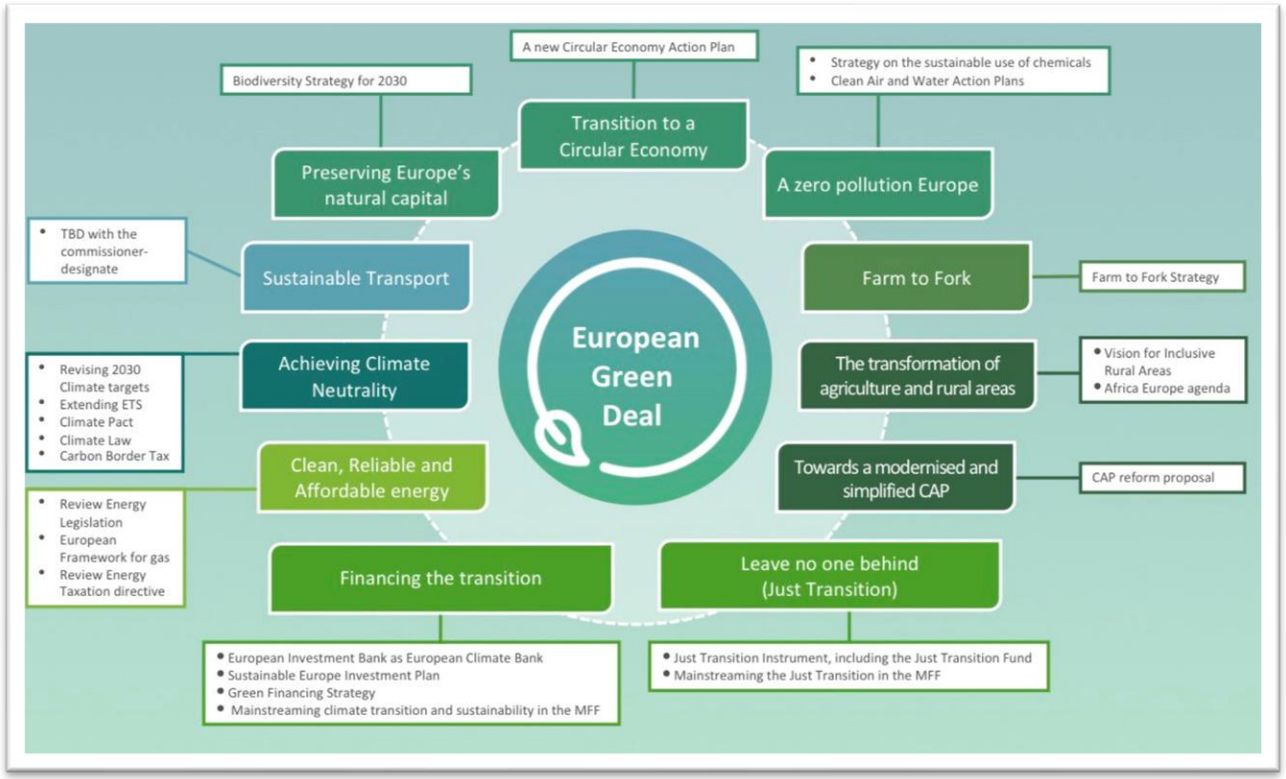
Environment / Sustainability in Health: drivers for change by the pharmaceutical industry

Kirsty Reid (EFPIA) and Dr Fiona Adshead (Sustainable Healthcare Coalition)

11 June 2024

European Green Deal

- The **European Green Deal** was launched by the Commission in December 2019.
- The European Green Deal is a package of policy initiatives, which aims to set the EU on the path to a **green transition**, with the ultimate goal of reaching climate neutrality by 2050.



Climate, Patients, Supply, Innovation and Regulatory Flexibility

Climate

Focused on achieving environment, sustainability and climate targets.

Global and EU legislation (E.g., Climate for action, Green Deal, REACH, the Montreal Protocol and Kigali amendment etc) **will increasingly impact supply of medicinal products.**

Patients

Changes to regulations and products can negatively impact supply.

It is vital to ensure **that critical medicines remain available to patients globally.**

Innovation and Regulatory Flexibility

General principles applied to all changes to enable sustainable medicines' supply.

- Reducing the climate and enviroment impact of medicines through introduction of alternative manufacturing processes and materials is a key area of innovation.

