TackSHS WP5

Health Effects of Secondhand Smoke Exposure in Outdoor Smoking Areas in Patients With COPD and Asthma (TackSHSWP5)

NCT03074734

Date: 21/10/2019

Tackling secondhand tobacco smoke and e-cigarette emissions: exposure assessment, novel interventions, impact on lung diseases and economic burden in diverse European populations (TackSHS)

Call: H2020-HCO-2014-2015 / H2020-HCO-2015

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Authors: S Keogan/ L Clancy

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Disclaimer

Acknowledgement

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More information

Public reports of the TackSHS Project and other information pertaining to the project are available through TackSHS public Web Site: http://www.tackshs.eu.

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Protocol title: Exposure to Secondhand smoke in exempted areas/outside areas and acute health effects in patients with chronic lung disease.

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- Funded by EU Horizon 2020
- Name and title of the WorkPackage 5 Leader: Professor Luke Clancy.
  Co-Investigator/co-ordinator: Sheila Keogan
- TobaccoFree Research Institute Ireland (TFRI), DIT, Focas Research Institute, Kevin Street, Dublin 8.
- Ph. + 353868364337, +353876887678
- Email lclancy@tri.ie; skeogan@tri.ie

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STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the EU Directive 2001/20EC on Clinical Trials and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

WP5 Principle Investigator: Professor Luke Clancy

Co-Investigator/co-ordinator: Ms Sheila Keogan

Project summary

This Project will try to elucidate the comprehensive impact that SHS and e-cigarettes emissions have on the European population and how health impacts vary according to socio-economic parameters with particular emphasis on specific vulnerable groups (patients suffering from pre-existing chronic lung diseases, heavy smokers, and other disadvantaged groups). Thus, we aim to develop and integrate implementation research on the determinants of SHS exposure, both assessed at the individual level and in the environment, the overall burden of disease caused (lung diseases and also cardiovascular diseases), including the specific respiratory health changes in patients and healthy people, the economic impact of both mortality and morbidity caused by these exposures, the methods to better characterize these exposures and novel interventions to reduce them. This will be achieved through a dedicated collaborative research effort involving expert, qualified scientists partnering a world class team to develop a comprehensive project to tackle secondhand tobacco smoke and e- cigarettes emissions.

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GLOSSARY OF ABBREVIATIONS:

Abreviation	Term
TFRI	TobaccoFree Research Institute Ireland
DIT	Dublin Institute of Technology
FCTC	Framework Convention for Tobacco Control
ELF	European Lung Foundation
COPD	Chronic Obstructive Pulmonary disease
EU	European Union
SHS	Secondhand Smoke
CO Monitor	Carbon Monoxide Monitor
PEFR	Peak Expiratory Flow Rate
bpm	Beats per minute
RR	Respiratory Rate

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Rationale & background information

Respiratory disease causes an important worldwide health burden. It is estimated that 235 million people suffer from asthma, more than 200 million people have chronic obstructive pulmonary disease (COPD), 65 million endure moderate-to-severe COPD, 1–6% of the adult population (more than 100 million people) experience sleep disordered breathing, 8.7 million people develop tuberculosis (TB) annually, millions live with pulmonary hypertension and more than 50 million people struggle with occupational lung diseases, accounting for more than 1 billion persons suffering from chronic respiratory conditions (GBD 2013 Mortality and Causes of Death Collaborators, 2014). In 2020, of 68 million deaths worldwide, 11.9 million will be caused by lung diseases, 4.7 by COPD, 2.5 by pneumonia, 2.4 by TB and 2.3 million by lung cancer.

Respiratory diseases burden the healthcare budgets within the European Union with direct costs of approximately €47.3 billion. Assuming a total EU expenditure on healthcare of approximately €800 billion (estimated from 9% of gross domestic product), the direct costs of treating respiratory diseases account for approximately 6% of the total EU healthcare budget. The four major respiratory diseases: COPD, asthma, pneumonia and TB have costs totaling €38.7, €17.7, €10.1 and €2.1 billion respectively (ERS, 2014).

Secondhand tobacco smoke (SHS) is a complex mixture of thousands of compounds including particulate matter emitted by the combustion of tobacco products and from smoke exhaled by smokers (IARC, 2004). It contains about 70 chemicals recognized as known and probable human carcinogens, other animal carcinogens, and many toxic and irritant agents (US Department of Health and Human Services, 2006). Over the past two decades, scientific evidence has accumulated linking SHS exposure to adverse health outcomes, including respiratory outcomes in children and adults, acute cardiovascular effects, and lung cancer (IARC, 2004; Ott et al., 2006; US Department of Health and Human Services, 2006). Most of this evidence is based on long-term SHS exposure research (IARC, 2004). Some recent studies have also reported evidence of effects following short-term exposure to tobacco smoke, such as eye irritation and respiratory irritation among non-smokers (Junker et al., 2001). Even brief and short-term exposures to SHS may generate significant adverse effects on the human

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respiratory system (Flouris and Koutedakis, 2011). Finally, the effects of acute exposure to tobacco smoke on cardiac autonomic function may contribute to pathophysiological mechanisms linking exposure to SHS to increased risk of cardiovascular mortality (Pope, III et al., 2001).

Smoke-free policies have been expanding worldwide since the World Health Organization (WHO) encouraged countries to follow Article 8 of the Framework Convention on Tobacco Control (FCTC) (WHO 2003) to protect people from SHS (Globalsmokefree Partnership, 2009). Legislation has been widely implemented in indoor public places, workplaces, and public transportation (WHO, 2009). Since the implementation of indoor smoke-free environments, several studies have demonstrated important reductions of SHS exposure, including an 80–90% decrease in previously high-exposure set- tings, such as workplaces and hospitality venues like bars and restaurants (IARC 2008). However, indoor smoking restrictions may increase the likelihood that smokers will gather at convenient outdoor locations such as public areas near building entrances (Kaufman et al. 2010a). In 2007, a revision of the FCTC Article 8 guidelines further recommended that quasi-outdoor and outdoor public places should be smoke-free under some circumstances, and called upon countries to "adopt the most effective protection against exposure wherever the evidence shows that hazard exists" (WHO 2009). Recently, some countries have extended smoking bans to some outdoor locations (Globalsmokefree Partnership 2009; Repace 2008), particularly health care centers and settings where children are present (Globalsmokefree Partnership 2009). However, there remain some outdoor locations close to smoke- free areas where people may be exposed to SHS, such as terraces and patios in hospitality venues and near entrances to smoke-free buildings (Globalsmokefree Partnership 2009).

Some controversy exists regarding whether smoking should be prohibited in outdoor settings (Chapman, 2008; Thompson et al., 2008). Health concerns about SHS exposure, nuisance from SHS, litter, fire hazards, concern about establishing positive smoke-free models for youth, and reducing youth opportunities to smoke (Bloch and Shopland, 2000; Brennan et al., 2010; Cameron et al. 2010; Chapman, 2008; Repace, 2008; Thompson et al., 2008; Thomson et al. 2009) exemplify the reasons why smoking should be banned in selected outdoors locations. Outdoor smoking bans might also support smokers who are trying to quit by limiting their

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overall cigarette consumption (Williams et al., 2009). Selected outdoor smoking bans should also help to denormalise smoking in outdoor areas (Thompson et al., 2008). In a number of jurisdictions, the majority of the public supports restricting smoking in various outdoors settings, and this support appears to be increasing over time (Thomson et al., 2009). However, those who oppose outdoor smoking bans argue that it is ethically unsustainable because it does not respect the principle of freedom and autonomy of individuals, and that there is insufficient evidence that SHS in these environments has an impact on health (Chapman, 2000; Chapman, 2008). Outdoor SHS has been scarcely evaluated. It has been hypothesized that the introduction of indoor smoking bans has led to a relocation of smokers to outdoor areas, with a subsequent increase of tobacco smoke levels in outdoor places (Sureda et al., 2011).

SHS exposure has been commonly studied in different indoor locations, especially in workplaces such as hospitality venues or health care centers (IARC, 2009); mainly before launching smoke-free legislation or, in a few countries, for the evaluation of smoke-free laws. In the US, it is estimated that SHS exposure causes more than 41,000 deaths among nonsmoking adults and 400 deaths in infants each year, and approximately $5.6 billion annually in lost productivity. Although population exposure to SHS has declined over the past two decades (Homa et al., 2015), many non-smokers remain exposed to SHS in workplaces, public places, homes, and vehicles (Max et al., 2012). The Eurobarometer survey has incorporated a few questions on exposure to secondhand smoke in recent editions, and previous work from some of the TackSHS partners have studied the exposure to secondhand smoke in some European countries to be between 20 and 60% of the non-smoker population, both using a population- based approach and cross-sectional surveys [Lukshenkova et al., 2008; Martínez-Sánchez et al., 2009; Sureda et al., 2014 (TackSHS Spanish partner) in Spain, Gorini et al., 2008; Martínez-Sánchez et al., 2012; (TackSHS Italian partners) in Italy, Wallner et al., 2010 in Austria, Vardavas et al., 2012 (TackSHS Greek partner) in Greece, Goodman et al., 2007 (TackSHS Irish partner) in Ireland], or performing environmental measures of particulate matter or airborne nicotine as SHS markers [Semple et al. 2007 (TackSHS UK partner) in Scotland, Schneider et al., 2008 et al. in Germany, Vardavas et al., 2014 (TackSHS Greek partner) in Greece, and Nebot et., 2005 and Lopez et al., 2008 in 8 countries in previous SANCO and FP7 projects.

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An inclusive understanding of the exposure to SHS in European populations and its societal mortality, morbidity and economic burden is however lacking. *A comprehensive survey using validated questions across countries will provide an actual picture of the exposure to this hazard, with the possibility to compare countries with different income and vulnerable groups, such as people with chronic dis- eases, and specifically chronic pulmonary diseases.* Moreover, we will be able to gain information about the attitudes of the population towards SHS, and the degree of agreement with smoke-free legislation. In addition to the survey, we aim at objectively measuring markers of secondhand smoke in non-regulated settings such as private places and outdoor public places. In a recent review of 18 studies that assessed secondhand smoke levels (Sureda et al. 2013), we found that SHS levels in outdoor smoking areas were not negligible, especially in areas that are semi-enclosed. This review clearly indicated the potential for high SHS exposures at some outdoor settings and indoor locations adjacent to outdoor smoking areas. We showed, moreover, that high smoker density, highly enclosed outdoor are as, low wind conditions, and close proximity to smokers generate higher outdoor SHS concentrations. *Thus, our aim in the TackSHS project is to perform new measurements in the same countries where we will be conducting the survey –hence with the possibility to compare individual perceptions and assess concentrations of SHS markers-- and to take into account those factors that modify the exposure.* Moreover, the project will quantify the proportion of Europeans exposed to secondhand tobacco smoke, thus enabling the estimation of the morbidity and mortality attributable to this hazard, and to estimate its economic burden by means of "Social Return on Investment" models.

Since 2007, the popularity of **electronic cigarettes (e-cigarettes)** has grown rapidly around the world. Among the general population of the United States (US) (King et al., 2013) the prevalence of ever-use, according to a web-based survey, showed a twofold increase between 2010 and 2011 (from 3.3% to 6.2%). Double similar scale of increase was also observed in US adolescents (Dutra and Glantz, 2014) and in middle and high school students (MMWR, 2013) between 2011 and 2012. In Europe, there is certain variability in the prevalence of use among studies, depending on the population and the questions used in the surveys (Dockrell et al., 2013; Goniewicz et al., 2012; Douptcheca et al., 2013; Mar- tínez-Sánchez et al., 2014). Using data from the 2012 Eurobarometer, Vardavas et al. 2014 (TackSHS Greek partner) showed that 7% of the European citizens have tried the e-cigarettes with experimentation significantly

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higher among current smokers. In Italy, a survey conducted by Gallus et al. 2014 (TackSHS Italian partner) showed that awareness of e-cigarettes was 91.1%, lowest among some vulnerable populations such as women, the elderly, and less educated subjects. In Italy, ever e-cigarette use was 6.8% overall and was inversely related to age, whereas no difference was observed according to sex. In Spain, studies form the TackSHS coordinators found an awareness of e-cigarettes lower than in Italy (82.3%) but a similar prevalence of ever e-cigarette use of 6.5% (1.6% current use, 2.2% past use and 2.7% only e-cigarette experimentation) and the predominant ever and current e-cigarette use was among current smokers (75% of ever e-cigarette users were current smokers) (Martínez-Sánchez et al. 2014a and 2014b)

Finally, reducing population exposure to secondhand tobacco smoke is a significant health priority. While evidence suggests that there has been an increase in the percentage of smokefree homes from 16% in 1998 to almost 50% in 2008 in England and Wales (Jarvis et al., 2012), and data from Scotland indicate that about 12% of children are regularly exposed to second-hand smoke within their own home (Akhtar et al., 2007). This is particularly the case for children living in socioeconomically dis- advantaged communities (Akhtar et al., 2009). Even though families across all levels of deprivation have shown increased restrictions towards reducing SHS exposure in their homes, homes with greater disadvantage tend to have fewer restrictions (Phillips et al., 2007). The Scottish Government is the first country in the EU to introduce a national target with the aim of reducing the proportion of children exposed to second-hand smoke by one-half by 2020. There is a clear and significant challenge to the public health community on how to deliver reductions in both frequency and intensity of children's exposure to SHS, particularly within socio-economically deprived communities. One known effective motivational tool in aiding change in smoking behaviour is the use of instruments to measure levels of PM2.5 as a marker of SHS, with some recent qualitative work suggesting that personalized biofeedback of exposure to SHS may be a key motivator to household smoking behaviour change (Jones et al., 2011). Additionally, there is evidence from the occupational health literature that suggests that measurement and feedback of information on personal exposure to hazards can help change behavior (Rosen et al., 2005). Thus, feedback on air quality within the home setting could work as a powerful tool to change the perceptions and behaviours of smokers. The Scottish partner of TackSHS used personalised feedback of PM2.5

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values in addition to other methods aimed at reducing children's SHS exposure (the REFRESH intervention) (Wilson et al., 2013). This feasibility study of an air quality feedback behavioural intervention was based on the evidence that people can make changes in response to receiving personalised health-based data along with evidence suggesting some effectiveness in reducing SHS exposure through counseling.

