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Rapid Technology Scan: Pulmonary Function Tests (PFTs) and the Prevention of the Generation of Aerosols

May 2021

Background: NIHR Innovation Observatory

- Horizon scanning centre based at Newcastle University
- Delivering horizon scanning and early awareness notification service to national healthcare bodies within the UK
- Identifying promising health innovations: medicine, medical devices, diagnostics and digital technologies
- Working closely with the Accelerated Access Collaborative (AAC), and national bodies such as NHS E&I and NICE, UK HSA to support accelerated access of new innovative health technologies and services to NHS patients

Objectives & Scope

- The Innovation Observatory (IO) sought to:
    1. Undertake a rapid horizon scan to identify technologies that prevent/mitigate the risks associated with aerosol generation during pulmonary function tests (PFTs)
    2. Summarise key findings regarding the outcomes of this scan and evidence gathered from business intelligence and grey literature (including opportunities and challenges in this area)
- This scan was carried out to identify innovative solutions that may help address the high level of disruption to respiratory function testing caused by COVID-19, and to support the restoration of respiratory lung function procedures.
- To be considered as part of this scan, a technology must (i) reduce the risks of respiratory droplets/dispersion of aerosols into the environment during or after the procedure respiratory lung function (directly/indirectly) and/or; (ii) increase the rate of air exchange to reduce environmental contamination and thus speed up the process of being able to perform lung assessment.