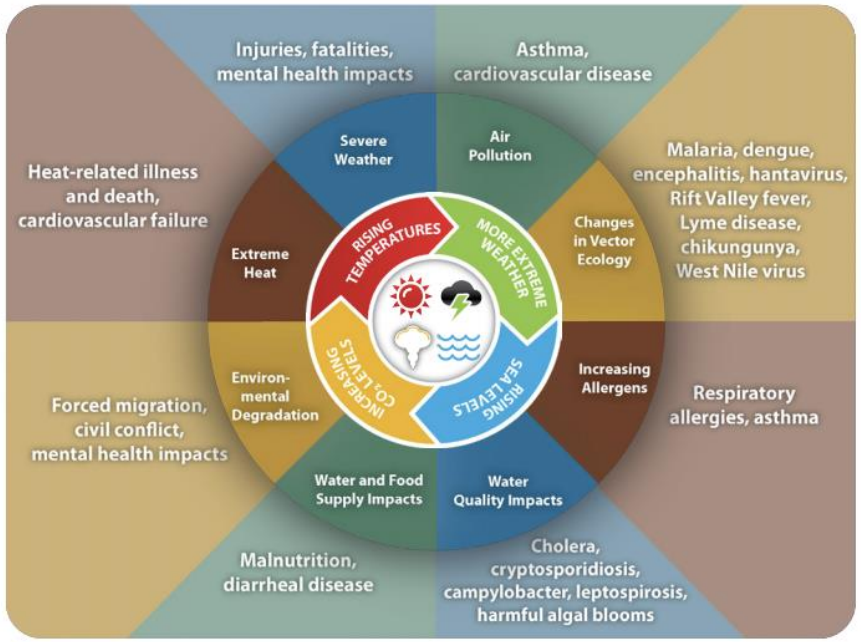
EU medicines regulators can play a vital role in enabling innovation to support climate and environment goals.

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Combatting Climate Change



- An EFPIA survey observed a **10% cut in scope 1 and scope 2 CO_2 emissions between 2020 and 2022**. This is equivalent to 1.5 million tons of CO_2 and was achieved despite a significant net sales increase.
- **95% of EFPIA companies engage with downstream suppliers** on climate action targets.
- **70%** have long-term targets for reducing scope 3 emissions generated by suppliers, and **45%** have short-term targets.
- **80%** of survey respondents reported using the greenhouse gas protocol (GHP)
- Benchmarked against high-impact industry sectors (such as chemicals), the pharmaceutical sector's global CO_2 emissions are reported to be **about 10 times lower in absolute emissions**

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Pharmaceuticals in the Environment

iPiE → PREMIER
PRIORITISATION AND RISK EVALUATION OF MEDICINES IN THE ENVIRONMENT

MEDSDISPOSAL → campaign to **raise awareness** on how to dispose of **unused or expired medicines** appropriately in Europe

MANUFACTURING EFFLUENTS MANAGEMENT *Technical guidance* → *Establish a shared set of principles to identify and mitigate the potential impacts of active pharmaceutical ingredients (API) in wastewater from manufacturing operations.*

eERA *Proposal for an extended ERA* → *Designed to strengthen the current ERA process and industry's commitment to conduct robust and risk-based ERAs without compromising environmental protection or patient access to medicines across the life cycle of the API.*

EPR → *Balancing challenges on Urban Wastewater Treatment with access to Medicines in Europe.*
I

amr INDUSTRY ALLIANCE → *Responsible supply chain management and better business conditions across the industry.*

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains → *Common antibiotic manufacturing framework and science-based assessments effectively control antibiotic releases*

EDQM 1964 - 2024 · COUNCIL OF EUROPE 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Sustainable Chemicals

EDQM driven activities

Concrete actions

- Avoid and reduce use of hazardous reagents (replacing hexane by heptane, reduce use of chloroform, dioxane, etc.)
- Reduce the amounts of solvents
- Avoid use of Mercury and mercury compounds

Restrictions stemming from EU legislation

- Replacement of substances of very high concern
- New amendment to annex XIV of REACH: DEHP as PVC plasticizer
- EU regulations on fluorinated gases
- Impact on anesthetics and propellants and heating systems

Future considerations – planning ahead

- Restrictions planned for Polyfluoroalkyl substances (PFAS) (Awaiting decisions on the scope of the restriction)
- PVC and additives – waiting on Commission restriction proposal

EU Strategy for Sustainable Chemicals

- Published in October 2020
- **Actions**
  - **ban** the most harmful chemicals in consumer products
  - **phasing out** the use of per- and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential
  - **boosting the investment and innovative capacity** for production and use of chemicals that are safe and sustainable by design
  - promoting the EU's **resilience of supply and sustainability** of critical chemicals
  - establishing "**one substance one assessment**" process
  - **Lead globally** by championing and promoting high standards and not exporting chemicals banned in the EU