Study goals and objectives

The project objectives are:

- To Measure Respiratory Health effects when exposed to SHS in
    - Patients with Asthma
    - Patients with COPD
- Exposure levels to Second Hand Smoke (SHS) in smoking areas provided by Bars Casinos and Bingo halls etc.

Study Design

Population:

The study population will consist of 30 Asthmatic and 30 Chronic Obstructive Pulmonary Disease (COPD) subjects to be recruited through the European Lung Foundation (ELF) in Hungary Spain and Ireland. (20 subjects in each country)

Inclusion criteria for each patient group:

Confirmed Dr Diagnosed COPD patients

Current or ex-smokers.

Fully ambulatory.

Frequent smoking areas*

Between 50yrs and 70yrs

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Confirmed Dr Diagnosed Asthmatic patients

Fully ambulatory

Frequent smoking areas

Over 18yrs

*Irish law has defined an outdoor smoking area as: A place or premises, or part of a place or premises that, is wholly uncovered by any roof, fixed or mobile. An out door place or premises that is covered by a roof, so long as not more than 50% of the perimeter (outside) is covered by a wall, windows, gate or similar.

Exclusion criteria:

Under 18yrs

On Oxygen therapy

Never smokers in COPD patient group

Undergoing treatment for acute exacerbations.

Pregnant women

Primary Endpoints:

- To monitor personal exposure to SHS in areas exempted from legislation in pubs, bars and casinos etc. using novel monitoring technologies.
- To simultaneously monitor the respiratory effects as indicated by changes in respiratory rate and flow and activity levels.

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Secondary Endpoints

- Any increase in medication usage
- Unscheduled Primary Care /Hospital visits
- Breath Carbon Monoxide (CO) monitoring pre and post study
- Spirometry pre and post exposure

Ethics:

Ethical approval will be sought from DIT Ethics Committee prior to beginning of the project. All documentation relating to the project will be provided for ethical review. There are no perceived Ethical issues as patients will be fully informed and there will be no intervention other than monitoring. It was considered that requesting subjects to go into outside smoking areas might be a problem so only subjects who already frequent such areas will be recruited.

All participants will be provided with a patient information leaflet and asked to sign an informed consent form. (Appendix 1)

Methodology:

Recruitment

Relevant patient organisations will be identified in each country through European Lung Foundation (ELF) (Mr Dan Smith) and project partners.

Patients will be contacted through ELF national organisation with input from national/project partners. Inclusion and exclusion criteria, Information sheet and a short recruitment questionnaire (Appendix 1 and 2) will be distributed to possible patient volunteers.

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Consent:

Once eligibility has been determined patients will be given an appointment (in a research room either Clinic/Hospital or University based, venue to be confirmed) where they will receive an information leaflet. Once this has been read and any concerns of the participant addressed and explained, they will then be asked to provide written consent prior to their study enrolment. Consent will be obtained from all participants. Consent is on-going and participants can revoke consent at any stage of the project. (Appendix 1)
Technicians and researchers will be trained in the use of monitoring devices by TFRI staff. The 60 patients will be fitted with equipment which will measure their exposure to pollutants including Secondhand smoke as well as measuring the effects on their breathing rate.

Devices used to gather data:

Carefusion CO Monitor

The CO Monitor features single-button operation and coloured light indicators to simplify patient understanding of the process: (Appendix 3)

- Green: 0 to 6ppm
- Amber: 7 to 10ppm
- Red: 11 to 20ppm
- Flashing red and alarm: >20ppm

Spirometer:

Spirometry measures the volume of air that the patient is able to expel from the lungs after maximal inspiration.

Spirometry is invaluable as a screening test of general respiratory health, similar to BP measurement in cardiovascular disease. It is a reliable method of diagnosing and differentiating between obstructive airways disorders (e.g. COPD, asthma) and restrictive diseases (where the size of the lung is reduced, e.g. fibrotic lung disease).

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Spirometry can also be used to determine the severity of asthma and COPD. This is important because the severity of these diseases cannot be predicted simply from the clinical signs and symptoms. The FEV_1 is the maximal volume of air exhaled in the first second of a forced expiration from a position of full inspiration (expressed in litres at BTPS). The forced vital capacity (FVC) is the maximal volume of air exhaled with maximally forced effort from a maximal inspiration (expressed in litres at body temperature and ambient pressure saturated with water vapour – BTPS).

RESpeck:

RESpeck is a monitoring device, which collects data via low power wireless link for processing at base-station in patient's home. RESpeck had been verified to be a reliable measure of RR when compared with RR derived from a nasal cannula in anaesthetised post-operative patients; instantaneous RESpeck RR matched the routine clinical measurement of RR within two breaths per minute (bpm) an acceptable limit of accuracy employed previously—on 86 % of occasions, with a mean absolute difference of 0.6 bpm. (15. Drummond GB, Bates A, Mann J, Arvind DK. Validation of a new non-invasive automatic monitor of respiratory rate for post-operative subjects (Br J Anaesth. 2011;107:462–469. doi: 10.1093/bja/aer153). It will be transmitted to a server at the Centre for Speckled Computing via broadband internet where the data will be analysed RESpeck files will be downloaded from the iPod or Android tablet and the gross activity and breathing signals will be plotted. The raw data files will then be processed post hoc using proprietary software (University of Edinburgh), which produces a separate file containing time and validated RR data. The software will actively exclude any data captured in excess of a pre-defined movement threshold. This means that only the fine movements associated with breathing will be analysed, and that larger movements not associated with breathing will be omitted. The number of validated breaths captured before, during and after exposure to SHS will be noted. The maximum, minimum and mean number of validated breaths captured before and after SHS exposure per minute will also be calculated; zero data (i.e. where no validated breaths are produced per minute) will be included in the mean data. Finally, maximum, minimum, and the mean (±1 SD) RR will be recorded. (Appendix 4),

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AIRSpeck:

AIRSpeck Personal/mobile monitor will be used for exposure measurements (Appendix 5)

- Includes humidity sensor and improved WiFi range
- Detect indoor fine particulate matter (dust, smoke, exhaust, etc.)
- Plot trends over time with our free visualization tools
- Access your home's data from your smart phone or computer anywhere, anytime
- Compare indoor and outdoor* air quality readings on screen

Patient Schedule:

Each patient will visit the centre on 2 occasions the first at enrolment and training in use of equipment, this should be at least 2 to 4 hours prior to exposure. The second will be at least 24hrs post exposure to secondhand smoke at, at least one outing to an outdoor smoking area. The duration of time to be spent in the outdoor smoking area is to be a minimum of 15 mins with a preferable time of 30-60 mins.
Spirometry and Breath Co are to be done for at least 2 to 4 hours prior to exposure and 24 hrs post exposure, at the second visit to the research centre.. At the follow up visit all data will be downloaded and checked and any anomalies will be addressed and clarified with the patient.

National Partners will be trained in the use of devices measuring exposure using AirSpeck and respiratory rate using RESpeck. Data will be transmitted to server at the
Centre for Speckled Computing via Internet or mobile phone technology where the data will be analysed.
Subsequently patients in each of 3 countries will be shown how to wear and carry the personal monitor devices , ensuring data is recorded.

Data collection, analysis and report writing: This will be carried out by TFRI in collaboration with Project Partners and in consultation with Prof DK Arvind.

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Table of tasks

	Baseline visit Minimum of 2 to 4 hrs pre exposure	Post exposure visit Minimum 24hrs post exposure
Consent and information sheet	✓	
Recruitment Questionnaire	✓	
CAT/ACT form	✓	
CO Reading	✓	✓
Spirometry	✓	✓
Training of fitting and use of Respiratory device	✓	
Training and fitting of Particle monitor	✓	
Retrieve equipment and check data recorded		✓
Check patient entries and resolve any data queries		✓
Download data and send to TFRI		✓
Check devices working correctly for next subject		✓

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Other support for the Project:

Prof DK Arvind

ELF

Asthma society Ireland

Advisory Panel: Tack Project Partners:

Dr Esteve Fernandez

Dr Silvano Gallus

Dr Sean Semple

Dr Ario Alberto Ruprecht

Dr. Joan B Soriano

Dr. Constantine Vardavas

Safety Considerations

The safety of all research participants will be considered at all times, they will be seen in an insured medical practice. All personnel dealing with patients will be fully trained and insured.

The Project will be registered at www.clinicaltrials.com

Data Management and Statistical Analysis:

All data will be stored on a secure server and will be de-identified. Data will be entered giving each participant a unique identifier code; neither their name, address nor date of birth will be recorded in order to protect the confidentiality of the participant. Analysis will be carried out on a blinded dataset using SPSS. Data will be presented as mean and standard deviation (±SD) for continuous variables, or percentage for qualitative variables, as appropriate, or their 95% confidence interval. Differences within groups will be compared with Chi^2 tests for categorical

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variables and Student t test for continuous variables. A *p* value lower than 0.05 will be considered statistically significant.

Quality Assurance:

Baseline and post exposure data re CO readings, Peak flows any change in medication usage or unscheduled hospital or Dr visits will be entered at source and will be verified by the clinical nurse specialist. Patients will be asked to keep a record of any increase medication usage as well as document any Doctor or Hospital visits as well as description of outdoor smoking area visited. (Appendix 6)

All digitally recorded data will be downloaded from the device to a secure server. A Post Doc and or a Research assistant working with TFRI with advice from partners will further examine study data. Any anomalies found will be addressed and resolved from source data.

Expected Outcomes of the Study

- Exposure levels in the home
- Exposure levels in Smoking areas
- Respiratory symptoms pre and post exposure

Dissemination of Results and Publication Policy:

It is intended that research findings will be published in the form of peer reviewed research articles in first-line high impact or open access journals, and also the presentation of the main results in international tobacco control conferences, such as the European Tobacco or Health Conference, or the Annual or the European Meetings of the Society for Research in Nicotine and Tobacco. There will be a final TackSHS conference in which the main findings will be presented to patients, stakeholders, and policy makers. Together with this, dissemination materials (i.e., factsheets, press releases) will be produced and published in

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the TackSHS website as well as disseminated through the websites of the collaborating partners and stakeholders. The results will also be EU deliverables for TackSHS project.

Problems Anticipated:

Recruitment

Co-operation of partners in Spain and Hungary at the appropriate time.

Lag time of symptoms post exposure.

Proof of smoking on site, photograph of venue will be needed to verify this

Translation and local adaption of documents

Project Management

Luke Clancy is WorkPackage 5 Leader.

Sheila Keogan will be responsible for the management of the project, obtaining consent of all participants in the project, project equipment and gathering and safety of all data. A Post Doc and research assistant working with TFRI will aid in verifying validity of data and the statistical analysis.

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Duration of the Project:

The project is to run for a 4-year period starting November 2015 and completion is expected by October 2019.

Gantt chart

Due Month Number					
	12	13	14	15 to 30	48
Protocol					
Local Ethical approval					
Study registration number					
Ethical approval of Spain and Hungary					
National Level Training in use of sensors					
Recruitment and data collection					
Report of Results					

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Appendix 1.

Patient Information Sheet and Consent Form

Tackling secondhand tobacco smoke and e-cigarette emissions: exposure assessment, novel interventions, impact on lung diseases and economic burden in diverse European populations. TACK SHS Horizon 2020

Exposure to Secondhand smoke in exempted areas/outside areas and acute health effects in patients with chronic lung disease.

What is this study about?

Smokefree legislation has been successful in its primary aim of eliminating smoking in public indoor places. However, the exemptions allowed for within the law (i.e. smoking shelters in pubs, smoking in prisons and nursing homes, and smoking within the home) raise further challenges. Along with adults, children are often exposed to secondhand smoke in homes, cars, and sporting venues. Our previous research has also shown that children are also exposed to Secondhand Smoke in cars in sporting venues and at home. As partners in the EU funded IMPASHS project we are aware of the undesired complications of the exemptions to the legislation.

To date, it has been very difficult to gather accurate, objective data on Secondhand smoke exposure among adults in Ireland. This study aims to measure Secondhand Smoke exposure during everyday activities in 3 European countries (Ireland, Spain and Romania) and monitor the associated health effects.

How do you measure air pollution?

Air pollution will be measured through the use of a cutting-edge, small portable instrument that can continuously and rapidly record changes in the air. Breathing will be measured by a peak flow meter and exhaled breath gases (e.g. Carbon Monoxide). Every participant will be given a peak flow meter and asked to blow into it at pre-designated times. A small sensor attached to each

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participant's chest will measure respiratory rate, this will transmit a signal to a tablet device where the data will be recorded. (RESpeck). This will not cause any undue discomfort or inconvenience to participants.

What does participation involve?

Step One: A researcher will contact you by phone to discuss participation in further detail and answer any questions you may have.

Step Two: If you agree to take part: A researcher will arrange an appointment for you to attend St James's Hospital or DIT Clinical Measurement Lab, where

- Any queries you may have will be addressed.
- You will be provided with an information sheet and a consent form, which you will be asked to read.
- The recording devices will be demonstrated to you and fitted in place.
- Carbon monoxide (CO) readings which is a breath test, will be carried out at both the initial and second visit.
- Breathing tests (Spirometry) will be carried out at both the initial and second visit
- You will be asked to complete a short de-identified questionnaire (which will ensure that your information is private).
- An agreed appointment will be made for the return of the devices 24hrs later when repeat breathing tests will be carried out as well as downloading of the recorded data from the supplied smartphone.

