terms of heating, ventilation, and air conditioning (HVAC). In fact, HVAC energy systems are responsible for 90-99% of the overall energy used in surgical rooms, and its rationalization on occupancy-based ventilation strategies may reduce unnecessary airflow and up to 50% of energy costs.

Considering these data is the opinion of the authors that there is need for a revolution in the way of thinking delivery of care, addressing clinical outcomes, patient reported outcome measures (PROM), and environmental impact. Environment related outcome measures (EROM) as carbon footprint or GHG emission should be introduced in clinical trials to determine a clinical pathway with the highest clinical standard and a reduced impact of care on climate change, for instance combining innovation of tissue

engineering in transplantation and sustainability or evaluating mini-invasive techniques in terms of GHG emissions and carbon footprint (30, 40, 41). Physician and health care workers should be aware that health systems worldwide are implementing (*e.g.*, delivering a net zero NHS by England NHS) zero-carbon programs to reduce their carbon footprint (42).

Under this perspective, breast cancer (BC) may represent a model disease where different strategies may be easily applied for many reasons. First, BC is the leading oncological diagnosis worldwide with more than 2 million women are diagnosed, yearly (43, 44). In fact, breast surgery, due to the high number of procedures yearly and the short surgical room occupancy, is a notable contributor to this environmental and subsequent financial burden (*e.g.*, prosthetic surgery) (45). Paradigmatic shift and preoperative marker evaluation in breast cancer care (46-48) has allowed a reduction in surgical impact, ensuring a de-escalation of surgery while maintaining oncological safety, providing a model for a replicable, awake, and fast surgery, which could be easily studied as a model disease to implement EROM in clinical trials and to evaluate treatment efficacy (49). Following calculation of the carbon footprint of different breast cancer surgeries, our research group aims at proving breast cancer care green protocols (Green Breast Surgery) to obtain an evidence-based protocol, which could reduce the carbon footprint of BC care with non-inferior oncological and non-oncological outcomes.

Conflicts of Interest

The Authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Authors' Contributions

Conceptualization: Oreste Claudio Buonomo, Gianluca Vanni, Marco Materazzo. Data curation: Marco Pellicciaro, Davide Marino Investigation: Oreste Claudio Buonomo, Marco Materazzo, Gianluca Vanni. Writing – original draft: Marco Materazzo and Oreste Claudio Buonomo. Writing –- review and editing: Gianluca Vanni. All Authors read and agreed to the submitted version of the article.

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