Industry is active

- Supports substitution however must avoid regretable substitution
- Public private partnership opportunities
- Close consideration of supply chain risk and possible shortages of medicines

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Animal Welfare

History of 3Rs at EDQM
(Human and Veterinary)

2012 - 2020

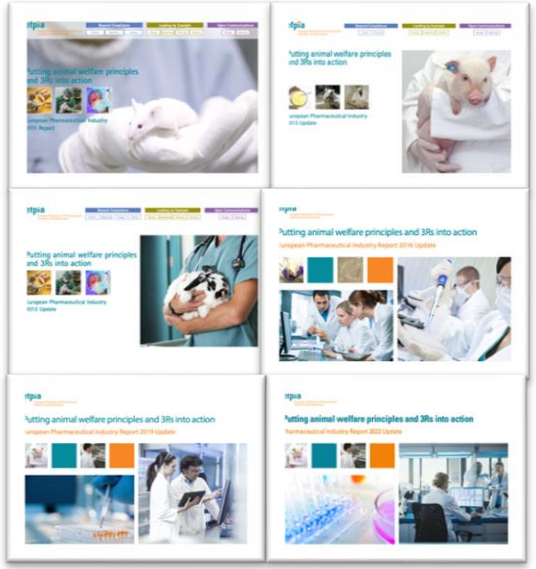
- ✓ Reduction of unnecessary use of animals in pertussis vaccines
- ✓ Adoption of 80 vet vaccine monographs reducing the number of animals used in testing
- ✓ ELISA alternative introduced in *Assay of hepatitis A vaccine*
- ✓ Revision of testing strategy for extraneous agents
- ✓ Revision of general monograph *Vaccines for veterinary use (0062)*: reduction of animal testing for veterinary vaccines
- ✓ Provision for additional systems for monitoring of production consistency and *in vitro* alternatives
- ✓ New chapter in Ph. Eur: *Substitution of in vivo method(s) by in vitro method(s) for the quality control of vaccines*
- ✓ Revised *Monocyte-activation test,* an alternative to pyrogen Suppression of the Test for Abnormal Toxicity from 49 monographs of the European Pharmacopoeia
- ✓ Replacement of the Histamine sensitisation test (HIST) for residual pertussis toxin testing
- ✓ Review of toxicity testing requirements for tetanus vaccines - three animal tests have been suppressed
- ✓ Review of veterinary vaccine monographs to promote the 3Rs

Next – 2026:

Endotoxin → the possibility to replace the "LAL" reagent (horseshoe crab) by the recombinant factor C
Pyrogen → development of a new strategy to phase out the Rabbit Pyrogen test

Phasing-In New Approach Methodologies

EFPIA members are committed to the **science-based phase-in of methods to replace the use of animals for scientific purposes** and the deletion of animal tests which are obsolete or redundant.



Commission Roadmap to phase-out use of animals for (chemical) safety assessments

- ➢ To be published in 2026
- ➢ Active engagement across all key players
- ➢ Close consideration of Supply chain risk an

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

epaa The European Partnership for Alternative Approaches to Animal Testing

Innovation and regulatory flexibility to meet climate environmental and sustainability goals

Many ambitious initiatives:*

Sustainable materials

- Recycling/circularity, bio-derived, PVC-free packaging, ePIL….

Chemistry

- Low-carbon or recycled solvents, use of surfactants, green chemistry routes….

Raw Materials

- F-Gas, PFAS replacement, non-animal derived materials (LAL)…

Manufacturing

- Process intensification, water, energy use, sterilisation, transport and storage….

Critical enablers

- Consistent frameworks to assess climate & environmental impact
- Medicines regulators' input to enable innovation to meet climate and environmental goals

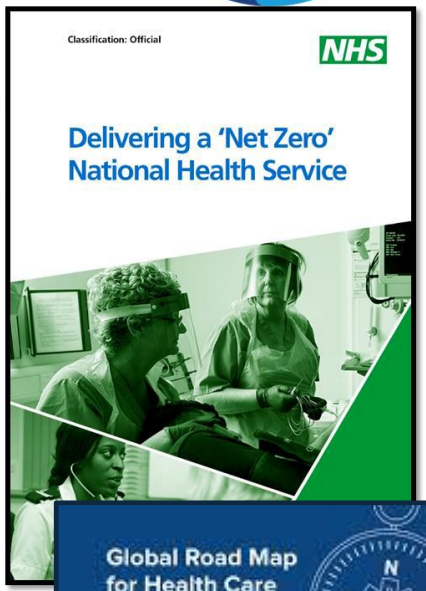
*Source: EFPIA MQEG and EHSEG joint brainstorm, February 2024