Do I have to participate?

Absolutely not, participation is 100% voluntary. No one will be included in any stage of the research unless they have given consent. Participants can revoke consent at any stage of the process.

Will this be confidential?

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All information that is gathered in this study remains 100% confidential. Your information will be stored in a de-identified form on a secure computer that is only used by members of the research team. No one will have access to the information gathered in this study aside from the researchers and it will only be used for research purposes. There will be no identifiable information stored in the computer at any stage during this research.

Who is running this study?

This project is part of a European Study funded by EU Grant Horizon 2020. The co-ordinator of the project is Dr. Estevez Fernandez of the Institut Catala D'Oncologia in Barcelona Spain. The part of the project you will be involved in is being run by the TobaccoFree Research Institute Ireland. The TFRI was formed on the basis of a partnership between the Office of Tobacco Control and ASH Ireland. The Institute supports the development of a tobacco free society by engaging in research in all aspects of tobacco from a public health perspective to provide the evidence base for action.

It is only by conducting studies such as these that we are able to understand the impact of Secondhand Smoke on our airways. Through studies like this, we are able to work towards promoting the health of people in Ireland and abroad.

We hope that you can support us in our work and we would thank you, in anticipation, for your help.

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Participant Consent

I have read the information sheet pertaining to the 'Exposure to secondhand smoke in exempted areas/outside areas and acute health effects in patients with chronic lung disease.' project,

I understand that research is being conducted by The TobaccoFree Research Institute Ireland and that my participation is completely voluntary.

I understand that by agreeing to take part in the study that it will involve me attending for at least 2 scheduled visits to the research centre. Visit one will involve: written consent, explanation and demonstration on the use of the recording device, and the keeping of an event diary. Visit two will involve the returning of the device and the handing in of the event diary.

Participant Name (Print) _____

Participant Signature: _____,

Date; _____,

Investigator Name: (Print) _____,

Investigator Signature: _____,

Date: _____

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Appendix 2:

Recruitment Questionnaire

Tackling secondhand tobacco smoke and e-cigarette emissions: **exposure assessment**, novel interventions, impact on lung diseases and economic burden in diverse European populations. The TackSHS Project.

New approaches to monitoring exposure to air pollution and health effects

Researcher: Sheila Keogan

This is a short questionnaire to ascertain personal smoking status, other sources of exposure, average weekly exposure in hospitality premises, and experience of respiratory symptoms. Please circle your response where appropriate.

Unique Identifier code: XXXX

1. Are you Male Female
2. What is your age?
3. Do you ever smoke cigarettes/tobacco? Yes/No

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If yes

- for how many years?
- At what age did you start to smoke?
- Do you smoke everyday Yes/No
- How many do you smoke on an average per day?

4. Do you currently live with any smokers? Yes/No

If yes

- how many?
- do they smoke in the home?

5. Are you exposed to smoking in cars? Yes/No

If yes

- How many trips per week?
- What is the average duration of these trips?

6. Do you visit smoking areas in the hospitality sector such as Pubs or Restaurants? Yes/No

If yes:

- How often per month?

7. Have you been diagnosed by a doctor with? Asthma COPD Neither

If yes how long is it since your diagnosis? ------Years -------Months

8. Do you suffer from any of the following?

Wheeze	Never	Sometimes	Often
Cough	Never	Sometimes	Often

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Shortness of breath	Never	Sometimes	Often
Stinging or irritation of the eyes	Never	Sometimes	Often

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Appendix 3:

CO Monitor

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All the tools you need for smoking cessation... from CareFusion

At CareFusion we are proud of our innovations and dedication to providing healthcare professionals with the best tools for the job.

As someone who is involved in the field of smoking cessation, you are only too well aware of the dangers caused by smoking. What you need is a means of quickly and effectively monitoring your patient's breath Carbon Monoxide levels, and then convincingly persuading them of the risks they bring upon themselves by smoking.

Design Innovation

Ergonomically designed unit of distinctive appearance, the textured handgrip encourages easy and reassuring use. Both the MicroCO™ and SmokeCheck™ are small, lightweight and are moulded from high impact ABS for durability.

CareFusion can offer you two types of carbon monoxide monitor:

MicroCO™

The MicroCO™ provides accuracy and simplicity in CO breath testing. Some of its many features include, fast response time, 1ppm resolution, immediate display of CO levels in PPM and %COHB, colour light indicators, capable of interfacing with COBRA™, (a complimentary Windows® based software package for performing and storing real time breath tests on your PC).

SmokeCheck™

The SmokeCheck™ is designed as a simple screening test for cigarette consumption. Giving an instant indication of breath CO breath ranges (expressed in PPM), and backed up with colour light indicators.

Conversion of PPM results to %COHB is easily done using the SmokeCheck™'s smoking cessation guide chart provided.

Complete with all accessories

Both MicroCO™ and SmokeCheck™ come complete with a hard shell carry case, sample cardboard mouthpieces, one-way plastic mouthpiece adaptor, calibration adaptor, calibration tool, 9V PP3 battery and operating manual.

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Customer Benefits and Features of the MicroCO™

The MicroCO™ is a powerful diagnostic tool for measuring alveolar Carbon Monoxide concentrations (in PPM) and percentage Carboxy haemoglobin. Operating from a single 9V PP3 battery for approximately 2000 tests the MicroCO™ combines accuracy and simplicity making it the perfect choice for professionals worldwide.

Ease of Use

Measurements are easily obtained from a single expiration and are aided by an auto-zero function at turn on, combined with a breath hold countdown timer. The results are then instantly displayed on the large, easy to read liquid crystal display, and are visually represented by the appropriate colour light indicator.

Customer Features and Benefits of the SmokeCheck™

The SmokeCheck™ is a low cost breath CO monitor available today. Four ranges of CO levels are featured on the custom LCD.

0 to 6 ppm and green light will indicate a non-smoker 7 to 10 ppm and amber light will indicate a light smoker 11 to 20 ppm and red light will indicate a moderate smoker 20+ ppm and red flashing light with audible alarm will indicate a heavy smoker.

Calibration Gases

In order to keep your MicroCO™ and SmokeCheck™ in precision working order, and always have at your disposal reproducible results, the MicroCO™ and SmokeCheck™ will require a calibration check at six monthly intervals. Calibration can easily and safely be carried out by the end user with our Medican, 1 litre size calibration gas cylinder. Alternatively, a calibration service is available by returning your MicroCO™/SmokeCheck™ to CareFusion or an authorised CareFusion agent.

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Specifications

MicroCO™

Display ranges	0–100ppm
Sensitivity	1ppm
Sensor life	2-5 years
Sensor drift	<2% per month
Display	31/2 digit custom LCD
Weight (Nett/packed)	160gm/1kg
Dimensions	170 x 60 x 28mm
Indicator levels	green - 0-6ppm; amber - 7-10ppm; red - >11+ppm poison audio alarm - >72ppm
PPM to %COHb	Conversion displayed on unit

SmokeCheck™

Display ranges	0–100ppm
Sensitivity	1ppm
Sensor life	2-5 years
Sensor drift	<2% per month
Display	31/2 digit custom LCD
Weight (Nett/packed)	130gm/950gm
Dimensions	170 x 60 x 26mm
Indicator levels	green - 0-6ppm; amber - 7-10ppm; red - >11+ppm poison audio alarm - >72ppm
PPM to %COHb	Conversion using CO Chart Supplied

International Sales:
CareFusion Germany 234 GmbH.
Leibnizstrasse 7,
D-97204 Hoechberg,
Germany.

Customer Services:
+49 (0) 931 4972 670 tel
+49 (0) 931 4972 423 fax
micro.internationalsales@carefusion.com

U.K Sales:
CareFusion UK 232 Ltd.
The Crescent, Jays Close,
Basingstoke,
RG22 4BS, UK

Customer Services
+44 (0) 1256 388550 tel
+44 (0) 1256 330860 fax
micro.uksales@carefusion.com

Research and Design Office:
CareFusion UK 232 Ltd.
Quayside, Chatham Maritime,
Chatham, Kent,
ME4 4QY, UK

+44 (0) 1634 899599 tel
+44 (0) 1634 899598 fax
micro@carefusion.com

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Appendix 4:

Respeck

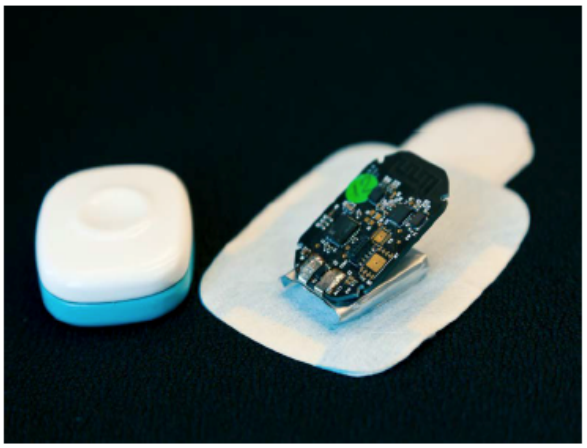
RESpeck Device

Wireless patch with a three-axis accelerometer

Sealed case and self-adhesive pouch

Measures chest wall rotations as the wearer breathes

Provides a respiratory effort waveform, respiratory rate and patient activity data



Specknet

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Wireless Healthcare of COPD

- Wireless patch worn on the torso
- Re-useable wireless sensor module
- Contained in a single-use sleeve for hygienic attachment to the torso
- Data collection and processing in a base-station via ultra low power wireless link
- Transmitted via broadband internet or via GPRS to server
- Remote respiratory monitoring service

Specknet

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Respiratory Monitoring Service

- Daily reports summarising hourly trends
- Option to access historical data
- Respiratory rate, respiratory effort/flow, activity, heart rate, cough frequency, speech episodes
- Remote examination of patient's breathing in real-time

Specknet

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Patient-centric design

- Long-term wear
  - Light-weight - 17gms (incl. battery)
  - Unobtrusive - 4.5 x 3.7 x 1.3 cm
  - Battery lifetime - 12 months
- Ease of use
  - No recharging of batteries
  - Data stored on wireless patch and downloaded to the base-station when within range – no manual intervention
- Remote monitoring of performance of sensor devices for scalable deployment
  - Diagnostic data on sensor performance
  - Wireless patch replaced due to malfunction or before the battery runs out

Specknet

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ORIGINAL RESEARCH

Lightweight physiologic sensor performance during pre-hospital care delivered by ambulance clinicians

Alasdair J. Mort · David Fitzpatrick · Philip M. J. Wilson · Chris Mellish · Anne Schneider

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Abstract The aim of this study was to explore the impact of motion generated by ambulance patient management on the performance of two lightweight physiologic sensors. Two physiologic sensors were applied to pre-hospital patients. The first was the Contec Medical Systems CMS50FW finger pulse oximeter, monitoring heart rate (HR) and blood oxygen saturation (SpO2). The second was the RESpeck respiratory rate (RR) sensor, which was wireless-enabled with a Bluetooth Low Energy protocol. Sensor data were recorded from 16 pre-hospital patients, who were monitored for 21.2 ± 9.8 min, on average. Some form of error was identified on almost every HR and SpO_2 trace. However, the mean proportion of each trace exhibiting error was ⩽10 % (range ⩽1–50 % for individual patients). There appeared to be no overt impact of the gross motion associated with road ambulance transit on the incidence of HR or SpO_2 error. The RESpeck RR sensor delivered an average of 4.2 (±2.2) validated breaths per minute, but did not produce any validated breaths during the gross motion of ambulance transit as its pre-defined motion threshold was exceeded. However, this was many more data points than could be achieved using traditional manual assessment of RR. Error was identified on a majority of pre-hospital physiologic signals, which emphasised the need to ensure consistent sensor attachment in this unstable and unpredictable environment, and in developing intelligent methods of screening out such error.

Keywords Physiologic monitoring Pre-hospital Ambulance clinicians Motion artefact

1 Introduction

The pre-hospital context is a notoriously difficult environment in which to measure patient physiology accurately and reliably. If the patient is trapped (e.g. following a road traffic collision) then it may be difficult to make appropriate manual assessments or to apply electronic monitoring equipment. There is often movement of unpredictable

A. J. Mort P. M. J. Wilson C. Mellish A. Schneider
dot.rural Digital Economy Hub, King's College, University of Aberdeen, Aberdeen, Scotland, UK

A. J. Mort (&) P. M. J. Wilson
The Centre for Rural Health, University of Aberdeen, Centre for Health Science, Old Perth Road, Inverness, Scotland, UK
e-mail: a.mort@abdn.ac.uk

D. Fitzpatrick
Scottish Ambulance Service, Gyle Square, Edinburgh, Scotland, UK

C. Mellish

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Department of Computing Science, King's College, University of Aberdeen, Aberdeen, Scotland, UK

amplitude and acceleration in multiple directions. For example, the patient may be moved in the process of immediate, potentially life-saving management. This might include clearing the patient's airway, inserting a device that protects the airway, conducting chest compressions where the patient is in cardiac arrest, or moving an unconscious but breathing patient into the recovery position.

Patients must also be moved to a location where they can receive definitive treatment for their illness and/or injury. However, it may take more than one journey and there may be intercurrent treatment at more than one site before definitive care is reached. In most cases pre-hospital patients are transported by emergency ambulance, which in the United Kingdom are staffed by a mixture of qualified Paramedics and

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Technicians; those qualified to a lower level than Paramedics with a smaller skill-set. The time taken to transport patients to hospital can vary greatly, influenced mainly by the geographic site of the emergency. That is, it can take much longer to transport rural patients to hospital than it might do in urban centres. Much of the patient assessment and physiologic monitoring conducted by rural ambulance clinicians thus takes place during road and air transit.