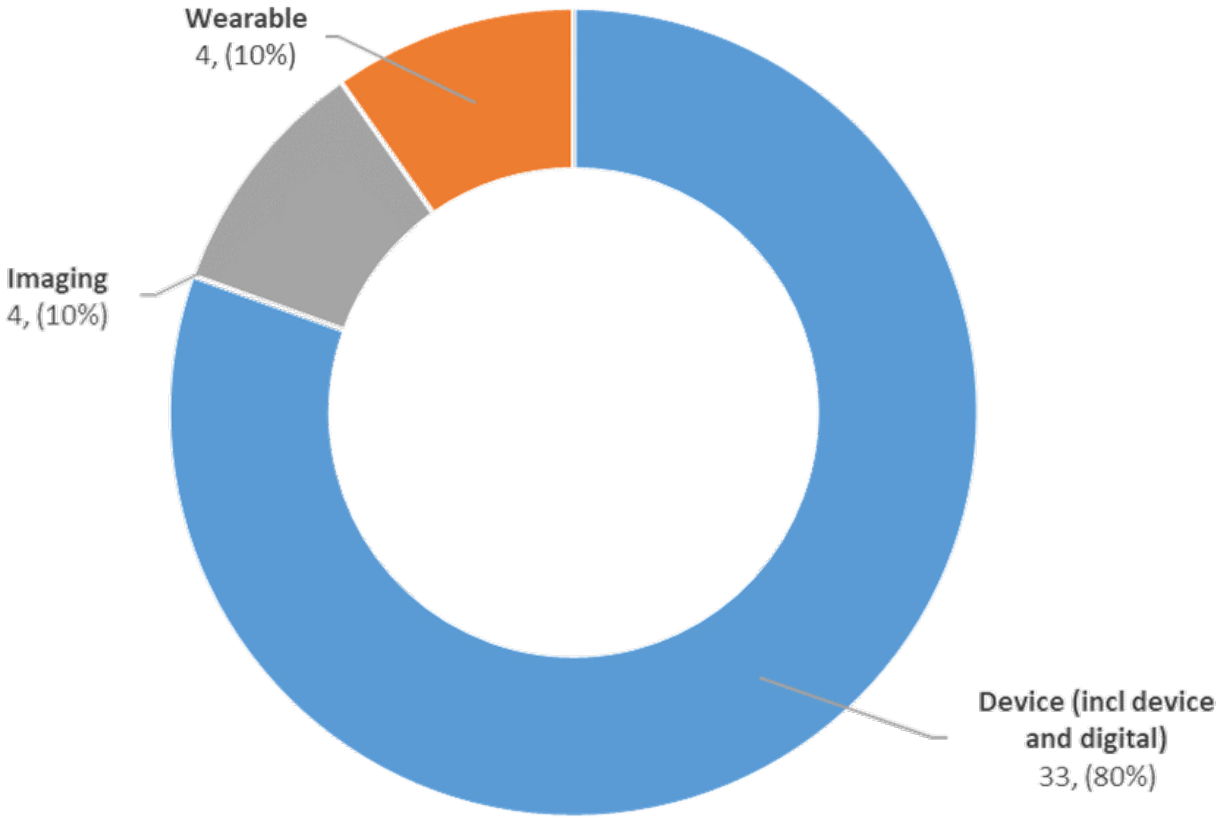
Methods

- For the purposes of this rapid technology scan:
  - IO developed a detailed dataset of technologies by formulating search strategies for PFTs and aerosol generating procedures (AGPs), based on a comprehensive list of terms with input from expert panels
  - Primary and secondary sources were systematically scanned using a combination of traditional scanning methods, automated and novel AI/machine learning techniques
  - Screened results and extracted intelligence was used in further data processing
- Information sources used as part of this scan included, *inter alia:*
  - Bibliographic databases, including PubMed, EMBASE and MEDLINE
  - MedTech news websites
  - Commercial websites, reports and press releases
  - Academic institution webpages
  - IO ScanMedicine trial database (11 clinical trial registries including UK, EU, USA)
  - Patent databases
  - Regulatory agency

Limitations

1. This is a rapid technology scan with a limited scope, and results should be interpreted as such
2. IO are not subject matter experts in in respiratory lung function or respiratory technologies
3. The classification of technologies was complex and at times subjective due to limited or incomplete information available for the technology or complex aspects of the technology or application which require expert knowledge

Innovations by Categories



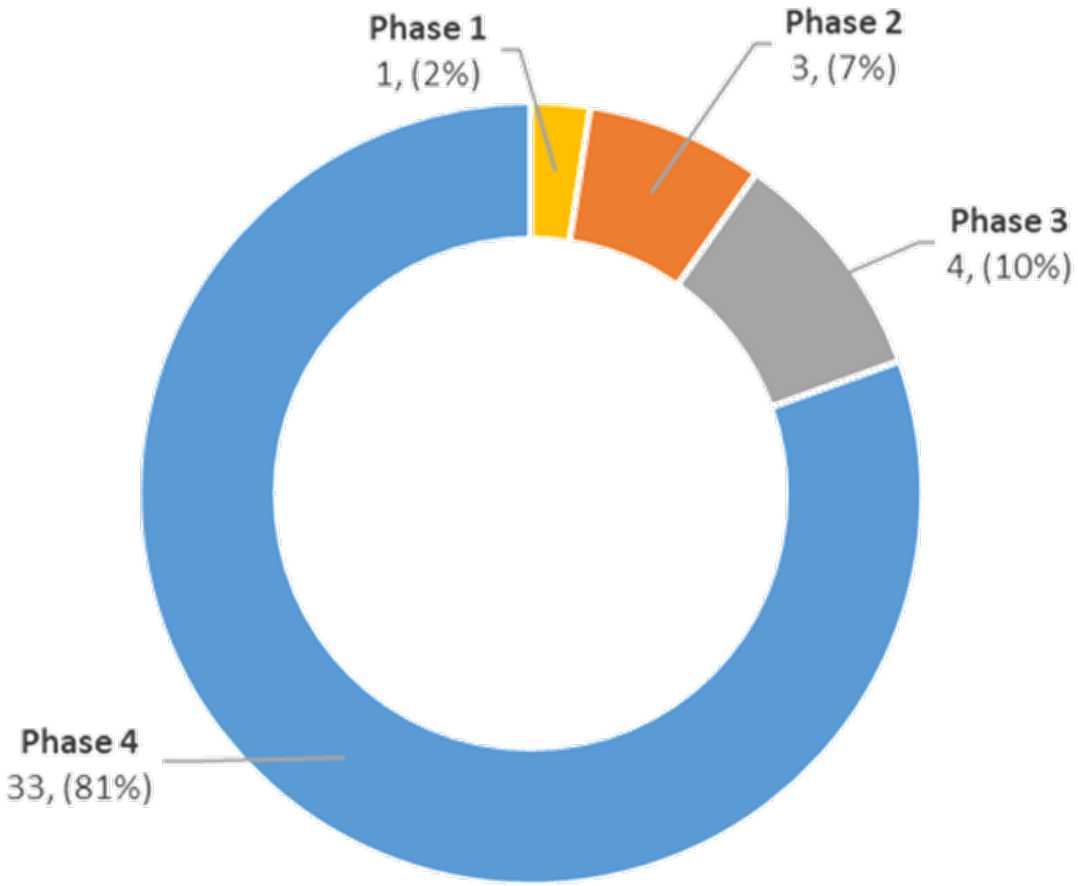
COVID-19 and technological advances have paved the way for promising solution that have the potential to better manage respiratory function testing and respiratory diseases

Overall, technologies identified through this scan were not developed for the primary purpose of preventing/mitigating the risks associated with aerosol generation. The majority of technologies incorporated novel approaches for the assessment of respiratory function that indirectly reduced or prevented the generation of aerosols

Technologies were grouped into the following categories:

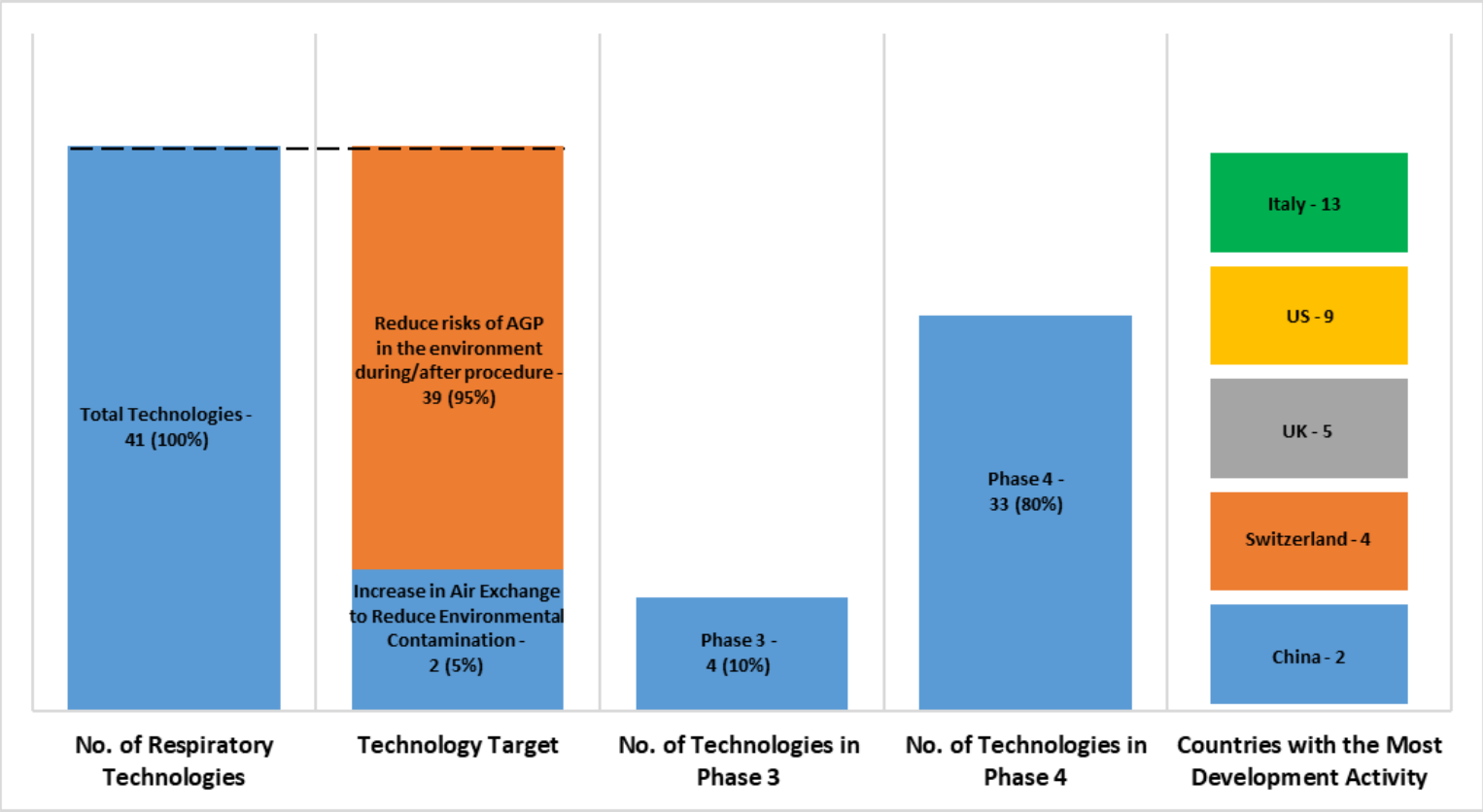
- Device (incl devices with a digital component)
- Wearable technologies
- Imaging

Development Stage of Technological Innovations



- 2% were Phase 1 (i.e. concept)
- 7% were Phase 2 (i.e. prototype/ early-stage research including preclinical)
- 10% were Phase 3 (i.e. product validated/ demonstrated in relevant environment/ clinical study)
- 33% were Phase 4 (i.e. product ready to launch/ regulatory approved)

Key Insights into Technological Innovations



- Over 40 innovations were identified from across 13 countries, with development activity largely concentrated in Europe and the US
- 95% targeted the reduction of risks of AGP in the environment during/after procedure
- 5% targeted the increase in air exchange to reduce environmental contamination
- Majority of innovations in phase 4 of development
- Over 20 developers were identified, with the majority categorised as SMEs. Other developers included large enterprises and academic research institutions

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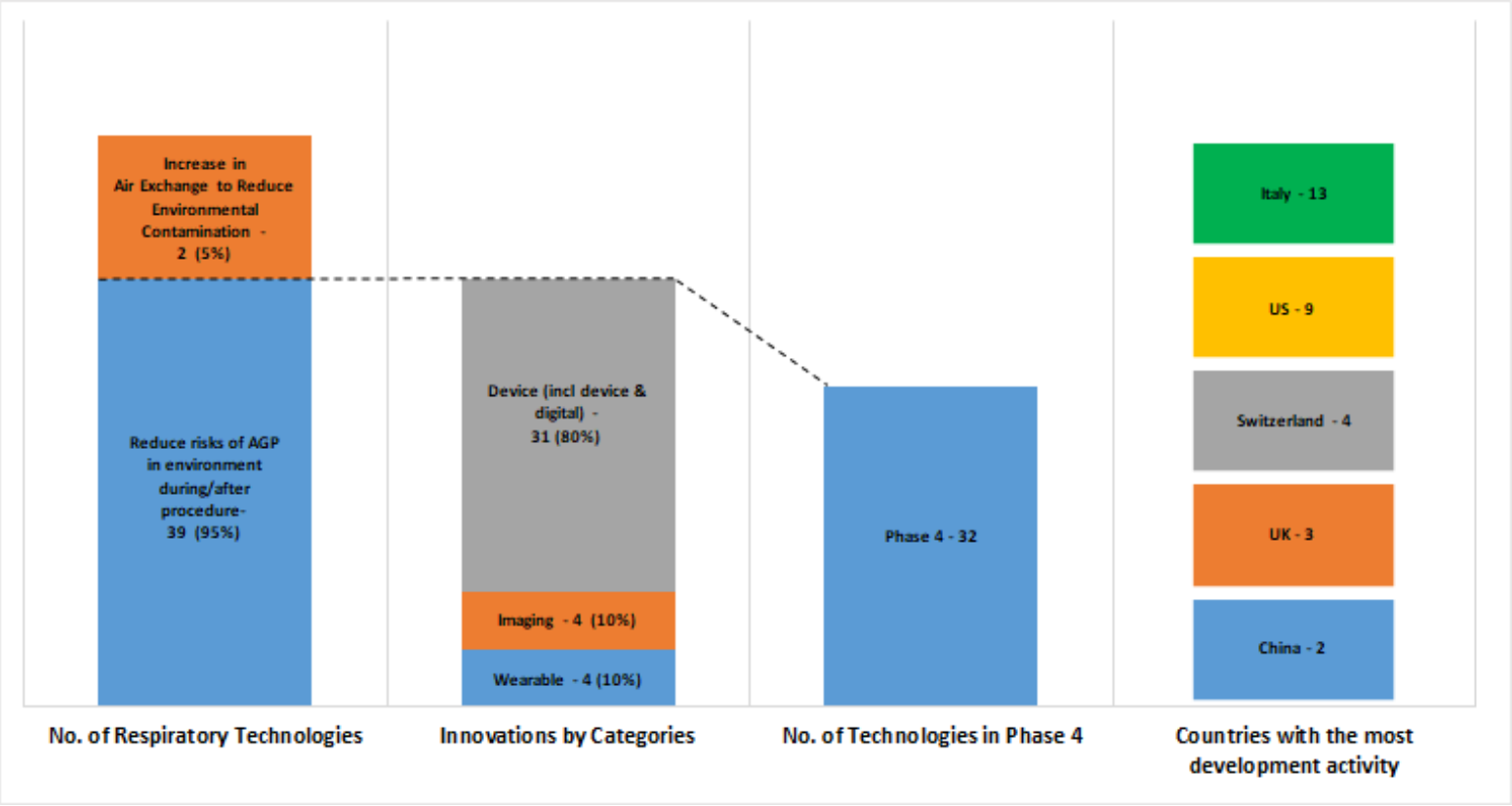
Key Insights into Innovations Targeting Reduction of AGP in Environment During/After Procedure



- Majority of innovations in development for the reduction of AGP were devices (80%)
- Most technologies were in phase 4 of development – commercialised and ready for market
- Novel solutions in development included Imaging and Wearables, which may transform the PFT procedure
- Technologies are in development for the clinical diagnosis and management of a variety of conditions: asthma, cystic fibrosis, COPD

Key Insights into Innovations Targeting Increase in Air Exchange to Reduce Environmental Contamination

CliniCabin

Purer Clean Air

- A small proportion of technologies identified were aimed at increasing air exchange to reduce environmental contamination
- These 2 technologies, developed in the UK, include both the device and digital software
- CliniCabin has developed a pod-style clinical room to increase air exchange. Whereas Purer Clean Air® has developed filters to convert pollutants, pathogens and particulates into water, carbon dioxide, and oxygen

Summary of Key Messages

Our rapid technology scan found:

- COVID-19 has dramatically impacted respiratory technologies for lung function testing
- Potentially promising technological solutions have been identified that may provide acceptable and actionable physiological information to support the restoration of respiratory lung function procedures
- Innovations in the pipeline include advancements in testing technologies as well as new approaches to respiratory function testing and the diagnosis of lung disease (e.g. imaging and wearables)
- Emerging evidence shows increased development of technologies that assist patients in self-monitoring and decision-making, and subsequently, driving a shift toward a care model increasingly centered on personal adoption and use of digital and web-based tools
- There is evidence that a high level of development activity and investment is concentrated on smart technologies and wearable technologies for respiratory assessment (e.g. lung volume and diffusion capacity measurement) and other physiological/non physiological parameters (activity, environment/air quality, heart rate, blood pressure, temperature etc.)
- Barriers to the implementation of new technologies include the need for more outcomes evidence to validate their use in respiratory procedures; the need for technical training and adaption of existing care workflows

Conclusion & Implications

- IO have identified immediately relevant data on the pipeline of technological innovations to allow decision-makers and healthcare organisations to evaluate the potential impact of these technologies against their priorities and anticipate some of the consequences for the care pathway
- There is evidence of a growing number of respiratory technologies in the pipeline, thus providing a unique opportunity for the respiratory community to engage in the rigorous clinical evaluation of new solutions and systems that may reduce the generation of aerosol and/or; ii) enhance the diagnosis and management of those with respiratory diseases
- The majority of technologies identified directly or indirectly aid the reduction of aerosol generation. Two companies were identified with technologies that increased air exchange to reduce environmental contamination
- The emerging number of technologies presents an opportunity for stakeholders to consider whether they may improve or compliment existing (traditional) technologies in the NHS (now and in the future).