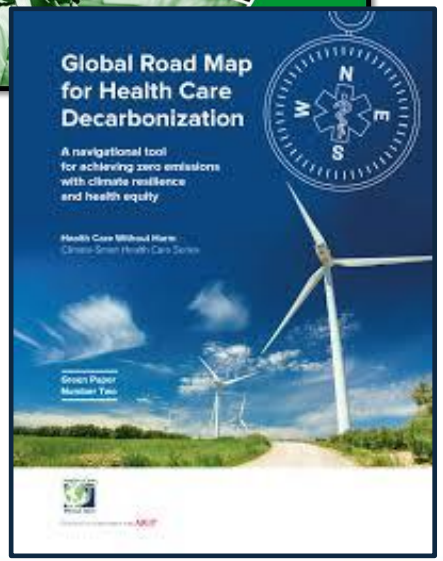
EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Net Zero: the inevitable future of healthcare

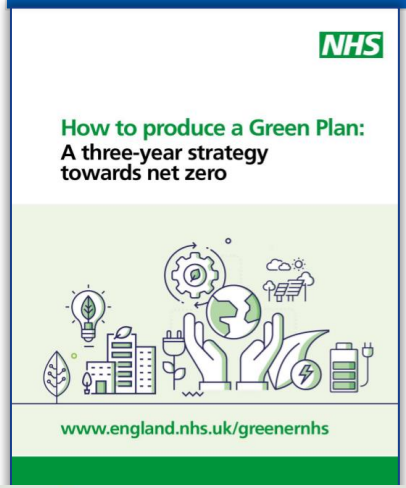




ATACH
Alliance for Transformative Action on Climate and Health
WHO hosted network

World Health Organization

UK International Development
Partnership | Progress | Prosperity



EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Lower Carbon Models are Key to Becoming Net Zero

Low carbon care settings

Provide the right care, at the right time in the right place

Keep people healthy over their life course

NHS England. Areas of focus. 2022. Available here: https://www.england.nhs.uk/greenernhs/a-net-zero-nhs/areas-of-focus/ (Accessed November 2023)

1. PREVENTION

Promoting health and preventing disease by tackling the causes of illnesses and inequalities

2. PATIENT SELF-CARE

Empowering patients to take a greater role in managing their own health and healthcare

PRINCIPLES OF **SUSTAINABLE CLINICAL PRACTICE**

3. LEAN SERVICE DELIVERY

Streamlining care systems to minimise wasteful activities

4. LOW CARBON ALTERNATIVES

Prioritising treatments and technologies with a lower environmental impact

Mortimer, F. The Sustainable Physician. Clin Med 10(2). April 1, 2010. D110-111.

Centre for Sustainable Healthcare. What we do. 2023. Available here: https://sustainablehealthcare.org.uk/what-we-do (Accessed October 2023)

Today, Tomorrow, Together for Public Health

About the Sustainable Healthcare Coalition

- We are a partnership of healthcare companies and other health agencies drawn together to address some of the most pressing sustainability issues in global healthcare.
- Our purpose is to facilitate the journey towards good health and wellbeing on a finite planet, through open-minded collaboration across public and private healthcare.

Our core group draws in participation from other health system players including trade bodies, state healthcare providers, public health institutions and international agencies.

AstraZeneca, Bayer, Baxter, BD, Boehringer Ingelheim, B Braun, Boston Scientific, Bupa, ERM, IQVIA, Johnson & Johnson, NHS, NHS Scotland, GIG Cymru NHS Wales, Novartis, parexel, Patients Know Best, novo nordisk, Smith+Nephew, ucb

Sustainable Healthcare Coalition

EDQM 60 1964 - 2024

Council of Europe 75 1949 - 2024 Conseil de l'Europe

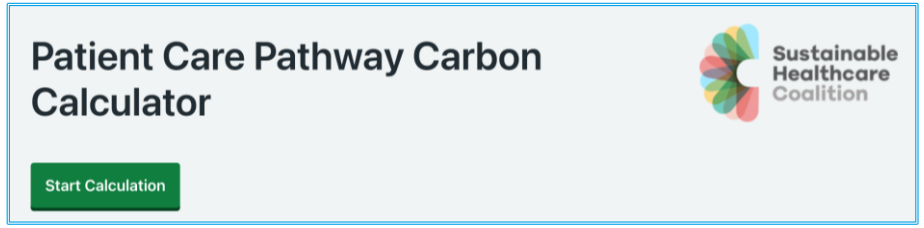
Measuring the Impact of Care Pathways

- World's first guidance on how to measure the **carbon footprint of pharmaceuticals and medical devices** and the environmental impact of **whole care pathways** through freely available guidance;
- Understand the current footprint of services and how **innovation can transform healthcare systems** through **case studies**;
- Freely available guidance and an **online calculator**: https://shcoalition.org/patient-care-pathways