Standard physiologic parameters (e.g. blood pressure, heart rate, respiratory rate) play a key role in the triage of pre-hospital patients as they may indicate present and future patient deterioration. For example, validated systems such as the National Early Warning Score are now widely used [1]. Hillman et al. [2] reported serious physiological abnormalities in 29 % of patients in the 8 h prior to death (excluding cardiac arrests and deaths whilst in intensive care). Also, one-third of patients who did not have 'do not resuscitate' orders had persistently abnormal physiology for 2 days prior to death. The physiologic abnormality reported most often was hypotension, followed by tachypnoea, then tachycardia. Other studies have also reported considerable instability in standard physiologic measures prior to a major, life-threatening event (e.g. respiratory arrest, cardiac arrest, haemorrhagic hypotension) [3–5], although this is not always the case [6, 7].

The physiologic monitoring systems operated by ambulance clinicians most often take the form of a single device that measures several parameters. For example, the Scottish Ambulance Service operated the Philips HeartStart MRx system (Philips, Netherlands), which apart from being a defibrillator measured blood pressure on the upper-arm, and blood oxygen saturation and heart rate through a pulse oximeter attached to a finger. The monitor also captured a 12-lead ECG, and could be linked via Bluetooth to a mobile phone from where the ECG was transmitted to a coronary care unit for expert advice. Monitors like these are suitable for ambulance use as they are rugged and can be removed from the vehicle to conduct monitoring where a patient is located (e.g. in their house, by the roadside). However, they tend to be relatively heavy (due to battery requirements) and the sensors are wired. Wires can be snagged, pulling on the site of attachment resulting in spurious readings and even pulling the sensor(s) off the patient altogether. There have also been anecdotal reports of emergency workers accidentally cutting cables during the extrication process. Such systems provide continuous monitoring, although the recording of individual values to care provider files is usually performed manually, limiting the volume of data recorded to perhaps two or three data points (depending upon the duration of patient transport). There is evidence that having a much larger volume of physiologic data is a better predictor of later mortality than relying upon a single value [8].

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Lightweight wireless physiologic monitors are now in existence, developed partly through an international effort to enable and enhance the monitoring of patients in their own homes (i.e. telehealth). We propose that such monitors could play a major role in the future of pre-hospital care, employed by ambulance clinicians where lightweight, wireless monitoring could convey an advantage over current heavy, wired systems. We also contend that these monitors may be beneficial to Community First Responders (CFRs) who volunteer to deliver basic first-aid for ambulance services whilst an emergency ambulance is on its way. Such devices, if simple to apply and use, could greatly increase the volume of data that such personnel are able to capture, and potentially alert them to patient deterioration that they may be able to address within their limited skill-set. Facilitating the capture of more physiologic data is particularly important given the general lack of evidence to support CFR activity; this would help to inform their practice and policy. However, this is only applicable if such technology can deliver accurate data reliably during the unstable and unpredictable context of pre-hospital care.

Commonly-recorded physiologic parameters are influenced by motion and in turn display artefact or 'noise'; physiologic waveforms deviate from their 'normal', characteristic patterns and erroneous data are potentially reported to the user. Such error could take the form of falsely low or high readings, often triggering alarms that then distract the operator from keeping a physical watch on the patient. Most physiologic sensors include some form of signal processing so that they can continue to deliver data in the face of motion or extreme physiologic compromise. However, it is reasonable to postulate that there is a threshold beyond which a physiologic sensor will no longer be able to deliver accurate data; for example, if finger perfusion is so low that it is impossible to generate valid blood oxygen saturation and pulse data.

The aim of our study was to explore the impact of ambulance clinician patient management and transport on defined parameters recorded from patients by two lightweight physiologic sensors. This contributed to the University of Aberdeen Managing Information in Medical Emergencies (MIME) project (see www.dotrural.ac.uk/mime), which developed and evaluated technology to support CFRs at the scene of rural medical emergencies [9].

2 Materials and methods

2.1 Design

The study employed a 'field-function' design, which involved controlled 'pseudo-deployment' of the physiologic sensors in a real-life situation [10].

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2.2 Setting

The study took place at a Scottish Ambulance Service station in the north of Scotland, UK (Fig. 1). The station responded to a variety of types of call-outs originating from urban and rural areas.

2.3 Participant identification and recruitment

2.3.1 Ambulance clinicians

Clinicians from two station 'watches' were invited to take part. Clinicians attended an evening presentation at which the study and their proposed role in the research were described. All clinicians who volunteered to take part were asked to provide written, informed consent.

2.3.2 Pre-hospital patients

The first approach to patients was made by recruited ambulance clinicians according to set inclusion criteria (Table 1). The decision of whether or not to approach each patient was made ultimately at clinicians' discretion. They were only to approach patients if the application of the physiologic sensors did not interfere with the timely delivery of their 'usual' care.

The first stage of consent involved clinicians describing the study to patients verbally. Patients were given the opportunity to ask any questions, and if they were happy to proceed they provided verbal informed consent on-scene. A preliminary verbal informed consent was deemed appropriate considering the relatively low risk nature of the study. The second stage of consent involved sending patients an opt-out form to their home address within a study information pack, at least 2 weeks after their contact with

Fig. 1 Scottish Ambulance Service emergency vehicle

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the research. Whilst consent mechanisms based on opting out are not the norm, these have previously been carried out in other pre-hospital emergency care research where patients were in a vulnerable state immediately after their emergency care visit, and are well recognised as being a difficult group to make contact with [11, 12]. We considered opt-out consent to be satisfactory in this situation where there was no significant risk of harm to participants and no risk to patient confidentiality. An opt-in approach could have resulted in lower recruitment and therefore lower generalisability of the results [13].

The local NHS Health Board was contacted prior to mailing study information packs in order to establish whether or not patients had been discharged from hospital. Patients who had died and those who completed the opt-out form were excluded from the study. All patients who participated were given a unique identification number in order to anonymise their involvement.

2.4 Physiologic parameters

Three physiologic parameters were selected to monitor; respiratory rate (RR), heart rate (HR) and blood oxygen saturation (SpO_2). RR was chosen as it is an essential clinical parameter that traditionally is difficult to monitor both reliably and repeatedly in anything but a resting, motionless patient. Indeed, RR has previously been described as the 'neglected vital sign' [14]. In the pre-hospital environment, ambulance clinicians will monitor RR by counting the rise and fall of the patient's chest/abdomen and/or the misting and de-misting of a non-rebreathing oxygen mask (not including RR monitored using capnography in the intubated patient). This means that only a small number of RR data points are recorded during the time that ambulance clinicians are with the patient. HR and SpO_2 were selected as they are also parameters that are monitored ubiquitously in the pre-hospital environment using pulse oximetry.

Respiratory rate, HR and SpO_2 formed the basis of a novel pre-hospital physiologic monitoring system that we developed within our research group for use by Ambulance Service CFRs. They are all parameters that can be monitored using lightweight physiologic sensors that are simple and quick to apply by non-medical experts.

2.5 Physiologic sensors

Two lightweight, non-invasive physiologic sensors were selected for application to ambulance patients. The first was the Contec Medical Systems CMS50FW pulse oximeter (Contec Medical Systems, Qinhuangdao, China), which monitored SpO_2, HR and also displayed the photoplethysmograph to the user.

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Table 1 Pre-hospital patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adults (18 years and above)	Unable to understand verbal explanations given in English—also including those with special communication needs
Males and females	Patients with injuries or in a position that prevented application of the sensors
Ability to represent own interests and to provide verbal, informed consent	
Able to apply the sensors to the patient	

The CMS50FW had Bluetooth capability to send data wirelessly. However, this facility was turned off in this study and the data stored on the device instead (NOT including photoplethysmograph data). Capturing data wirelessly would have necessitated a separate laptop computer and time-consuming device pairing, both of which were inappropriate in the space-restricted and time-dependent emergency ambulance environment. Non-averaged HR and SpO_2 data were recorded in a comma separated value file at a rate of 1 Hz.

The second monitor was the RESpeck RR sensor (University of Edinburgh Department of Speckled Computing, School of Informatics, Scotland), which was an encapsulated tri-axial accelerometer positioned on the left side of the abdomen just under the costal margin. RESpeck recorded changes in abdominal position in three orthogonal axes, relative to gravity. These data were automatically integrated and differentiated into a derived 'activity' signal, and a RR signal with a shape similar to inspiratory and expiratory flow. RESpeck had been verified to be a reliable measure of RR when compared with RR derived from a nasal cannula in anaesthetised post-operative patients; instantaneous RESpeck RR matched the routine clinical measurement of RR within two breaths per minute (bpm)—an acceptable limit of accuracy employed previ- ously—on 86 % of occasions, with a mean absolute dif- ference of 0.6 bpm [15]. However, our study was the first time that RESpeck had been implemented in the pre-hos- pital environment. RESpeck was entirely wireless and all data were transmitted using a Bluetooth 4.0 Low-Energy protocol to an iPod (Apple, Cupertino, CA, USA) on which the data were displayed and recorded. Accelerometer data were recorded at a rate of 12.5 Hz. Figure 2 displays both medical sensors and their method of attachment to the body.

2.6 Study protocol

Upon arrival on-scene, ambulance clinicians approached each patient and carried out a primary survey of their clinical status. If the patient provided verbal informed

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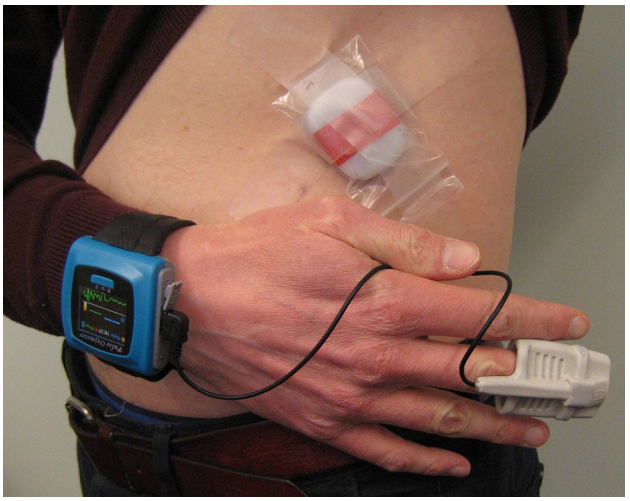

Fig. 2 Medical sensors employed in the pre-hospital fieldwork

consent the aim was to apply the sensors as early as appropriate. The pulse oximeter was attached first by ambulance clinicians to patients' index fingers. A stopwatch was started at the point that pulse oximeter data recording was initiated, which provided a 'time zero' reference. Secondly, the RESpeck RR sensor was enclosed in a protective plastic sleeve (to meet infection control requirements) and attached to the abdomen using Transpore™ medical tape (3 M Healthcare, USA). It was then paired with the iPod and data recording commenced 30 s after the pulse oximeter data stream began. Data were recorded from both sensors until the end of ambulance clinician management, which was most often at the point of handover to hospital Emergency Department staff. However, there were a small number of occasions where patients were transported directly by ambulance to a receiving ward (i.e., for referrals by General Practitioners), or were not transported by ambulance at all if it was deemed appropriate to leave them at home.

A researcher (AM) travelled as an observer in the ambulance, and only came into contact with patients if they had provided verbal consent. The researcher oversaw the

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application of the sensors by ambulance clinicians and was responsible for starting and stopping data recording on each device. He also carried a Getac Z710 rugged tablet computer (Getac, Irvine, CA, USA) that ran software (University of Aberdeen) that captured the input of contextual information about patient management and clinical status. This was essential in order to explore the effect of patient management on sensor data. A copy of the electronic Patient Report Form (ePRF) was retrieved for each patient in order to gather as much contextual data about each patient and their management as possible. The ePRF contained all clinical data, including interventions, recorded by ambulance clinicians. The form permitted the formal handover of information between ambulance clinician and Emergency Department staff on arrival at hospital. Each record contained its own unique incident number that enabled calls to be traced and patients identified at a later date if necessary.

Data collection proceeded until reasonable "saturation" (defined as the point at which no new patterns of data were emerging) was achieved, assessed by author AM. This approach to sampling is commonly used in qualitative research and was appropriate in this exploratory study.

2.7 Data analysis

2.7.1 Pulse oximetry

Heart rate and SpO_2 data were initially reviewed and plotted to explore for any gross deviations from 'normal' physiologic values. In particular, the pulse oximeter logged a non-physiologic value of 255 BPM for HR and 127 % for SpO_2 when the sensor was removed from the finger, or if finger attachment was sub-optimal. The frequency of such values was noted. The maximum, minimum, mean and standard deviation for HR and SpO_2 were then calculated on a patient-by-patient basis. Further analyses explored for the presence and length of any periods of pulse oximeter data that appeared 'abnormal'. Our definition of 'abnormal' also included any incidence of a sudden, apparently non-physiologic, increase or decrease in blood oxygen saturation and/or heart rate from a stable value. The total time that each sensor exhibited 'abnormality' was expressed as a percentage of the total monitoring time. This was also expressed as the proportion of 'abnormality' at nominal rest, and the proportion of 'abnormality' during ambulance transit, in order to explore for any apparent impact of gross motion on signal quality.

2.7.2 Respiratory rate

RESpeck files were downloaded from the iPod and the gross activity and breathing signals were plotted. Patient management data were plotted on top of each trace, noting

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in particular the start and end of gross motion associated with ambulance transit. The raw data files were then processed post hoc using proprietary software (University of Edinburgh), which produced a separate file containing time and validated RR data. The software actively excluded any data captured in excess of a pre-defined movement threshold. This meant that only the fine movements associated with breathing were analysed, and that larger movements not associated with breathing were omitted. The number of validated breaths captured before, during and after ambulance transit were noted. The maximum, minimum and mean number of validated breaths captured before and after ambulance transit per minute was also calculated; zero data (i.e. where no validated breaths were produced per minute) were included in the mean data. Finally, maximum, minimum, and the mean (±1 SD) RR were recorded.

2.8 Ethical approval

The study was approved by an NHS Research Ethics Committee and by the Scottish Ambulance Service's Research Governance Group.

3 Results

3.1 Patients

A total of 20 pre-hospital patients gave verbal consent to take part in the study. Data for four patients were excluded: three patients opted out, and one patient died sometime after admission to hospital. This left a total of 16 patient data sets for inclusion (ten male, six female; age range 42–96 years). Patients were managed by ambulance clinicians for a wide variety of suspected medical problems and injuries (Table 2); there were 12 emergency calls, three urgent call-outs (requested by local General Practitioners) and one patient transfer from hospital to a local airport. A majority of patients (n = 13) were transported to the local hospital (10 to the Emergency Department and three to an acute receiving ward). Two patients (both emergency calls) were not transported to the Emergency Department; one was a diabetic whose blood sugar levels returned to normal after treatment, and the other was a bariatric patient who had fallen but on assessment did not have any injury or illness.

3.2 Monitoring time

Mean sensor monitoring time was 21.2 ± 9.8 min (total = 5.7 h; range 7.4–41.5 min). For patients who were transported to hospital, mean monitoring time at nominal

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Table 2 Pre-hospital patient clinical status

Patient ID PM—male PF—female	Working clinical assessment	Response	Airway	Breathing rate range (breaths per min)	Pulse rate range (beats per min)	SpO_2 range (%)	Glasgow coma scale
PM1	Central chest pain	Alert	Clear	14–20	46–62	99–100	15
PM3	Road traffic collision injuries (some pain, abrasions and contusions)	Alert	Clear	16	74–76	98	15
PM4	Chest pain	Alert	Clear	16	97–105	97–100	15
PM5	NA—transfer from hospital to airport after discharge	Alert	Clear	16–17	73–74	93–95	15
PM7	Non-traumatic back pain	Alert	Clear	16–24	80–100	94–99	15
PM8	Unknown problem	Alert	Clear	16	106	100	15
PM9	Diabetic	Alert	Clear	16	70–75	93–96	15
PM10	Sick person	Alert	Clear	12–14	62–65	94	14
PM11	Diabetic	Alert	Clear	14–16	100–110	95–97	15
PM12	Fall	Alert	Clear	15	114	92	15
PF1	Fall	Alert	Clear	Not recorded	81	98	15
PF2	Back pain	Alert	Clear	16–24	70–88	98–99	15
PF3	Sick person	Alert	Clear	20	101	100	15
PF6	Stroke, numbness, paralysis, or movement problems	Responding to pain	Clear	15	70	95	14–15
PF7	Abdominal pain	Alert	Clear	32	74	99	14
PF8	Stroke history	Alert	Clear	19	64	98	15

NB these are the clinical working assessments recorded by ambulance clinicians immediately prior to ending their management

rest (i.e. before and after gross motion associated with ambulance transit) was 11.4 ± 9 min (range 3.3–36.8 min), and mean road transport time was 12.9 ± 8.2 min (range 3–27.4 min).

3.3 Heart rate and blood oxygen saturation

The pulse oximeter was applied successfully to all patients. Mean HR was 83.7 ± 10.5 BPM (maximum = 166 BPM, minimum = 49 BPM). Mean SpO_2 was 93.9 ± 0.9 % (maximum = 99 %, minimum = 79 %). Non-physiologic, 'abnormal' values and signal patterns were present on a majority of HR and SpO_2 traces (n = 12/16 for HR, n = 13/16 for SpO_2). HR traces mirrored the 'abnormalities' seen on SpO_2 traces, and vice versa, on all but one occasion.

3.3.1 Heart rate

The most frequent non-physiologic HR value returned was 255 BPM (n = 12/16), which was what the sensor recorded in its memory when it was removed from the finger. However, it was apparent from observing the monitoring process that the pulse oximeter was removed from patients' fingers in the middle of monitoring on only two occasions.

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Hence, 255 BPM was recorded when the pulse oximeter monitoring conditions were sub-optimal, whilst the sensor was still attached to the finger. The other type of apparent error noted (n = 3/16) was rapid, non-physiologic drops and increases in HR, with periods in-between where HR remained artificially static. This was contrary to the normal physiologic undulations in HR that were evident in other parts of the trace for the same patient (Fig. 3).

The absolute duration of individual HR errors ranged from 2 s up to almost 20 min in the most extreme case (mean 80.9 ± 237.5 s). HR error occurred between one and five times for each patient. The proportion of each HR trace that exhibited apparent error ranged from under 1 to almost 50 % (mean 8.8 ± 13.9 %); however, the proportion of error was ⩽10 % on 9/12 occasions, and ⩽5 % on 7/12 occasions, where error presented. There appeared to be no effect of gross motion associated with ambulance transit on the incidence of HR error, or on the duration of individual HR errors.

3.3.2 Blood oxygen saturation

The non-physiologic SpO_2 value recorded most frequently was 127 % (n = 12/16). SpO_2 traces also exhibited fluctuations in the form rapid drops and rises, a minority of

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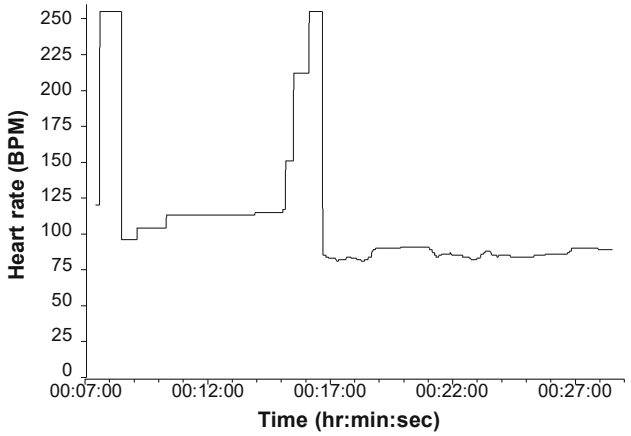

Fig. 3 Example of pulse oximeter HR abnormality (Patient PM7)

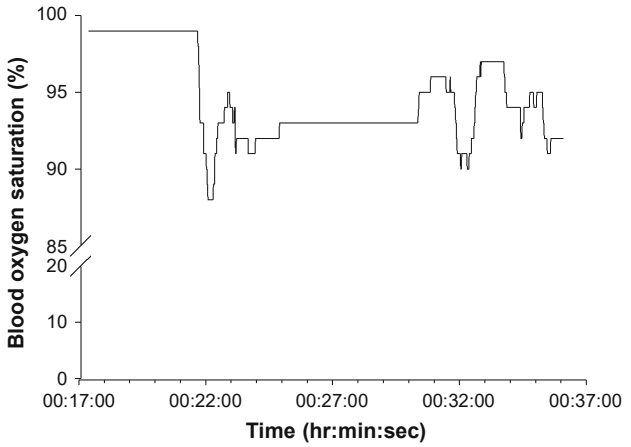

Fig. 4 Example of SpO_2 apparent error (Patient PM7)

which appeared to be error (n = 3/16) (Fig. 4), whilst others appeared physiologically feasible (Fig. 5). SpO_2 was more stable for some patients, and less so for others.

The range of duration of individual SpO_2 errors was almost exactly the same as for HR, with each error occurring between one and four times for each patient. The proportion of each SpO_2 trace that included apparent error ranged from under 1 % to almost 50 % (mean 7.6 ± 13.2 %); 10/13 traces ⩽10 %, and 8/13 traces ⩽5 %. Just as for HR, there appeared to be no effect of gross motion associated with ambulance transit on the incidence of SpO_2

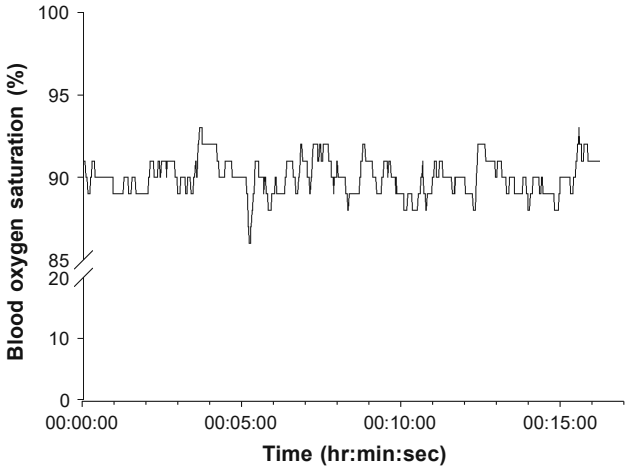

Fig. 5 Example of 'normal' SpO_2 fluctuation (Patient PF3)

error, or on the duration of individual errors. HR and SpO_2 errors tended to occur at the same time.

3.4 Respiratory rate

The RESpeck sensor was applied successfully to 14/16 patients. On two occasions the patient's clothing impeded

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application to the abdomen. On average, 40 % of activity data were below the pre-defined activity threshold, and 60 % (±18.9, 1 SD) were above it. This meant that 60 % of data were actively excluded from the RESpeck post hoc analysis. However, the proportion of data in excess of the activity threshold ranged between 27.4 and 86.5 % in individual patients, meaning that the level of motion varied widely.

The total number of validated breaths captured at nominal rest (i.e., without the gross motion associated with ambulance transit) during individual patient management ranged from 5 to 255, with an average of 54.6 breaths captured per patient (±65, 1 SD). The maximum number of validated breaths returned by RESpeck for each patient ranged between 3 and 18 breaths per minute. The mean number of validated breaths reported per minute, including zero values for minutes where no validated breaths were returned, ranged from 0.5 to 7.9 (overall mean across all patient data = 4.2 ± 2.2, 1 SD). Breathing rate ranged from 5.3 to 35.3 breaths per minute, whilst mean breathing rate for each patient ranged from 9.7 to 21.2 breaths per minute.

Only 29 validated breaths were captured during ambulance transit across 3/11 patients (n = 15, 12, 2), compared to 765 breaths recorded at nominal rest from 14 patients.

4 Discussion

This was the first study of its kind to robustly measure the impact of pre-hospital motion on commonly monitored physiologic parameters. Our research study identified some form of error in nearly every blood oxygen saturation, heart rate and breathing rate signal. For most pre-hospital patients error accounted for a relatively small proportion of

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pulse oximeter recording. The breathing rate sensor delivered considerably less data, but still produced many more data points than would be achievable through manual assessment alone.

Signal artefact is a key limitation of pulse oximeter technology, which can arise from low signal-to-noise ratio and from false signals [16]. Pulse oximetry relies on the assumption that all of the pulsating blood is arterial. However, motion mobilises venous blood, which has a lower SpO_2 and mixes with the arterial component. Motion thus tends to lower SpO_2 and produce false alarms [17]. This effect is exaggerated if there is low perfusion to the site of monitoring. Clinical studies have demonstrated this effect. For example, Wikilund et al. [18] noted that, post-anaesthesia, the pulse oximeter alarmed every eight minutes, on average. Some 77 % of oximeter alarms were found to be false, with motion indicated as one contributing factor. It also appeared that finger pulse oximeters demonstrated a poorer true/false ratio than ear pulse oximeters (18 vs. 29 %). Tsien and Fackler [19] reported that [90 % of SpO_2 and heart rate alarms generated by pulse oximeters in an intensive care unit were false positives. Generally speaking, pulse oximeters result in more false-positive alarms than other physiologic monitoring systems. The clinically-relevant positive predictive value (=number of clinically-relevant true positives divided by clinically-relevant true positives ? clinically-irrelevant true positives ? false positives) for pulse oximetry has, accordingly, been reported to be very low (B6 %, for both SpO_2 and the derived heart rate value, Ibid). However, it is important to note that the threshold of alarms will vary from study to study, and the threshold is open to adjustment by users.

Langton and Hanning studied the ability of four different pulse oximeters to identify simulated hypoxaemia in healthy volunteers during two levels of controlled vibration (sine wave 4 Hz and intermittent 8 Hz; the 8 Hz condition was representative of the motion experienced during patient transport) [20]. The vibration sometimes resulted in false decreases in SpO_2 in 3/4 oximeters, which was similar to the current study, but was not identical as such patterns were not identified across all of our 16 patients. Vibration also lengthened the time taken for the pulse oximeters to detect hypoxaemia. There were also differences between the individual pulse oximeters under test, reflecting the varying capacities of the different algorithms to deal with motion.

Perhaps the seminal piece of research on characterising motion in a very wide variety of clinical environments was that conducted by Tobin et al. [21]. Some 350 patients were monitored, of whom 70 exhibited motion (20 %); 35/70 moving patients were instrumented for detailed analysis. This included three patients who had been transported by

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ambulance. Ambulance transit at reasonably high speed (60 mph) resulted in a very noisy pulse oximeter signal; indeed one of the largest in the study's clinical cohort. However, the investigators did note that the magnitude of disturbance to the underlying photoplethysmograph was not directly related to the absolute force of movement. For example, a patient flexing their foot resulted in more oximeter signal deformation than that caused when the leg twitched. This indicated that there were underlying, vascular mechanisms at play. One of the difficulties in studying pulse oximetry during the gross motion of ambulance transit is that it is difficult to ascertain just how much error is due to vehicle motion, and how much is due to the patient moving the site of monitoring; using an accelerometer as a reference sensor may be an appropriate solution. Silbergleit et al. [22] attempted to quantify the forces experienced during road ambulance transport at 35 mph. They identified that road ambulance vibration varied greatly—generally occurring ⟍l Hz and from 10 to 15 Hz—and was highest in the inferior and superior axes. The largest peak accelerations were also in the inferior and superior planes (0.8 and 0.7 g respectively).