CARE PATHWAYS MODULES

- GP consultation
- Patient travel
- Emergency Department visit
- Inpatient bed day
- Surgical procedure
- Self-management
- Diabetes Management

GP visit x6 + In patient stay x1 + Surgery x1 + Patient Travel to GP x3 + Patient travel to Hospital = Care pathway



Clinicians Driving Innovation

Trusted partnerships join up the system and accelerate change by learning together:

- **Carbon footprint of renal haemodialysis services** at Newcastle UTH informing local and national carbon reduction plans with an **international carbon calculator;**
- **Shifting towards prevention and early intervention** such as testing for pre-eclampsia, vaccination for influenza, and modifying disease progression;
- **Digital innovation to reduce impact;**
- **General practice carbon calculator** to identify and manage non-clinical emission hotspots;
- **Measuring the impact of clinical trials** with
- a standardised framework.

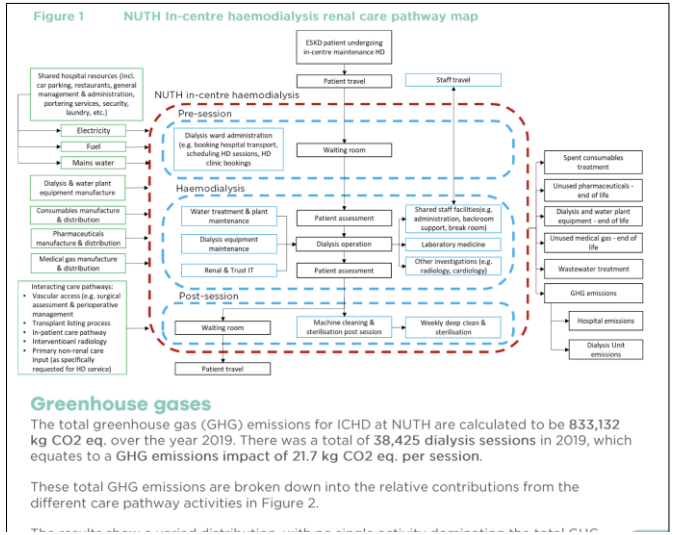
Care Pathways Approach for Renal Replacement Therapy

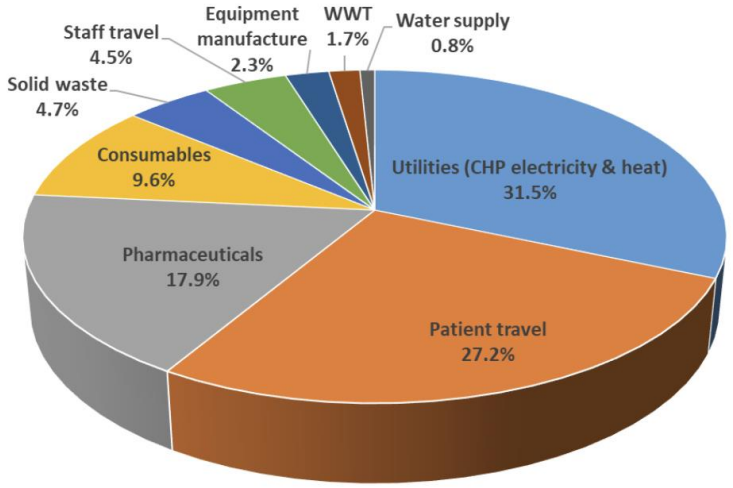
- Pathway mapping of in-centre haemodialysis;
- 21.7 kg CO_2e per patient session at NUTH or 3.4 tonnes CO_2e per patient per year[1]