This was the first application of the RESpeck breathing rate sensor in a pre-hospital context. However, no validated breathing rates were delivered by the sensor during ambulance transit; the fine excursions of the abdomen with breathing were lost amongst the large, random movements of the ambulance. Also, even the entry and exit of clinicians into and from the ambulance (without the patient) was sufficient for it not to deliver validated data. Despite this, only reporting on rhythmic, regular breaths is more diagnostic than reporting on irregular, noisy breathing rate data. For example, Chen et al. [23] employed the technique of impedance pneumography (measuring the changes in resistance across the chest with breathing, using a conventional electrocardiogram trace) combined with a novel algorithm (applied retrospectively) on 898 trauma patients monitored during helicopter transit. Breathing rate based upon reliable breaths only was a better predictor of a patient receiving a respiratory intervention at a later stage, and of identifying patients with haemorrhage. Impedance pneumography (available on some pre-hospital multi-parameter monitoring systems) will inevitably capture more data on respiratory rate than the RESpeck during gross motion. However, our proposed model of employing the RESpeck on pre-hospital patients managed by Community First Responders will not mean exposure to ambulance transit. As such, the RESpeck may be an effective way for non-experts to gather considerably more breathing rate data than would be achievable using manual methods alone. It may also be more objective.

There were some limitations to this study. Pulse oximeter photoplethysmograph data were displayed on the

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screen of the commercially-available pulse oximeter, but the device did not permit recording of the raw photo-plethysmograph to file in 'non-wireless' mode. Wireless data transfer for the pulse oximeter under test was time-consuming and necessitated a separate laptop computer; there was neither sufficient time nor space to effect this in the emergency ambulance. This prevented any detailed analysis of the impact of motion on the underlying signal (e.g. motion artefact issues during driving). However, some data to this effect have been reported previously [21]. Our next study will be a 'laboratory-function' experiment where there will be more time and space to conduct wireless data transfer and capture raw data. A single pulse oximeter was tested in this study; it is likely that other sensors employ different algorithms and thus respond to motion differently. The study was also a proxy for the proposed context of employing the sensors in our MIME system; i.e. patients managed by ambulance clinicians, and not Community First Responders. This meant that the motion that the sensors was exposed to was much greater, although the study did still include periods of reduced motion before and after ambulance transit. However, conducting the study in emergency ambulances was the quickest and safest method for collecting our data; first responders see relatively few patients and have limited first-aid training. Finally, the study only included patients who did not have immediately life-threatening medical conditions or trauma (i.e. only those who were able to provide verbal informed consent).

To conclude, this study identified that all of the physiologic sensors exhibited some error on almost every patient recording during ambulance clinician patient management. However, this accounted for a relatively small proportion of the total monitoring time, on average. Error mostly took the form of non-physiological blood oxygen saturation and heart rate values, and rapid step changes often to much lower values. The RESpeck breathing rate sensor did not exhibit error per se. Rather, if the pre-de- fined threshold of motion was crossed it did not deliver breathing rate data, which was as it was designed to do. It was very positive that many more validated breathing rate points were achieved through employing RESpeck than via manual assessment. The almost complete lack of validated breathing rate data during ambulance transit was inconve- nient, but would not be problematic in our proposed model of use by CFRs (i.e. where there is no ambulance transit).

Future work in this area should focus on sensor-produced breathing rate data during motion, which is currently not recorded during ambulance transit. The development of a single sensor to monitor all three parameters (RR, HR and SpO_2) would also be valuable, minimising the time taken to apply equipment and simplifying the process for non-expert users such as CFRs.

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Conflict of interest None declared.

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amplitude and acceleration in multiple directions. For ex- ample, the patient may be moved in the process of im- mediate, potentially life-saving management. This might include clearing the patient's airway, inserting a device that protects the airway, conducting chest compressions where the patient is in cardiac arrest, or moving an unconscious but breathing patient into the recovery position.

Patients must also be moved to a location where they can receive definitive treatment for their illness and/or injury. However, it may take more than one journey and there may be intercurrent treatment at more than one site before definitive care is reached. In most cases pre- hospital patients are trans- ported by emergency ambulance, which in the United King- dom are staffed by a mixture of qualified Paramedics an

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Appendix 5:

AIRSpeck

The AirSpeck family of static and mobile wireless air quality monitors

D K Arvind, Janek Mann
Centre for Speckled Computing, School of Informatics
University of Edinburgh, Scotland, UK.
dka@inf.ed.ac.uk

Andrew Bates and Konstantin Kotsev
Centre for Speckled Computing, School of Informatics
University of Edinburgh, Scotland, UK.

***Abstract*— The Automatic Urban and Rural Network (AURN) [1] is a set of high quality reference monitoring sites for recording air quality in the United Kingdom. They are costly to install and expensive to run, and are therefore limited in numbers. The data from these networks are used to inform regulatory compliance with the Ambient Air Quality Directives [2]. There is also a requirement to monitor air pollution at sufficiently high spatial and temporal resolutions around people to estimate personal exposure to particulates, and gases such as Nitrogen Dioxide and Ozone for better understanding their health impacts. Such high resolution measurements can also be used for validating the air quality models' estimates of variability over space and time due to complex interactions. Networks of air-quality monitors using inexpensive sensors offer a cost- effective alternative approach for recording trends in air quality at a higher spatial resolution, albeit not as accurately as the reference monitoring sites. This paper describes the design, implementation, and deployment of a family of air quality monitors: stationary (AirSpeck-S) monitors for measuring ambient air quality, and mobile wearable AirSpeck-P for monitoring personal exposure to air borne particulates (PM_{10}, $PM_{2.5}$ and PM_1), and the gases - Nitrogen Dioxide and Ozone. Results are presented for characterising the ambient air quality in public spaces gathered from people wearing the AirSpeck-P monitors who are out and about in two cities as pedestrians (Edinburgh, Scotland) and as car passengers (Delhi, India). The paper demonstrates the viability of using inexpensive static and mobile AirSpeck monitors for mapping trends in particulate concentrations in urban spaces. Results are presented for comparisons of the mobile personal exposure data from pedestrians with static AirSpeck-S monitors along the same route, and the characterization of urban spaces based on levels of particulate concentration using the AirSpeck-P monitor.**

Keywords— Ambient air quality; wearable sensors; AirSpeck; k-NN classifier.

I. INTRODUCTION

Progress in electrochemical sensors and laser-based compact optical particle counters, such as Alphasense's OPC-N2 [3], has led to the development of low-cost air quality monitors. This paper presents the AirSpeck platform for connecting particulate counters and electrochemical gas sensors, for processing the raw sensor data and transmitting them wirelessly to remote servers for analysis. The platform is

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configured in two ways: AirSpeck-S is a static version tethered to street furniture such as lamp posts (Fig. 1(L)), or attached to vehicles such as buses and cars; AirSpeck-P is a personal exposure monitor worn as a belt by pedestrians (Fig. 1).

AirSpeck platform is equipped with two wireless radios for transferring sensor data to the server: a Bluetooth Low Energy (BLE) radio connection to a mobile device such as a phone or a tablet for onward transmission using a WiFi link to the broadband internet; an on-board GPRS radio for uploading data via the cellular network. Stationary air quality monitors would normally use the GPRS radio whereas personal exposure monitors would use BLE to transfer to an App on the mobile phone to store and forward to the server.

The wearable AirSpeck-P personal exposure monitors can be used to map ambient air quality in public spaces based on numerous personal exposure readings taken when the wearers are out and about. The preliminary experiments in fingerprinting the urban environment using particulate data was conducted in the Meadows area in Edinburgh and then extended to a route in the city which spanned six urban environments.

The novel contributions of this paper are the design of the AirSpeck platform which can be easily configured for stationary measurements of ambient air quality and for mobile measurements of personal exposure, and pedestrians and car passengers contributing data to characterise air quality in urban spaces.

II. The AirSpeck Platform

The principal consideration in the design of the AirSpeck-S (Fig. 1) is the ability to deploy for a period of several weeks powered by a battery pack housed in a water-resistant enclosure. The stationary configuration supports the OPC particulate counter, up to 4 gas sensors, an auxiliary fan to circulate the flow of air to the gas sensors, a battery pack, a switch to turn off the system between deployments, and data transmission over the GSM network (Figure 2).

In contrast, the design of AirSpeck-P as a body-worn personal exposure monitor gives prominence to size, weight and wearablity issues and an App running on the mobile device orchestrates its operation to measure particulate matter and two gases (NO_2 and O_3).

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Fig 1. (Top-left) AirSpeck-S monitor attached to a lamp post in the Meadows area in Edinburgh (Top-right); (Bottom-left) AirSpeck-P monitor worn as a belt (Bottom-right).

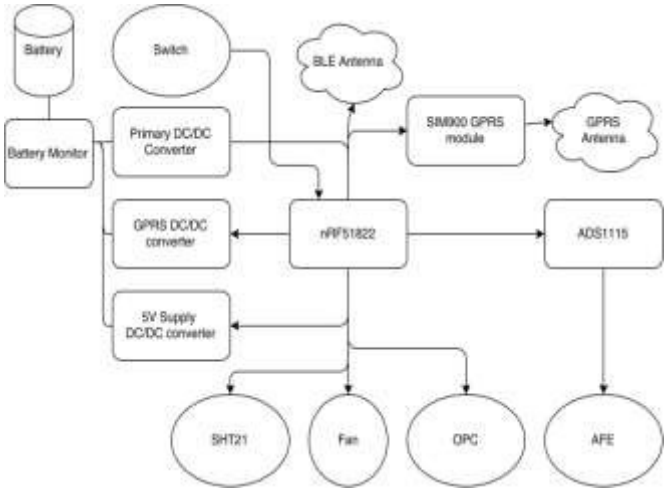

Fig 2. Block diagram of the principal components of the AirSpeck hardware platform.

A. Sensors

Optical Particle Counter (OPC): The OPC is connected to the AirSpeck using an SPI interface and powered from the 5V rail along with the other external sensors. It provides particle counts in 16 bins categorised in terms of ranges of spherical equivalent sizes between 0.38µm to 17µm (Figure 3). It uses a high intensity laser source to illuminate the particle as it passes through the detection chamber and the redirected light is detected by a photo detector. It also outputs derived concentrations in PM1, PM2.5, and PM10 equivalent ratios. The 5V rail supplying the OPC and other external sensors are switched off between measurement sessions to extend the battery lifetime.

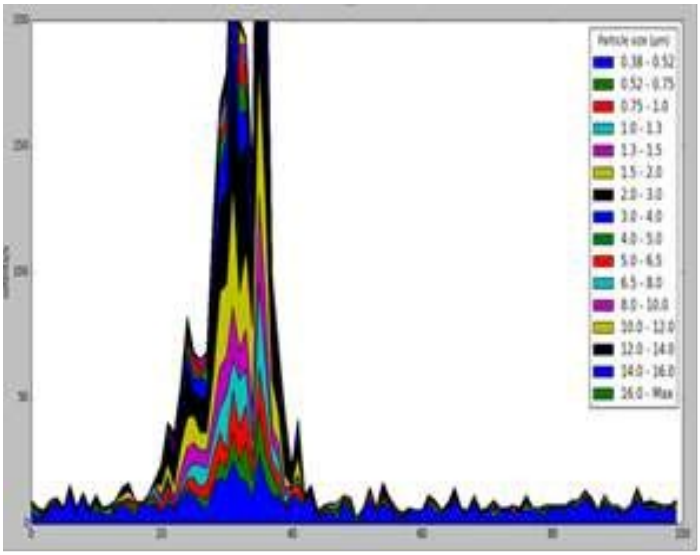

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Fig. 3. A "spectrum" of particulate numbers (Y-axis) over time (X-axis) ranging in diameter sizes between 0.38µm and 17.0µm distributed across 16 bins (inset) detected by the laser-based Optical Particle Counter (OPC).

Temperature & Humidity Sensors: A Sensirion SHT21 temperature and humidity sensor [6] is included on the AirSpeck PCB to enable integrated sensing of temperature and humidity without requiring the connection of external sensors.

FS200 Temperature & Humidity Sensor: An interface is provided for the FS200 waterproof temperature and humidity sensor, comprising a Sensirion SHTXX series temperature and humidity sensor [7] in a waterproof (sintered metal) enclosure. This sensor is placed to protrude outside the enclosure either into the ambient air or into the soil for measuring soil moisture content.

B. Processing and Communication

Bluetooth Low Energy (BLE): The NRF51822 SoC [8] has an in-built Bluetooth LE radio which communicates with a custom Android Application on the mobile device for receiving and stamping the sensor data with time and location (GPS) information and then forwarding them to the server via the cellular network or WiFi.

GPRS module: A SimCom SIM900 GPRS module [9] in the AirSpeck platform is used to transfer sensor data to the server over the GSM network for the stationary AirSpeck-S monitors. Transmissions take place every third sampling period (once every 5 minutes) to reduce battery drain due to the GPRS module. It consumes considerably more energy to connect to the GSM network, and initialise an HTTP connection, compared to transmitting each additional byte of data once connected.

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C. Power Supply

In the AirSpeck-P configuration, a compact, rechargeable 7.4V (2S) LiPoly battery pack is used. For the stationary AirSpeck-S, an 8400mAh, 13.2V (4S) rechargeable LiFePo4 battery pack is used with sufficient capacity for around 20 days of operation. LiFePo4 chemistry was chosen as it has a higher intrinsic safety than LiIon type of batteries, while still providing a high energy density compared to sealed lead acid and other rechargeable battery types.

The AirSpeck board requires 3 power rails, 3.3V for the microcontroller, BLE radio, the on-board sensors and sensor interfaces; 4.2V for the SIM900 GPRS module; and 5V for external sensors and the auxiliary fan. Each power rail is supplied using an LMZ12003 DC/DC converter module capable of sourcing up to 3A of current. A key switch enables the system to be turned off between deployments.

The OPC and the auxiliary fan each consumes around 200mA when active, and the GPRS module around 100-150mA, depending on its state (idle/transmitting) of operation. Due to their higher power consumption, care is taken to only enable them for the minimum period of time. The AirSpeck-S is configured for long battery life and operates at an average current of around 30mA, whereas AirSpeck-P keeps the OPC turned on continuously for sampling when mobile and consumes around 250mA.

D. Firmware

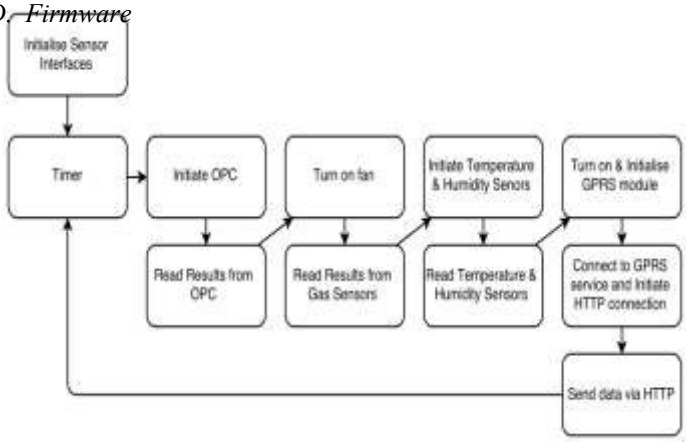

Fig. 4. Block diagram of the principal components of the AirSpeck firmware.

The AirSpeck firmware has been designed to operate primarily in a sequential fashion which simplifies the code for interfacing with the sensors, and increasing the reliability of operations. A timer peripheral supports both low-power delays during sequential operation as well as global events such as starting a new measurement cycle. Once initialised, the firmware sets up interfaces to the sensors (I2C for the temperature and humidity sensors, SPI for the OPC, I2C for the ADCs for reading the output from the gas sensor interface module, and UART for the GPRS module), as well as setting up the startup power supply states for the 5V, 4.2 and 3.3V rails.

At the start of each measurement cycle, the firmware turns on the 5V rail used for the OPC and the gas sensors, then initiates the measurement cycle of the OPC, including turning on the built-in fan in the OPC. A sequence of OPC measurements is taken at 1second intervals and the results aggregated. Once the OPC measurement cycle has completed, the OPC fan is turned off and the gas sensor fan is turned on for 2 seconds. At the conclusion of the gas sensing period the output voltages from the gas sensor interface board are read using the ADS1115 ADCs and the 5V power supply rail is turned off. The temperature and humidity sensor readings are next initiated for the measurement period and the sensor results are read out. Results from all the sensors are aggregated in a results array and uploaded using the GPRS module every third sensing cycle. The 4.2V rail for the GPRS module is turned on when an upload event is scheduled and instructed to connect to the GPRS service of the service provider set up for the SIM card inserted in the AirSpeck board. Once connected to the network, an HTTP service connection is set up, the data is uploaded to the GPRS module and instructed to perform a HTTP POST request to the server. At the conclusion of the HTTP request, the AirSpeck enters a low-power state waiting for the timer event to start a new measurement cycle.

The firmware for the AirSpeck-P version operates in a fashion similar to the AirSpeck-S firmware; however, unlike the stationary firmware, the personal one keeps the fan for the OPC turned on permanently and performs readings from the OPC at 1 second intervals. In contrast to the stationary firmware, the GPRS module is not normally used and instead the Bluetooth LE radio is used to transmit the sensor readings to the mobile device at the conclusion of each measurement interval.

III. Power Optimisations

The AirSpeck platform is required to operate for extended periods in the field, without the opportunity to recharge the batteries or with reliable access to solar energy (in the northerly latitudes), and therefore an important consideration is the optimisation of the energy consumption by the hardware and firmware.

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A. Hardware Power Optimisation

The use of switching DC/DC converter modules allows for efficient interfacing to different battery types. By utilising three separate DC/DC converters, the efficiency of the energy conversion is maintained for each of the separate power domains in the design.

During optimisation of the power consumption of the gas sampling subsystem of AirSpeck-S it was found that replacing the whole volume of air inside the enclosure was consuming considerable energy, as the fan needed to be operated for an extended period of time to replace the full volume of air in the enclosure.

A custom baffle was designed in which the gas sensors were placed and connected directly to the outside of the AirSpeck-S enclosure. A smaller fan is adequate to replace only the volume of air inside the baffle. The lower-power fan (100mA at 5V)

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was required to be turned on for only 2s compared with 5s for the larger fan (200mA at 5V), while still ensuring sufficient turn-over of the air in the gas sampling chamber. Additionally, the baffle is equipped with a series of apertures designed to trap rain falling on the ingress port, allowing the baffle to be directly ported to the exterior of the enclosure without risking water entering into the system.

B. Firmware power optimisations

Optimising the energy consumption in the firmware was an important consideration in its design. Key parameters affecting energy consumption are the sensor sampling interval and the duration of each sampling period. The NRF51822 SoC used at the core of the system is based around a very energy-efficient ARM Cortex-M0 microcontroller core.

The firmware has been designed to put the microcontroller to sleep between the different state machine transitions. The Cortex-M0 core consumes around 4.1mA while executing code from Flash, but less than 5uA while in sleep state (with the 32.768kHz oscillator running).

Data collection from the OPC sensor was optimised to achieve a tradeoff between energy consumption and accurate data collection. The OPC sensor is typically used in a continuous monitoring scenario, and will aggregate readings over periods of time. The sensor is equipped with an internal fan which requires a startup period before providing accurate readings. The firmware first activates the fan in the OPC and then takes a succession of readings at 1s interval, aggregating the results from the sensor. Such a sampling approach was found to result in more accurate readings when optimising the sensor for lower average energy consumption. In the AirSpeck-S, the OPC is sampled for a 30s period in each 5-minute interval, thus giving readings with a high degree of accuracy.

The electro-chemical gas sensors used in AirSpeck consume less energy than the OPC. However, for accurate readings it is important that the gas sensor is exposed to air for a period of time which is achieved by a fan pulling fresh air into the sampling chamber in which the gas sensors are placed.

The proportion of energy consumed in the different subsystems of the AirSpeck-S were as follows: OPC sensor – 54%; GPRS module – 36.5%; Gas Sensors – 4%; Power distribution – 3%; Gas fan – 2%; NRF51822 SoC – less than 0.5%.

IV. Results

The AirSpeck-P was used by pedestrians to characterise the air quality in the cities of Edinburgh, Scotland and Delhi, India. The pedestrian data in Edinburgh was also used to "fingerprint" a route by classifying it in terms of six urban environments based on the OPC particulate data from Bin0 (particulate diameter ranging between 0.38µm – 0.42µm) as it was by far the most active bin in the relatively clean environment in Scotland.

A. Characterising the urban environment in Edinburgh

Figure 5 shows the visualisation of the quantiles of particulate data collected along three routes in the Meadows area in the city of Edinburgh. It is a green space south of the central

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University campus which is bounded on the north by a path (North Meadows Walk) favoured by cyclists and pedestrians, and on the south by a road (Melville Drive) with moderately busy vehicular traffic. Three routes were walked carrying the AirSpeck-P, and the resulting dataset contains 260 data points, including 85 readings from within the park, 86 readings on North Meadows Walk, and 89 readings along the pavement on Melville Drive. Figure 6 shows the differences in Bin 0 counts as a boxplot for the three environments and the results of one-way ANOVA applied shows significant differences with a p-value < 2e-16.

Fig. 5. Characterisation of three routes in the Meadows area in Edinburgh using Bin0 (0.38µm – 0.42µm) particulate data.

The walk in the centre of the park is confidently picked up as a stretch of points with values below the median. The only outliers were at the intersection of the route with a busy pedestrian walk in the middle of the park. Finally, the route in North Meadow Walk is a mixture of mainly red and yellow points with outliers in the zone where all the walkways meet which has a heavy footfall from pedestrians. The graphs in Figure 7 show the PM10, PM2.5 and PM1 particulate data for a period of 70 hours from three stationary AirSpeck-S monitors placed along the three routes in Figure 5: Melville Drive (Blue) showing diurnal variations due to vehicular traffic, interior of the Park (Green), and the Upper Meadow Walk (Yellow). The results in Figure 5-7 confirm that the AirSpeck-P mobile personal exposure monitor worn by pedestrians does differentiate between the three types of urban environments in the Meadows area, and which was validated by the data from the stationary AirSpeck-S monitors along the same routes.

Next, a pedestrian route (Figure 13) in the centre of Edinburgh was characterised in terms of Bin0 (0.38µm – 0.42µm) particulate data for six types of urban environments enumerated in Figure 8: (i) Indoor environment inside the university library; (ii) Middle of the park; (iii) Pedestrian walk; (iv) Quiet street - one with little or no traffic; (v) Medium- traffic street; (vi) Congested street/junction. Figure 9 shows the box plot of the OPC particulate data points for the six different types of urban environments. One-way ANOVA test applied to

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the data gives a p-value < 2e-16. The particulate counts are the lowest inside the Library and the highest in the street with moderately busy traffic and the traffic junction with high traffic. The environment types inside the park, the park walk, and the quiet street have small differences in PM counts.

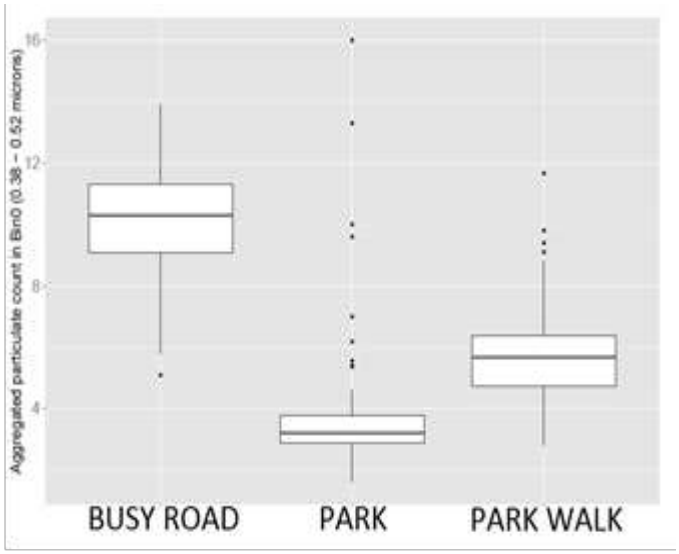
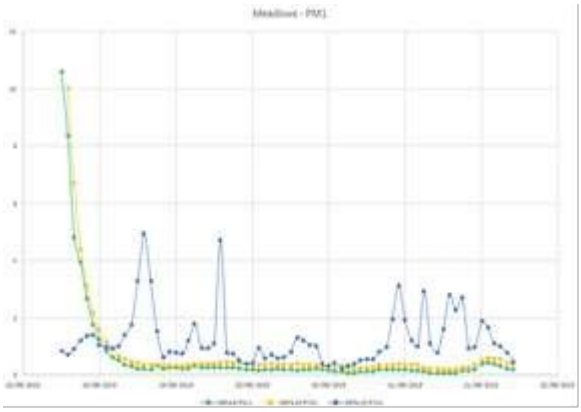
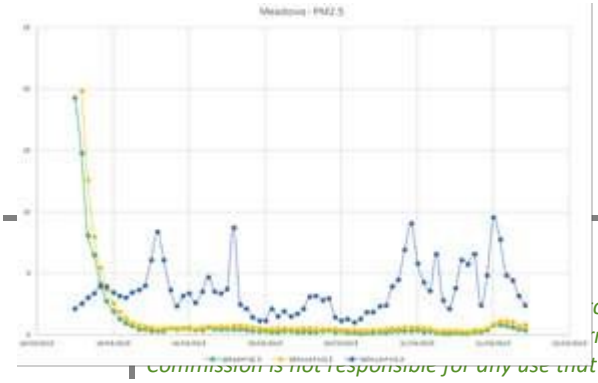


Fig. 6. Box plot for the walks along three paths in the Meadows





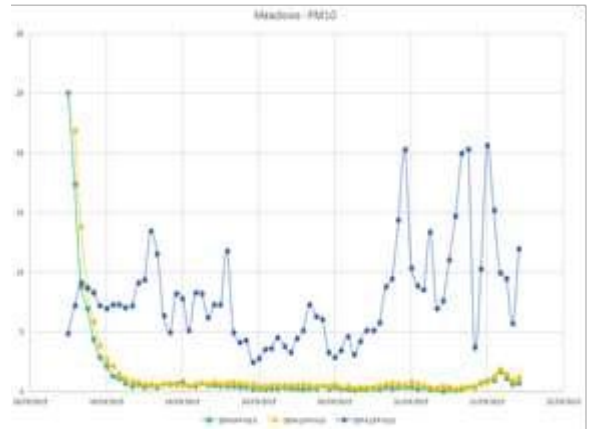


Figure 7. PM10, PM2.5 and PM1 particulate data for a period of 70 hours from three stationary AirSpeck-S monitors placed along Melville Drive (Blue), interior of the Park (Green), and Upper Meadow Walk (Yellow).

B. Characterisation of the particulate concentration in Delhi

Fig 8. Map of the route in Delhi, India for personal exposure data collection using AirSpeck-P indoors in a shop, walk in a park, and the car journey.

The results in the previous section had established that the AirSpeck-P was capable of monitoring the personal exposure to particulates when attached to the subject moving around. The Figure 8 shows the map of the circuit taken in New Delhi on 11th May, 2015 during the period from 10:00 to 14:00, covering three distinct types of urban environments. Figure 12 displays this journey to better effect: the top graph shows the

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speed of the person (in m/s) – three phases of car journeys (identified by the elevated speeds), firstly to a shop followed by 90 minutes stay within the indoor environment; next to a park with roughly 60-minute worth of exposure data in the outdoors; and finally the car journey back to the starting location. The other three graphs in Figure 12 shows the PM10, PM2.5 and PM1 values measured by the AirSpeck-P during the circuit. The three distinct plateaus of high particulate exposure coincides with the phases of the car journey, and the bottom

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two graphs in Figure 12 shows elevated values for PM2.5 and PM1 values during the journey. A comparison of the boxplots in Figure 11 and Figure 9 for the two cities reveals that worst case exposure in Delhi during the road journey is approximately 60 times higher compared to the equivalent type of environment in Edinburgh. These two graphs are directly comparable as they used the same AirSpeck-P device for monitoring particulate levels.

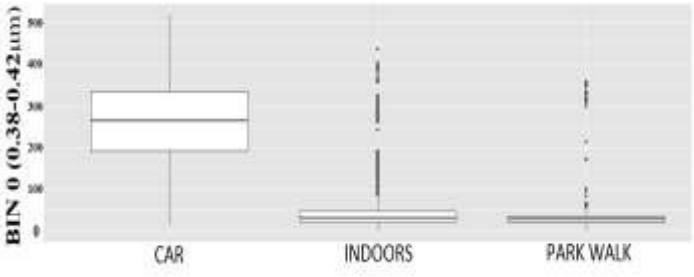
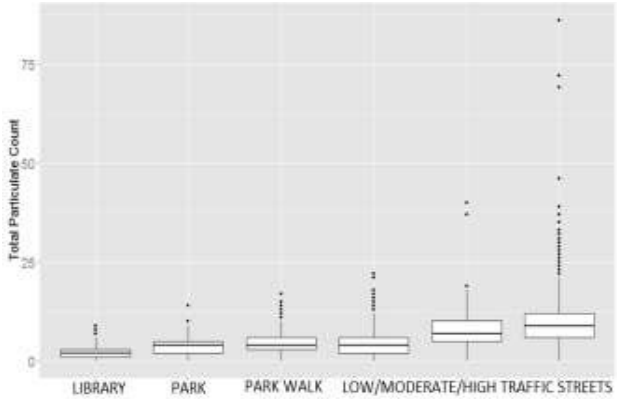


Fig 9. Boxplot of personal exposure using AirSpeck-P in terms of Bin0 (0.38µm – 0.42µm) particulate count for three environments: inside a shop (middle), in a garden (right), and in the car (left) when travelling between the two sites.

Fig. 10. (Clockwise from top-left) Inside of the University Library; Middle of the park; Pedestrian park walk; Congested street/junction; Moderate traffic road; Low traffic street.



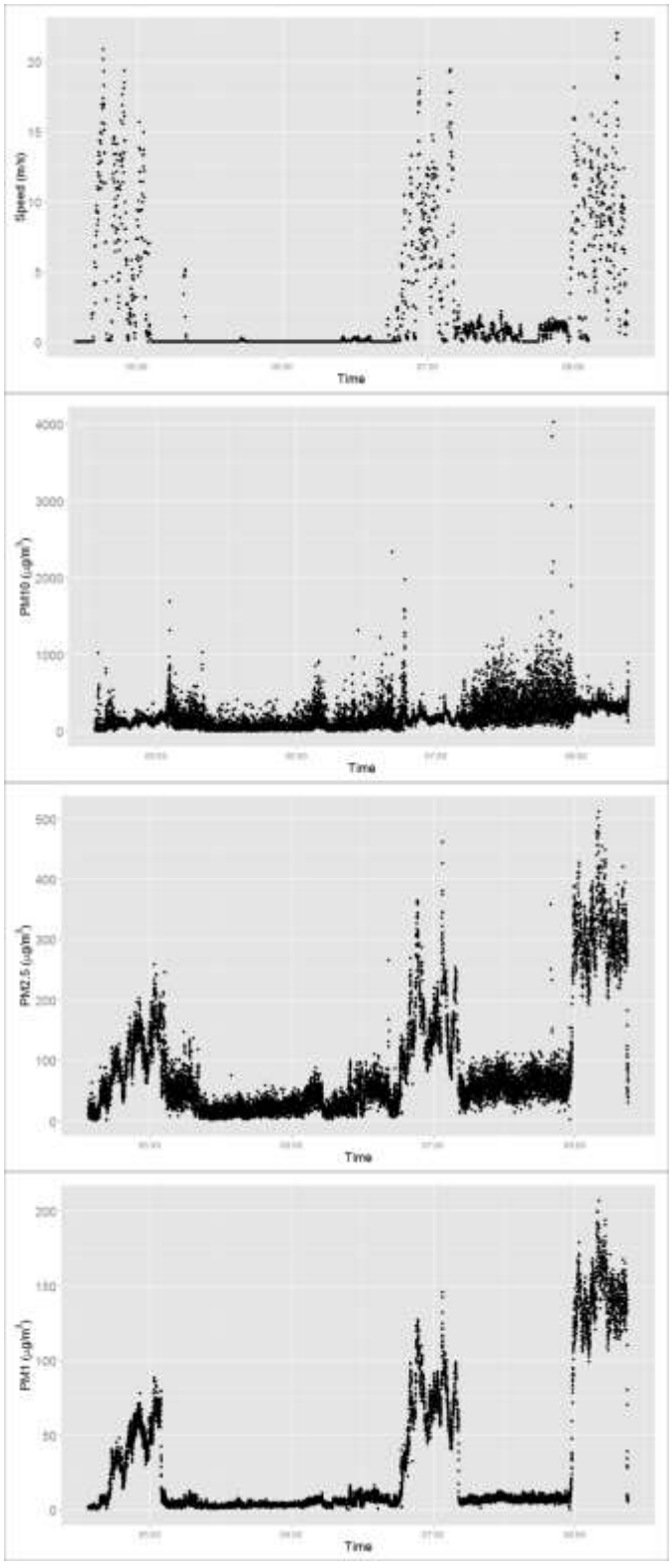


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Fig. 11. Boxplot for the Bin0 (0.38µm – 0.42µm) particulate dataset for a route differentiating six types of urban environments in Edinburgh.

Fig. 12. (Top) Speed (m/s) of the person carrying the AirSpeck-P personal exposure monitor; (Middle) Bin0 (0.38µm – 0.42µm) particulate count during the journey; (Bottom) PM_{10} values during the journey.

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C. *Classification of urban environments in Edinburgh*

Figure 13 summarises the results of personal exposure datasets collected over seven walking trips in Edinburgh and the route has been automatically classified into six types of urban environments described in Figure 10. Data preprocessing involved aggregating on the GPS location within each sample and applying the k-means clustering technique to discover 50 clusters of points based on their location along the route.

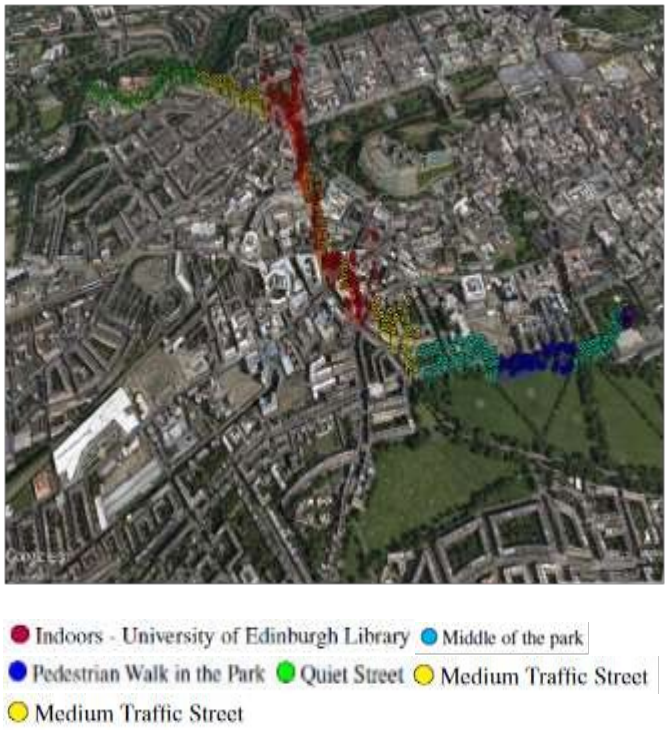

Fig. 13. Classification of six urban environment types for seven walking trips in Edinburgh with the AirSpeck-P personal exposure monitor.

The data points are then aggregated by location clusters and the mean of all the readings within the cluster was taken. Each point in the final data set can be thought of as a summary of the sensor readings around the cluster centres. k-means clustering technique in R [10] was once again applied to the size-resolved bin counts and total particulate counts to discover six types of urban environments with each cluster shown as a distinct colour in Figure 13. A visual examination of classification of the route tallies with manual classification, with the nuances along the route such as air quality effects due to waiting at traffic lights and different levels of traffic along a long street, being discernable.

V. Related Work

Steinle *et al* [14] present a review of the myriad of issues to be considered for quantifying personal human exposure to air pollution when moving away from static measurements. Cho *et al.* [11] examined the relationship between exposure to particulate matter and mortality. Particulate mass (PM10 and PM2.5) and size-resolved particulate counts from 0.3µm to 25 µm were measured. The interquartile range of fine and

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respiratory particles number concentrations were associated with a 5.73% and a 5.82% increase in respiratory disease associated mortality, respectively. Stationary sensors using Optical Particle Counters have been used to study the effects on the environment at Healthrow airport in the UK [12].

Pedestrian exposure to particulate matter was studied by Ozgen *et al.* [14] along a selected route in the city centre of Milan. Data was collected using an optical particle counter and a GPS receiver carried in a backpack. Particulate counts were collected by the OPC every minute in the range from 0.3µm to 10µm and PM mass concentrations were calculated from the counts. Colombi et al. [13] studied passenger exposure in the underground transport system in the same city.

VI. Conclusions

The paper has presented the AirSpeck static and mobile air quality monitors and methods for pedestrians (Edinburgh) and car passengers (Delhi) to characterise urban environments wearing the AirSpeck-P personal exposure monitors. The same monitor was used to gather data in Edinburgh and Delhi for comparison which showed that the exposure to particulates in Delhi could be as high as 60 times that of Edinburgh. The statistical differences between six locales in the urban environments have been characterised for fingerprinting a walking route in Edinburgh and the exposure to particulates visualized in a map. The data from the mobile AirSpeck-P was validated against equivalent measurements along the same route using stationary AirSpeck-S monitors in the Meadows area in Edinburgh. Future work will investigate the spatial and temporal predictions of PM2.5 and PM10 concentrations using data from network of static AirSpeck-S monitors located in the Meadows and supplemented by mobile data from subjects wearing AirSpeck-P monitors moving within the area covered by the static network.

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Appendix 6

TACK SHS Work Package 5 Subject Data collection Form:

Subject code: _ _ - _ _ - _ _ **Date of baseline visit: _ _ / _ _ / _ _**	**Collector Name: _____** **Country : _____** **City: _____**

Date: dd / mm / yy; [3] **Time**: hh:mm (24h format);

Please, write down the following information:

Date of going to Smoking area					_ _ / _ _ / _ _	
Start of Exposure time[3]					_ _ / _ _ / _ _	
End of Exposure time[3]					_ _ / _ _ / _ _	
Duration time of exposure (Hour/min):					_ _ / _ _	
Number of walls in premises	**1**	**2**	**3**	**4**		
Number of smokers present	**0**	**1-5**	**6-10**	**11-15**	**16-20**	**>20**
Number of E cig users present	**0**	**1-5**	**6-10**	**11-15**	**16 -20**	**>20**

Any unusual events during monitoring, (please list)	**Time of event**
Medications	**Amount taken**
Time/date of next appointment:	

Appendix 7

ASTHMA CONTROL TEST™

Know your score

The Asthma Control Test™ provides a numerical score to help you and your healthcare provider determine if your asthma symptoms are well controlled.

Take this test if you are 12 years or older. Share the score with your healthcare provider.

Step 1: Write the number of each answer in the score box provided.

Step 2: Add up each score box for the total.

Step 3: Take the completed test to your healthcare provider to talk about your score.

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what the score, bring this test to your healthcare provider to talk about the results.

					SCORE
1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?					
All of the time **[1]**	Most of the time **[2]**	Some of the time **[3]**	A little of the time **[4]**	None of the time **[5]**	.....
2. During the past 4 weeks, how often have you had shortness of breath?					
More than Once a day **[1]**	Once a day **[2]**	3 to 6 times a week **[3]**	Once or twice a week **[4]**	Not at all **[5]**	.....
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?					
4 or more nights a week **[1]**	2 to 3 nights a week **[2]**	Once a week **[3]**	Once or twice **[4]**	Not at all **[5]**	.....
4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?					
3 or more times per day **[1]**	1 or 2 times per day **[2]**	2 or 3 times per week **[3]**	Once a week or less **[4]**	Not at all **[5]**	.....
5. How would you rate your asthma control during the past 4 weeks?					
Not Controlled at All **[1]**	Poorly Controlled **[2]**	Somewhat Controlled **[3]**	Well Controlled **[4]**	Completely Controlled **[5]**	.....

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what your score is, share the results with your healthcare provider.

TOTAL: .....

Your name:

Today's date:

CAT
COPD Assessment Test

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	

TOTAL SCORE