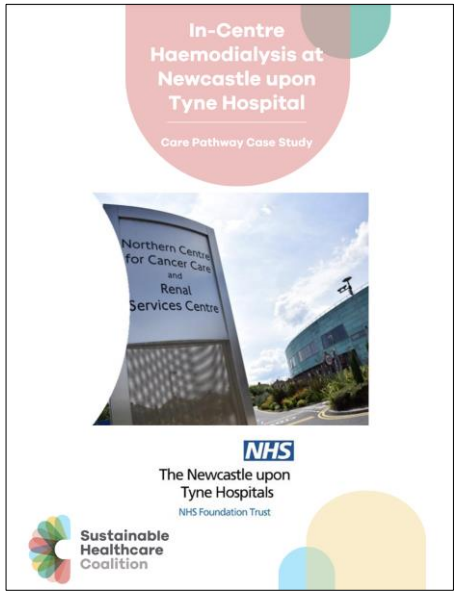
Note: the average global citizen footprint is 4.3 tonnes CO_2e per year[2]

- Hotspots – Utilities, Travel, Pharmaceuticals

- Recommendations identified:
  - Work with supply chain on manufacture, packaging + distribution
  - Reduce energy use and increase efficiency
  - Reduce transport emissions
  - Bulk delivery system







1. The Newcastle upon Tyne Hospitals NHS Foundation Trust. A Care Pathway Environmental Assessment of In-Centre Haemodialysis at Newcastle upon Tyne Hospitals NHS Foundation Trust. 2022. Available here: **https://shcoalition.org/in-centre-haemodialysis-at-newcastle-upon-tyne-hospital/** (Accessed October 2023) 2. The World Bank. CO2 emissions (metric tons per capita). 2020. Available here: https://data.worldbank.org/indicator/EN.ATM.CO2E.PC (Accessed November 2023) 3. Liyanage T, Ninomiya T, Jha V, Neal B, Patrice HM, Okpechi I, et al. Worldwide access to treatment for end-stage kidney disease: a systematic review. Lancet (2015) 385:1975–82. 10.1016/S0140-6736(14)61601-9

Today, Tomorrow, Together for Public Health

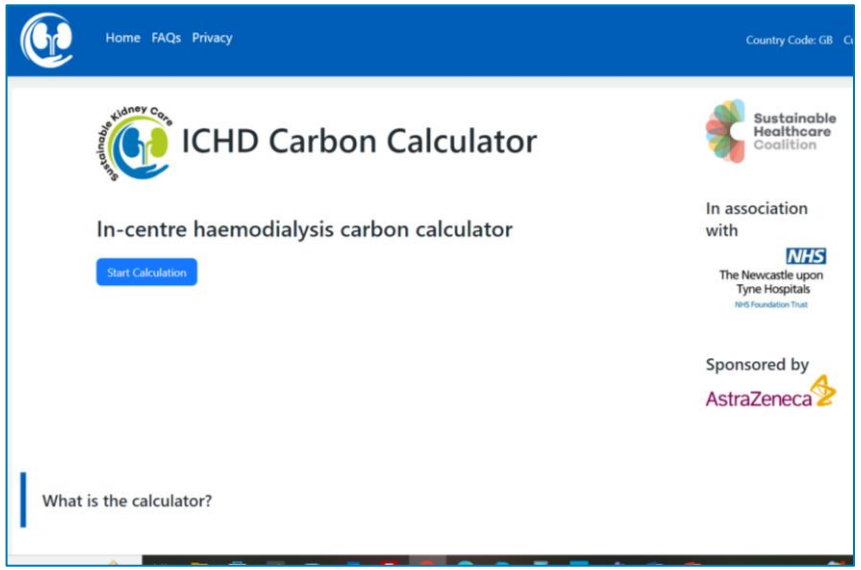
Practical Guides for Healthcare Action

12 steps to GREEN A KIDNEY UNIT

SCAN ME

1. **Communication:** nominate a staff Sustainability Champion to be the link to best practice with other units and encourage all staff to join the wider Kidney Care Sustainability Network
2. Reduce and decarbonise patient travel
3. Reduce energy consumption of kidney care estates
4. Decarbonise energy sources
5. Focus on acid concentrates
6. Save water
7. Reduce and decarbonise staff travel
8. Encourage patients to bring own blankets to dialysis
9. Move charitable and research accounts to greener banks
10. Consider carbon implications in procurement
11. Tackle prevention and tailor dialysis
12. Develop resilience/ contingency plans

This is a summary of UKKA Sustainable Kidney Care Committee's "12 Steps to Green a Kidney Unit". For the full version go to: Networks.sustainablehealthcare.org.uk/resources/12-steps-green-kidney-unit

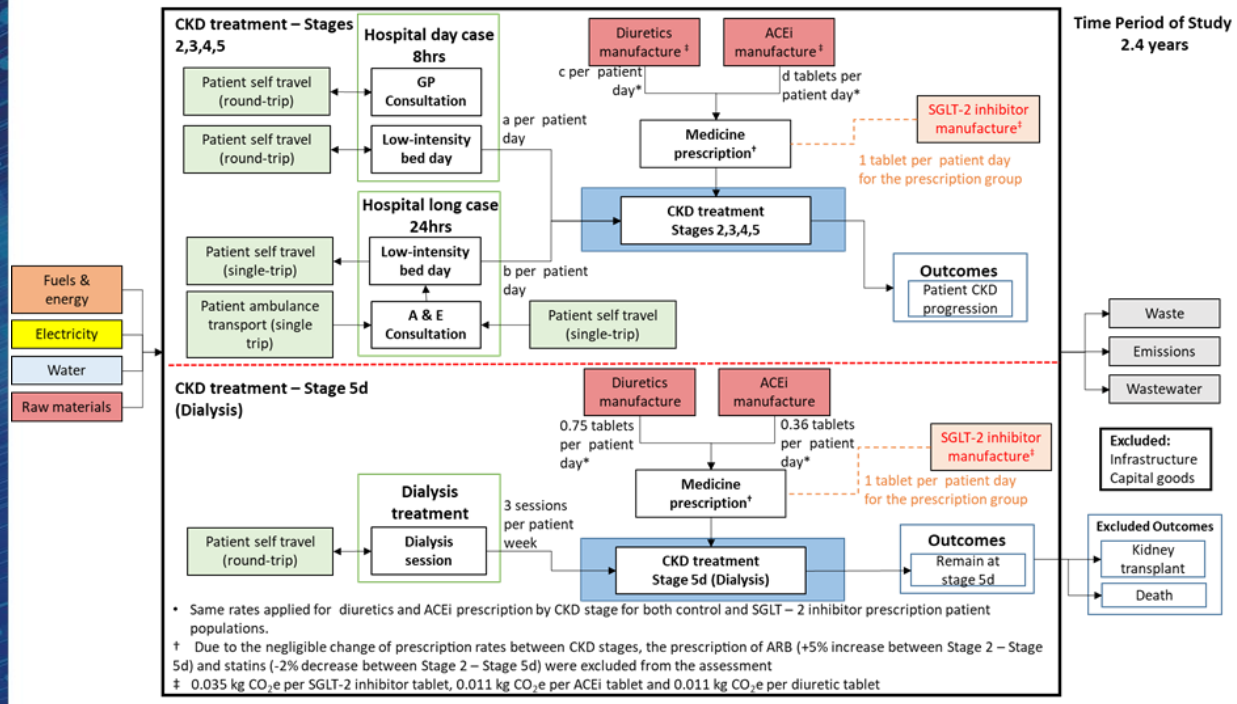


https://ichdcarbon.org

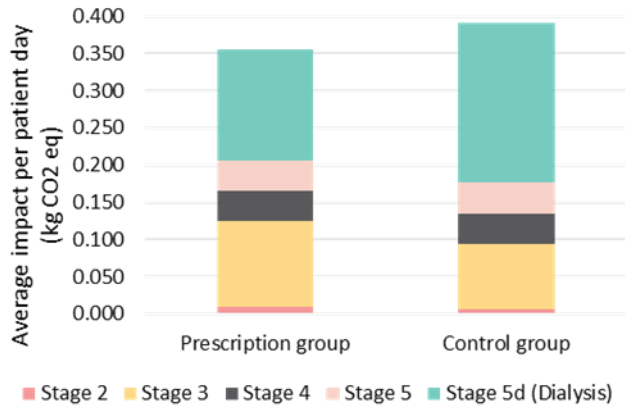
EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Impact of Reducing Chronic Kidney Disease Progression: Opportunities for Innovation



CKD Stage	GHG Impact per Control Patient Day in Stage (kg CO_2 eq)	UK CKD Population	UK CKD Patient GHG Impact (tonnes CO_2 eq/year)
Stage 2 (eGFR 90-60)	0.064	210,000	5,000
Stage 3 (eGFR 60-30)	0.140	2,430,000	124,000
Stage 4 (eGFR 30-15)	0.325	120,000	14,000
Stage 5 (eGFR <15)	0.325	38,000	5,000
Stage 5d (Dialysis)	9.39	30,000	103,000



https://shcoalition.org/environmental-impact-of-the-care-pathway-for-chronic-kidney-disease-in-the-uk/

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Opportunities for Collaboration Across The Value Chain

The SMI Health Systems Task Force Commitment

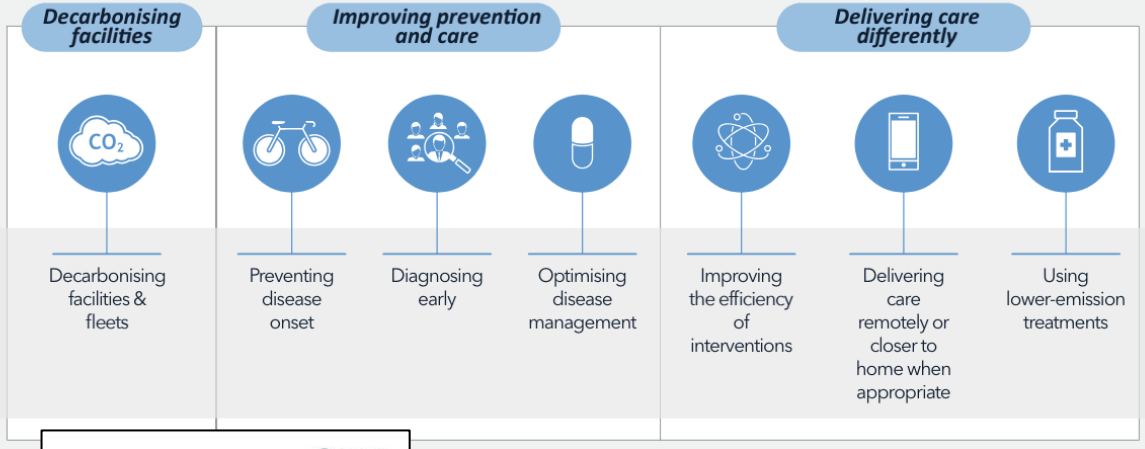
Meaningful change will require all stakeholders to work together. As a collaborative alliance of public and private sector leaders, the SMI Health Systems Task Force is uniquely positioned to accelerate decarbonisation efforts across the entire health ecosystem. With relevance to patient care pathways, it is committed to:

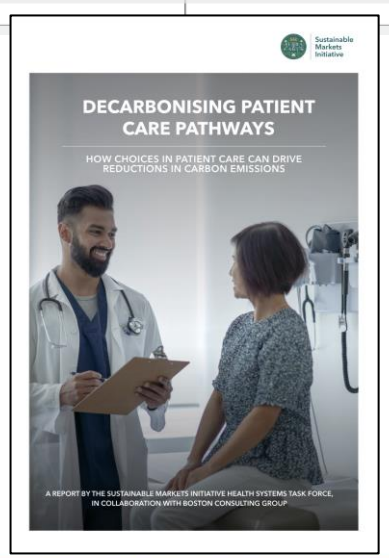
Engage and collaborate with health policy makers, regulators, payers and providers, and hospitals from across the globe to raise awareness of the need and the opportunity to decarbonise care pathways

Build an end-to-end care pathway emissions calculation standard and tool for specific diseases that allows stakeholders to **measure and track emissions** across the care pathway and assess decarbonisation strategies

Align on a common framework to perform lifecycle assessments (LCA) – with private sector members also committed to publishing product-level LCA data across their product portfolio to increase transparency on treatment emissions

Seven levers to reduce emissions in care pathways





TERRA CARTA

Sustainable Markets Initiative

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together for Public Health

Recommendations towards sustainable healthcare

1. Collaboration and Partnerships
Foster collaboration among stakeholders including governments, healthcare providers, industry, and non-profit organisations. Seek new perspectives and possibilities from clinicians and patients.

2. Research and Innovation
Invest in research and development of new technologies, therapies, and healthcare delivery models that prioritise sustainability without compromising on patient access to medicines or health outcomes. Focus on service delivery problems to release energy for innovation.

3. Efficient Resource Management
Optimise the use of healthcare resources by reducing waste, improving supply chain management, and adopting sustainable practices.

4. Promote Sustainable Practices
Encourage industry and healthcare providers to adopt environmentally friendly practices such as energy efficiency, waste reduction, and the use of renewable resources in their operations…

5. Measure Environmental Impact of care routinely so that it is an integral part of all health system decisions. In effect we need to reimagine healthcare system rules so that healthcare quality is based on environmental impact as well as clinical outcomes and cost

6. Education and Awareness
Promote awareness among industry, healthcare professionals, patients, and the general public about the environmental impact of healthcare and the importance of sustainability

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Today, Tomorrow, Together
for Public Health

Thank You!

EDQM 60 1964 - 2024

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE