Chemical exposure and lung function in fragrance industry employees.

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Abstract

Introduction

Production employees within the UK fragrance industry are exposed to large quantities of chemical substances and mixtures over working shifts. Occupational respiratory exposure within this industry is managed in line with relevant legislation and guidelines. There is a lack, however, of published literature studying the effects of respiratory exposure to chemicals on fragrance production employees.

A multi-site cross-sectional study was conducted using employees from the UK fragrance industry. The primary aim was to answer the research question:

In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?

The secondary aim was to use the data acquired to develop a weighted questionnaire that is predictive for potential lung function problems, for use as a pre-placement occupational health tool within the fragrance industry.

Methods

A cross-sectional study was designed, using an exposed group (fragrance production and associated functions, $n = 60$) and a control group (non-exposed fragrance industry employees, e.g. office staff, $n = 52$). 5 UK companies took part, giving a total of 112 participants. This was calculated as sufficient to achieve 80% power and 5% significance.

Spirometric measurements (FEV_1, FVC and PEF*) were taken pre-shift and post-shift. Information was provided by participants for information on potential confounding factors (smoking, personal or family history of respiratory problems, body mass index). Post-shift measurements were compared between groups, using analysis of covariance (ANCOVA) to adjust for the baseline pre-shift measurements.

* FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; PEF = peak expiratory flow

A pilot questionnaire was developed. The weightings for each of the questions contained within the questionnaire were found by performing simple and multiple linear regression on the spirometric and demographic data. The unstandardised coefficient (B) was used as a measure of effect size in order to calculate a weighted score for each question response.

Results

Adjusted mean difference in post-shift measurements between groups (exposed vs. control) for each outcome measure was **NOT** observed to be statistically significant. Adjusted p-values for FEV_1, FVC and PEF were 0.722, 0.883, and 0.676, respectively.

Internal validation checks showed that the weighted questionnaire scores correlated with FEV_1 measurements, with a high score correlating with a reduced FEV_1 performance. Further validation is necessary to determine a threshold score corresponding to FEV_1 of <80%predicted, the lower limit of normal for FEV_1 performance.

Conclusions

The present study showed no significant effects of occupational respiratory exposure on the spirometric performance of the study population,

On first inspection the present findings support the suggestion that protective measures in place in the fragrance industry are sufficient in minimising occupational risk to respiratory health. Further validation of airway hypersensitivity measurement methods used in spirometry and the questions asked in the questionnaire is vital in order to determine a threshold score corresponding to FEV_1 of <80%predicted, the lower limit of normal for FEV_1 performance.

The pre-placement occupational health questionnaire has potential to be employed as a predictive tool for potential lung functionality in fragrance industry employees, subject to further development.

Subsequent external validation in future studies will be required before the questionnaire can be released for widespread use.

In conclusion, this work is the first step in a novel area of research, and the industry would benefit from the follow-up or expansion of this research.

Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

The named candidate's employer – CPL Aromas, UK – had no input in the content of this thesis.

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Abbreviations

%pred / %predicted percentage-of-predicted values for lung function test data

ANCOVA analysis of covariance

BMI body mass index

CASP Critical Appraisal Skills Programme

CHIP Chemicals Hazard Information and Packaging for Supply Regulations 2002

CI confidence intervals

CINAHL Cumulative Index to Nursing and Allied Health Literature

COPD chronic obstructive pulmonary disease

COSHH Control of Substances Hazardous to Health Regulations 2002

df degrees of freedom

FEF forced expiratory flow

$FEF_{25-75\%}$ forced expiratory flow, mean of the flow during period where 25-75% of FVC remains

$FEF_{75\%}$ forced expiratory flow with 75% of FVC remaining

FEV forced expiratory volume

$FEV_{0.4}$ forced expiratory volume in 0.4 seconds

FEV_1 forced expiratory volume in one second

FVC forced vital capacity

GNP gross national product

HP hypersensitivity pneumonitis

HSE Health and Safety Executive

IFRA (UK) International Fragrance Association (United Kingdom)

LBW low birth weight

LL femur leg length

MEF_{50} maximal expiratory flow with 50% of FVC remaining

MRT medical radiation technologist

MWF metalworking fluids

OA occupational asthma

OEB occupational eosinophilic bronchitis

OR odds ratio

PASW Predictive Analytics SoftWare Statistics (version 18.0)

PICO population, intervention, comparison, outcome

PECO population, exposure, comparison, outcome

PEF(R) peak expiratory flow (rate)

PR prevalence ratio

RIFM Research Institute for Fragrance Materials

R-phrase risk phrase

RR relative risk

SBCT specific bronchial challenge test

SD standard deviation

SES socioeconomic status

SH standing height

SHS second-hand smoke

SHSSW School of Health Sciences and Social Work, University of Portsmouth

SIC specific inhalational challenge

SiH sitting height

SSCI Social Sciences Citation Index

SWAIN (analysis) strengths, weaknesses, aspirations, interests, needs

SWOT (analysis) strengths, weaknesses, opportunities, threats

UBS upper body segment

VC vital capacity

WHR waist-to-hip ratio

Acknowledgements

Dedication

The most important acknowledgement goes to my wife, Sylvy, to whom this whole body of work is dedicated. Without her support and understanding, it would not have been possible for me to complete this course.

Dissemination list

● *Professional Doctorate Research Proposal: Chemical exposure and lung function in fragrance industry employees.*

Presentation to:

Executive Committee meeting, International Fragrance Association United Kingdom (IFRA-UK), London, UK, 3rd March 2011;

Managers' meeting, CPL Aromas, Brixworth, UK, 21st March 2011.

● Dix, G.R. (2012). Assessing the impact of journals: A review of journals in the field of respiratory research, in the context of industrial occupational health. *Occ Health [at Work], 8*(5), 30-33.

● *Chemical exposure and lung function in fragrance industry employees: preliminary results.*

Presentation to:

Meeting of Respiratory Sciences Working Group, Research Institute for Fragrance Materials (RIFM), New Jersey, USA, 20th April 2012;

Meeting of Safety Health and Environment Committee, International Fragrance Association (IFRA), Brussels, Belgium, 21st June 2012.

● *Chemical exposure and lung function in fragrance industry employees: preliminary results.*

Poster and summary report, sent to participating companies, 26th July 2012.

● *Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study.*

Poster presentation, European Respiratory Society Annual Congress, Vienna, Austria, 2nd September 2012.

Chapter 1 Background and context

The aim of this first chapter is to outline the background underlying the research study which forms the core of this thesis. This will be achieved by:

● giving background information on the industry which provides the setting and context for the research;

● providing justification for the research by identifying a gap in the literature;

● defining the formal aims and objectives relating to the research study.

1.1 Background

The creation and development of fragrances has progressed from simple beginnings into a global, commercialised industry which has successfully married the artisan skills of the perfumer with the profit-driven aims of the business world.

The origins of the fragrance industry lie in pre-historical Asia, and the chance discovery that certain plants would give off a fragrant smoke when burned as fuel. This discovery led to the burning of fragrant materials as religious offerings, and the manufacture of the first perfumery material – incense – for this purpose, dated to approximately 1500BCE in India (Curtis & Williams, 2001, p.425). Subsequent technological advances such as solvent extraction (Curtis & Williams, 2001, p.427) led to more efficient manufacturing and processing, and so fragrances gradually became available to a wider populace – from deity offerings and anointing royalty through the nobility and the wealthy, and finally to the general population. The rapid development of large fragrance houses such as Guerlain in the 1800s and Coty in the early 1900s established fragrance as a fashionable, trend-based consumable, and also cemented the idea of fragrances as a part of ordinary, everyday life (Hockey, 2011).

Today, it is a global industry, with creation and development centres and manufacturing sites spread around the world. The market size of the fragrance industry globally was reported as greater than US$43 billion in 2011 (Wray, 2012). Approximately 150,000 people are directly employed within the industry globally (with 2,500 of those employed in the UK [personal communication, September 25,

2012]), with many more employed by other parties along the supply chain, such as raw material producers and retailers; contribution to the UK's gross national product (GNP) is estimated at 0.1% (personal communication, September 25, 2012). The fragrance manufacturer, however, typically does not produce the final product as purchased by the consumer, and this sector is therefore the invisible arm of the industry, with the majority of consumers unaware of its existence – it is the brand of the final product that achieves consumer recognition.

What is produced and sold by the fragrance manufacturer is the fragrance component of the product, briefed, designed and safety-assessed for inclusion in a specific application or range at a defined usage level. The purpose of the fragrance component is to ensure the final product emits a pleasing odour when used by the consumer, and sometimes to also mask undesirable odours. A wide variety of consumer products are fragranced in this way, and so the fragrance industry is an integral, if unnoticed, part of everyday life in the developed world.

Applications can be divided into three broad categories: fine fragrance, cosmetics/personal care, and air care/household. Examples of applications in each category are given in table 1.1. Safety assessments are carried out by fragrance industry regulatory personnel, based on the application and usage level of the fragrance in the final product.

Table 1.1: Examples of fragranced product applications*	
Category	**Application**
Fine fragrance	Hydroalcoholic products applied to recently shaved skin (eau de toilette for men)
	Hydroalcoholic products applied to unshaved skin (eau de toilette for women)
Cosmetics / personal care	Deodorant and antiperspirant products (roll-on, underarm and body)
	Facial creams and balms
	Bath gels, foams, mousses, salts, oils and other products added to bathwater
Air care / household	Hard surface cleaners of all types (bathroom and kitchen cleansers, furniture polish)
	Machine wash laundry detergents
	Air fresheners of all types (plug-ins, ambient, electrical)

*RIFM Expert Panel, 2011

The fragrance manufacturing process uses a variety of chemicals as raw material constituents. These may be natural materials extracted directly from botanical sources, or synthetic materials. Each chemical is assessed for its intrinsic hazards and usage restrictions in potential final product applications, and this information is collated and used to determine the permitted usage levels of the fragrance.

Table 1.2 shows examples of commonly-used raw materials and their associated hazards.

Table 1.2: Examples of fragrance raw materials and associated hazards				
Name	**Chemical / Botanical name**	**Origin**	**Label(s)***	**Risk phrases (R-phrases)***
Dipropylene glycol	1,1'-Oxydipropan-1-ol	Synthetic	None required	None required
Cedarwood Oil, Chinese	*Cupressus funebris*	Natural		R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R65 Harmful: may cause lung damage if swallowed.
Clary Sage Oil, Russian	*Salvia sclarea*	Natural		R38 Irritating to skin. R43 May cause sensitisation by skin contact. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

*Home Office, 2009

The fragrance manufacturer keeps a palette of these raw materials for use in fragrance production; limiting the size of the palette ensures that safety and physical data can be effectively kept up-to-date and accurate. Taking the researcher's workplace, CPL Aromas, as an example, the palette is maintained in the region of 1500-1600 raw materials. Each fragrance compounded in the production facility may be comprised of 5-10 raw materials for a simple base fragrance, or >200 raw materials for a complex fragrance (personal communication, May 02, 2012). It is impractical to risk-assess production of each compound when an average of 60 fragrances are compounded every day (personal communication, March 23, 2012), and the formula database of even a small-to-medium fragrance company consists of approximately 78,000 formulas, any of which may be selected for production (personal communication, May 02, 2012). Given these figures, the usage levels and combinations of chemicals vary greatly each day, and thus personal respiratory exposure on a given day is unpredictable.

The fragrance industry is regulated by the International Fragrance Association (IFRA). IFRA are responsible for establishing standards for maximum levels for substances in final consumer products, and also prohibiting substances where necessary (IFRA, 2011a). Member companies of IFRA are bound by IFRA limits, and cannot supply fragrances for use in a given application at levels greater than those stipulated by IFRA. IFRA ensures adherence to these limits via its conditions of membership, regular cross-company collaboration and information exchange, and the IFRA compliance programme, whereby random consumer products are selected and tested for compliance with defined fragrance usage levels (IFRA 2011b).

IFRA work in conjunction with the Research Institute for Fragrance Materials (RIFM), an independent testing organisation which carries out the testing and evaluation on raw materials which underlies the restrictions imposed by IFRA. These restrictions have historically been revised and updated annually (now biannually), and released to the industry as the IFRA Standards, currently on the 46th amendment (RIFM Expert Panel, 2011).

In addition to the IFRA standards, designed for consumer protection, legislation is in place intended to provide protection for the employee. The Health and Safety at Work Act 1974 (Home Office, 1974) provides general guidelines on workplace safety, such as using and maintaining the correct protective wear and equipment, and the correct reporting of incidents. The Control of Substances Hazardous to Health Regulations 2002 (Home Office, 2002) gives more specific guidance on handling and using potentially hazardous chemicals, and implementing health surveillance of employees where appropriate.

Figure 1.1 shows the legislation and regulatory bodies relevant to the fragrance industry.

1966: Research Institute for Fragrance Materials (RIFM) formed	

1973: International Fragrance Association (IFRA) formed	

1973: first release of IFRA Code of Practice / IFRA Standards	→	Specifies fragrance materials subject to restriction or prohibition

1974: Health & Safety At Work Act	→	General workplace protective measures

2002: Control of Substances Hazardous to Health (COSHH) Regulations	→	Specific protective measures for substances: health surveillance/monitoring, risk assessment, exposure control

2002: Chemicals Hazard Information and Packaging for Supply Regulations (CHIP)*	→	Labelling of final consumer product, and transport labelling: hazard symbols, risk phrases, safety phrases

2006-7: IFRA Compliance Programme begins	→	Consumer products tested at random to ensure compliance with IFRA Standards

Figure 1.1: History of industry regulation and relevant legislation

*Home Office, 2009

1.2 Context

Individuals employed as compounders and associated functions within the fragrance industry work with large quantities of chemicals as a regular part of their jobs, and so experience regular inhalation exposure over considerable periods of time. Legislation exists to specify the measures necessary to minimise this exposure (Home Office, 2002), and safety information to be passed on to users (Home Office, 2009), while industry regulation is intended to protect the consumer at the fragranced product's end-point (IFRA 2011a).

Legislation such as COSHH (Home Office, 2002), however, refers to single chemicals and basic polymers, and does not take into account the complexity of the fragrance compound, which may contain dozens or even hundreds of basic chemical components.

There is therefore a need for additional measures to ensure employees are monitored for respiratory changes. COSHH recommends a health surveillance system to monitor employees' health in such a situation (Home Office, 2002, Regulation 11), and this has been established at the researcher's workplace as part of the occupational health service. Employees undergo periodic spirometry assessments to monitor their lung function; any reduction in lung function can then be observed, investigated, and any necessary action taken.

As in any industry involving occupational respiratory exposure, there is a conceivable risk of irritation or damage to the lungs. A literature search was conducted to explore the available research on occupational respiratory exposure in all industries, and showed a distinct lack of recent research investigating the respiratory effects of chemical exposure on fragrance industry employees. Research has been undertaken in other industries where respiratory exposure is a concern, such as metalworking (Kezunovic, 2008; Musk et al., 2000) and woodworking (Baran & Teul, 2007; Osman & Pala, 2009). Within the fragrance industry, however, published work consists mainly of commentaries and editorial-style articles (Bridges, 2002; Cadby, Troy, Middleton & Vey, 2002), and research investigating the effects of the final fragranced product on the consumer (Kumar et al., 1995). Fragrance industry-specific research focussing on occupational exposure was not, therefore, retrieved in this search. Only two specific examples of employee exposure within the fragrance industry were found (Galperina, Perekrest & Preobrazkenskii, 1986; Xuev, 1964), but these articles were too old to be of any current relevance. Both articles pre-date the COSHH Regulations, and the article by Xuev (1964) also pre-dates the Health and Safety at Work Act (1974). Also, the fragrance industry has updated its standards for inclusion levels and prohibitions annually, often resulting in dramatic restrictions. Research published in 1986, for example, will bear no relevance to chemical usage levels – and thus exposure and effects – today. These articles were also published in the Russian language.

The articles retrieved are considered below. A consideration of the available relevant literature is necessary in order to examine the nature, quality and quantity of studies investigating occupational respiratory exposure and to provide justification for similar research to be undertaken within the fragrance industry.

Literature review

A review of published literature investigating occupational respiratory problems in different industries

Respiratory exposure is a significant issue within a variety of occupational settings. The aim of this review was to collate the available research on occupational respiratory exposure and therefore demonstrate the variety of occupations in which this research has been conducted.

Methods

Data collection

Search strategy

Databases used for the literature search are given in table 1.3, along with refined search terminology and number of results. Only articles published from 2000 onwards are considered relevant, to ensure a focus on recent research.

Table 1.3: Search strategy, showing databases and search terms used, alongside initial and refined results			
Database	**Refined search terms**	**Initial results**	**Relevant results**
SSCI (Social Sciences Citation Index)	lung function AND workplace OR occupational AND chemical AND respiratory in TOPIC, 2000-2012	380	**18**
PubMed	lung function AND occupational OR workplace AND chemical AND respiratory in TITLE/ABSTRACT, 2000-2012	95	**6**
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	lung function AND workplace OR occupational AND chemical in ABSTRACT, 2000-2012	182	**5**
Google Scholar	lung function AND workplace OR occupational in TITLE, 2000-2012	43	**4**

Selection

The following inclusion criteria were used to select relevant articles from initial results:

• must be written in the English language;

• must investigate respiratory exposure within the workplace;

• the exposure must be to a clearly defined substance, material or group of related substances;

• quality of study design was appraised using appraisal checklists developed by the Critical Appraisal Skills Programme (CASP) (Public Health Resource Unit, 2004a; Public Health Resource Unit, 2004b); studies considered to be poorly-designed were excluded (CASP checklists are included as appendix entries 1 and 2).

The total number of relevant articles included in this review was 33.

Data analysis

Selected articles were organised into groups based on the occupation being investigated. Each group was then considered in turn.

Results

Tables 1.4a-1.4e show the summaries of studies for the articles retrieved and organised by industry, followed by a brief commentary.

Table 1.4a: Summary of studies, investigations of occupational respiratory exposure					
Industry	**Type of study**	**Sample size**	**Measure (exposure)**	**Measure (outcome)**	**Results / significance**
Wood-working	Cross-sectional with controls (Osman & Pala, 2009)	n=656	Measured for 1 employee, extrapolated	FEV_1, FVC	Significant decline (p = <0.001)
	Cohort (Kogevinas et al, 2007)	n=6837	Interview	Relative risk (RR) of occupational asthma (OA)	RR = 2.22 (95%CI 0.69-7.17), non-significant
	Cohort (Baran & Teul, 2009)	n=1100	Measured	Incidence of lung cancer	No incidence found
Agriculture	Case-report (Hoy, Pretto, van Gelderen & McDonald, 2007)	n=2	Occupational history	Hyper-sensitivity pneumonitis (HP)	HP diagnosed
	Cross-sectional with controls (Rylander & Carvalheiro, 2006)	n=82	Measured	FEV_1	Significant decline (p = 0.003)
	Cohort (Venier et al, 2006)	n=265	Self-reported	FEV_1, FVC	Significant decline, FEV_1 (p = <0.05); FVC (p = <0.01)
	Cross-sectional (Faria, Facchini, Fassa & McDonald,2005)	n=1379	Interview	Symptom prevalence	Odds ratio (OR) for pesticide spreading = 2.54 (95%CI 1.36-4.72)
	Case-report (van Heemst et al, 2009)	n=1	Measured	HP	HP diagnosed

Wood-dust exposure in the furniture manufacturing industries was investigated in three studies. A cross-sectional study (Osman & Pala, 2009) found that FEV_1 (forced expiratory volume in one second) and FVC (forced vital capacity) were significantly lower in furniture workers than in controls (p = <0.001). The authors state that they were unable to measure exposure levels for each worker, and one measurement

was assumed to be representative. A large population-based study investigating multiple industries across Europe (Kogevinas et al., 2007) for risk of occupational asthma (OA) found wood-working to have a relative risk (RR) of 2.22 (95% CI 0.69 – 7.17), but this was not significant due to the confidence intervals crossing 1.0. The carcinogenic properties of wood-dust were also investigated (Baran & Teul, 2007). The authors found no incidence of lung cancer, and also were unable to attribute any cases of occupational respiratory disease to wood-dust exposure in the 1100 subjects.

Five articles investigated exposure within the agricultural industry. A case-report (Hoy, Pretto, van Gelderen & McDonald, 2007) describes two cases of hypersensitivity pneumonitis (HP) following exposure to organic dust resulting from mushroom farming (referred to here as 'mushroom worker's lung', also known as 'farmer's lung'). Airways inflammation was also reported following exposure to poultry-house dust (Rylander & Carvalheiro, 2006), with a significant reduction in FEV_1 in poultry-house workers compared to controls (p = 0.003). FEV_1 following methacholine challenge was further reduced in workers compared to controls (p = <0.001), suggesting airways hyperreactivity resulting from exposure to bacterial endotoxins, a significant component of this type of organic dust. A cohort study investigated the effects on respiratory function of the general modernisation of dairy farms (Venier et al., 2006), postulating that advanced methods and improved ventilation may result in significantly improved spirometric values. The authors cite micro-organisms within stored hay as the significant exposure for small dairy farmers. FEV_1 and VC (vital capacity) were reduced in traditional farm workers in comparison to those using modern techniques and equipment (p = <0.05 and <0.01, respectively). Pesticides exposure among farmers was investigated for its relationship to prevalence of respiratory symptoms in a cross-sectional study (Faria, Facchini, Fassa & Tomasi, 2005). A greater than twofold risk was shown for development of asthma symptoms following pesticide exposure. For example, adjusted OR for pesticide spreading >2 days per month was 2.54 (95% CI 1.36 – 4.72). The enzyme phytase – used in animal feed – was described as a novel allergen in a case-report describing a case of hypersensitivity pneumonitis in an agricultural foodstuff production worker (van Heemst et al., 2009). Spirometric

testing, workplace exposure rechallenge and positive response to steroids contributed to the diagnosis.

Table 1.5b: Summary of studies, investigations of occupational respiratory exposure

Industry	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Construction & associated	Cross-sectional (Ghasemkhani et al, 2006)	n=880	Self-reported	Symptom prevalence	Prevalence chest tightness 37.5% (p = <0.009); nasal irritation 30.8% (p = <0.0001)
	Cross-sectional (Moshammer, Hochgatterer, Angerschmid & Hutter, 2007)	n=994	Occupational history	MEF_{50}	Significant decline (p = 0.002)
	Cohort (Burstyn et al, 2003)	n=58962	Estimated	RR	RR of mortality from obstructive lung disease = 4.06 (95%CI 1.35-12.19)
Health-care	Cross-sectional (Delclos et al, 2007)	n=3650	Self-reported	OA prevalence	OR = 2.07 (95%CI 1.29-3.33, p = 0.03)
	Cohort (Kogevinas et al, 2007)	n=6837	Interviews	RR of OA	RR = 1.80 (95%CI 1.01-3.18)
	Case-report (Ong, Tan, Lee & Eng, 2004)	n=1	Occupational history	OA	OA diagnosed
	Cross-sectional (Liss et al, 2003)	n=2633	Self-reported	OA incidence	OR = 5.3 (95%CI 1.4-20.2) for males, non-significant for females

In a study comparing respiratory symptoms across a number of occupationally-hazardous industries (Ghasemkhani et al., 2006), the construction industry had the highest prevalence for chest tightness (37.5%, p = <0.009) and nasal irritation (30.8%, p = <0.0001); the construction industry is named here as one of the two most significant industries in this study, along with the textile industry. Quartz dust exposure from stone-working (Moshammer, Hochgatterer, Angerschmid & Hutter, 2007) was shown to be associated with a significant decrease in MEF_{50} (maximal

expiratory flow with 50% of FVC remaining) (p = 0.02). The control group used, however, consisted of other workers exposed to other/mixed sources of dust. The lack of an effective control group is questionable, as the selection of an unexposed control group would potentially have increased the significance of results; the authors do not state why such a group was not selected. A large cohort study of respiratory mortality in asphalt workers (Burstyn et al., 2003) showed that in the group with highest exposure, relative risk (RR) of mortality from obstructive lung diseases was 4.06 (95% CI 1.35 – 12.19), a four-fold risk in comparison to the unexposed.

A cross-sectional study of prevalence in health-care workers (Delclos et al., 2007) found an OR of 2.07 (95% CI 1.29 – 3.33, p = 0.003) for occupational asthma in those responsible for medical instrument cleaning. A large multi-industry study (Kogevinas et al., 2007) also found RR of 1.80 (95% CI 1.01 – 3.18) for occupational asthma resulting from use of cleaning products in the health-care industry. OA was also attributed to use of glutaraldehyde (a chemical commonly used for cleaning medical equipment) in a case-report describing a medical technician's symptoms and diagnosis (Ong, Tan, Lee & Eng, 2004), confirmed with a specific inhalational challenge (SIC) and subsequent 25% drop from baseline FEV_1. Glutaraldehyde was cited alongside another aldehyde used for this purpose – formaldehyde – in a study of asthma prevalence among medical radiation technologists (MRTs) (Liss et al., 2003). Using a non-exposed control group (physiotherapists), the odds ratio for new-onset asthma in MRTs was not significant for females, but was 5.3 (95% CI 1.4 – 20.2) for males, a five-fold risk.

Table 1.4c: Summary of studies, investigations of occupational respiratory exposure

Industry	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Metalworking & associated	Cross-sectional with controls (Johnsen, Kongerud, Hetland, Benth & Soyseth, 2008)	n=3294	Occupational history	FEV_1	Significant decline in never-smokers (p = 0.03)
	Case series (Gupta & Rosenman, 2006)	n=7	Measured	HP	HP diagnosed
	Case report (Beckett, Kallay, Sood, Zuo & Milton, 2005)	n=1	Measured	HP	HP diagnosed
	Case report (Di Stefano, Giampaolo, Verna & Gioacchino, 2007)	n=1	Occupational history	Occupational eosinophilic bronchitis (OEB)	OEB diagnosed
	Cross-sectional with controls (Kezunovic, 2008)	n=296	Occupational history	FEV_1, FVC, PEF	Significant decline, FEV_1 (p = 0.04); FVC (p = 0.03); PEF (p = <0.01)
	Cross-sectional with controls (Musk et al, 2000)	n=2639	Self-reported	FEV_1, FVC, FEV_1/FVC	Significant decline, FVC (p = 0.03); FEV_1/FVC (p = <0.001); FEV_1 non-significant
	Cross-sectional with controls (Fishwick Bradshaw, Slater, Curran & Pearce, 2004)	n=75	Measured	FEV_1	OR for reduction of FEV_1 of ≥5%, aluminium exposure = 5.8 (95%CI 1.7-20.6) OR for respiratory symptoms, nickel exposure = 7.0 (95%CI 1.3-36.6)
	Cross-sectional with controls (Jakubowski, Abramowska-Guzik, Szymczak & Trzcinka-Ochocka, 2004)	n=238	Measured	FEV_1, PEF	Significant decline (highest vs. lowest exposure), FEV_1 (p = 0.0208); PEF (p = 0.0488)

Occupational exposure to dust in the smelting industry (Johnsen, Kongerud, Hetland, Benth & Soyseth, 2008) was significantly associated with a reduction in FEV_1 when compared to non-exposed workers (p = 0.001). Further analysis to examine the confounding effect of smoking showed that a significant difference in FEV_1 between exposed and non-exposed was only seen in those workers who had never smoked (p = 0.03).

Metalworking fluids (MWFs) were associated with hypersensitivity pneumonitis (HP) in a case-series reporting outbreaks of HP (Gupta & Rosenman, 2006). The authors suggest that mycobacterial contamination of MWFs was responsible for the condition. This is further supported by another case-report of an individual developing HP following MWF exposure (Beckett, Kallay, Sood, Zuo & Milton, 2005), where the mycobacteria growing within five out of six MWF reservoirs in the workplace were cultured and identified as *Mycobacterium immunogenum*, an organism previously associated with HP (Suuronen, Henriks-Eckerman, Riala & Tuomi, 2008; Khan, Selvaraju & Yadav, 2005; Shelton, Flanders & Morris, 1999; Wallace, Zhang, Wilson, Mann & Rossmoore, 2002). Occupational eosinophilic bronchitis (OEB) – a non-asthmatic respiratory condition – was diagnosed in a foundry worker (Di Stefano, Giampaolo, Verna & Gioacchino, 2007). The OEB case was diagnosed via induced sputum testing, as spirometry is not typically a useful diagnostic tool in such cases.

Aluminium exposure was investigated in three studies (Kezunovic, 2008; Musk et al., 2000; Fishwick, Bradshaw, Slater, Curran & Pearce, 2004). Prevalence of respiratory symptoms in an aluminium factory was found to be high (e.g. breathlessness 56.7%) in one study (Kezunovic, 2008), but no significant changes in spirometric results were found. Significant spirometric changes were found between working groups in an aluminium refinery (Musk et al., 2000), but the authors concluded that these were not consistent and were unlikely to be of clinical importance. High aluminium exposure from welding (Fishwick et al., 2004) was, however, found to have a greater than five-fold risk of a reduction in FEV_1 of at least 5% (OR = 5.8 [95% CI 1.7 – 20.6]). In the same study, high nickel exposure from welding was found to have a seven-fold risk of work-related respiratory symptoms (OR = 7.0 [95% CI 1.3 – 36.6]). A study of cadmium exposure in a cadmium battery plant (Jakubowski,

Abramowska-Guzik, Szymczak & Trzcinka-Ochocka, 2004) showed a significant decrease in spirometric values only in the highest exposure group compared to the lowest exposure group; for FEV_1, p = 0.0208, and for PEF, p = 0.0488.

Table 1.4d: Summary of studies, investigations of occupational respiratory exposure					
Industry	**Type of study**	**Sample size**	**Measure (exposure)**	**Measure (outcome)**	**Results / significance**
Bakers	Case report (Di Stefano et al, 2007)	n=1	Occupational history	OEB	OEB diagnosed
	Retro cohort (Karjalainen, Kurppa, Virtanen, Keskinen & Nordman, 2000)	n=2602	Occupational history	OA incidence	Incidence rate 444 per 100 000 (males) (95%CI 362-540) Incidence rate 408 per 100 000 (males) (95%CI 337-489)
Textiles	Cross-sectional (Ghasemkhani et al, 2006)	n=880	Self-reported	Symptom prevalence	Prevalence of cough 30.8% (p = <0.035); phlegm 53.8% (p = <0.004); dyspnoea 65.0% (p = <0.002)
	Case report (Kim et al, 2001)	n=1	Measured	OA	OA diagnosed, confirmed with specific inhalational challenge (SIC)
Hairdressing	Case control (Hashemi, Boskabady & Nazari, 2010)	n=238	Occupational history	FEV_1, FVC, PEF	Significant decline (p = <0.001)
	Cross-sectional (Munoz et al, 2003)	n=8	Occupational history	OA	OA diagnosed

Occupational exposure to flour in a bakery was shown in a case report (Di Stefano et al., 2007) to be associated with respiratory symptoms corresponding to occupational eosinophilic bronchitis (OEB). OA was also shown to have the highest incidence rate in bakers in a study of various occupations (Karjalainen, Kurppa, Virtanen, Keskinen & Nordman, 2000); incidence rate was 444 per 100 000 (extrapolated from a population of 3248) for male bakers (95% CI 362 – 540) and 408 per 100 000

(extrapolated from a population of 4101) for female bakers (95% CI 337 – 489), almost double the rate of the next highest occupation.

Formaldehyde exposure in the textiles industry was shown to be associated with OA in a case-report (Kim et al., 2001), confirmed with SIC. FEV_1 was measured at 36.3% of the predicted value, which rose to 81.9% of predicted following steroid treatment. The textiles industry was also shown to have the highest prevalence for cough (30.8%, p = <0.035), phlegm (53.8%, p = <0.004) and dyspnoea (65.0%, p = <0.002) in a multi-industry study (Ghasemkhani et al., 2006).

A case-control study comparing spirometric values in hairdressers and matched controls (Hashemi, Boskabady & Nazari, 2010) found a significant reduction in FEV_1, FVC and PEF (p = <0.001 for all). Persulfate salts, used in hair bleaching powder, were found to be the substance with the greatest level of respiratory irritation. Another study (Munoz et al., 2003) showed that persulfate salts caused occupational asthma in both the employees preparing bleaching powder in a factory and the hairdressers using the powder in salons. OA was confirmed with specific bronchial challenge tests (SBCT) in all seven individuals tested; work-related changes in serial PEF measurements were also observed.

Table 1.4e: Summary of studies, investigations of occupational respiratory exposure

Industry	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Working with coal-dust	Cross-sectional with controls (Drivas et al, 2007)	n=165	Measured	FEV_1	Increased prevalence FEV_1 <80%pred. (p = <0.05)
Printing	Cross-sectional with controls (Gioda & Neto, 2007)	n=135	Measured	Symptom prevalence	87% symptom prevalence vs. 78% prevalence in controls
Spray-painting	Case report (Minov, Karadzinska-Bislimovska, Vasilevska, Risteska-Kuc & Stoleski, 2008)	n=2	Occupational history	OA	OA diagnosed
Flavourings	Cross-sectional with controls (van Rooy et al, 2009)	n=175	Estimated	Symptom prevalence	Prevalence ratio (PR), ever asthma attack = 2.0 (95%CI 1.2-3.4); PR asthma attack previous 12 months = 4.7 (95%CI 1.9-11.4)
Cleaning	Case-control (Medina-Ramon et al, 2005)	n=195	Measured	Symptom prevalence	OR, high frequency ammonia use = 3.1 (95%CI 1.2-8.0) OR, high frequency bleach use = 2.4 (95%CI 1.0-6.1)
Pharmaceutical production	Case series (Klusackova et al, 2007)	n=5	Occupational history	OA	OA diagnosed
Paper recycling	Case report (Tran, Francis, Hoyle & Niven, 2009)	n=2	Occupational history	OA	OA diagnosed

Only one article was retrieved for each of the occupations listed in table 1.4e.

A cross-sectional study examining the effects of lignite dust (coal dust) respiratory symptoms and spirometric values in power station workers (Drivas et al., 2007) found an increased prevalence of FEV_1 below 80% of predicted compared to non-exposed workers (p = <0.05). A similar level of increase was also found, however, in smokers compared to non-smokers (p = <0.05). The difference in mean FEV_1 values between exposed and non-exposed was not significant, whereas the same comparison between smokers and non-smokers was significant (p = <0.05), suggesting that smoking is a strong confounder here. The authors acknowledge this, and their calculation of odds ratios suggest a possible combinatory effect of both smoking and lignite dust exposure. Odds ratio (OR) for smoking as a predictor of chronic bronchitis symptoms was 3.47 (95% CI 1.45 – 8.33), and OR for lignite dust exposure as a predictor of chronic bronchitis symptoms was 3.48 (95% CI 1.46 – 8.2). The OR for smoking and lignite exposure *combined*, however, was 5.4 (95% CI 1.49 – 19.6), showing a five-fold risk for chronic bronchitis symptoms in exposed employees who smoke.

Prevalence of respiratory symptoms was investigated in a printing facility (Gioda & Neto, 2007). Individuals working near solvents reported 87% prevalence of at least one respiratory symptom; the control group, however, reported a 78% prevalence. The authors do acknowledge that the control group (office workers) was poorly chosen, as air sampling was not performed in the office area. If, however, the control group was ineffective due to solvent air contamination of the office area, this is suggestive of the risk posed by solvent use without appropriate extraction.

Occupational asthma was diagnosed in two employees exposed via car spray-painting (Minov, Karadzinska-Bislimovska, Vasilevska, Risteska-Kuc & Stoleski, 2008). Asthma was diagnosed via spirometry (PEF) and bronchoprovocation testing. The authors state that they were unable to perform a specific inhalational challenge that may have revealed the specific causative agent.

A cross-sectional study within the flavourings industry compared exposed employees with a non-exposed group (van Rooy et al., 2009). The authors found a prevalence ratio (PR) of 2.0 (95% CI 1.2 – 3.4) for having ever suffered an asthma attack, and a PR of 4.7 (95% CI 1.9 – 11.4) for suffering an attack within the previous twelve months.

A case-control study conducted on occupational domestic cleaners (Medina-Ramon et al., 2005) found high frequency use of household bleach and ammonia to be associated with asthma/chronic bronchitis symptoms (OR for bleach = 2.4 [95% CI 1.0 – 6.1]; OR for ammonia = 3.1 [95% CI 1.2 – 8.0]).

Occupational asthma was diagnosed in a case-report describing five workers using lasamide as a pharmaceutical intermediate in the production of diuretic medicines (Klusackova et al., 2007). Specific bronchoprovocation testing confirmed OA due to lasamide exposure in three out of the five subjects. The authors describe the discovery of lasamide as a novel allergen.

A case-report on two employees within the paper recycling industry described occupational asthma resulting from exposure to hydroxylamine, a potential replacement for glutaraldehyde (Tran, Francis, Hoyle & Niven, 2009) highlighting the difficulties of chemical substitution. OA was diagnosed in one individual following a positive response to SBCT with hydroxylamine, suggesting that in this case one sensitiser has been replaced with another, although the authors did propose that this was the first reported case of OA to hydroxylamine.

Conclusions

Occupational health and health surveillance strategies should take into account the frequency of identified respiratory problems relevant to their workplace exposure conditions. The benefits of modernisation of ventilatory equipment and personal protective equipment were observed (Venier et al., 2006) in terms of ensuring reasonable employee protection from occupational respiratory exposure. The potential hazards behind chemical substitution for health reasons was also observed (Tran et al., 2009). Evidence should be sought on the safety and/or sensitisation potential of possible replacements before a substitution is made.

No articles investigating respiratory exposure within the fragrance industry were retrieved for review. This lack of previous research on industry employees is remarkable, considering that the consumer's exposure to the fragrance component of a product may be orders of magnitude lower than the employee who compounded

that fragrance. A typical eau de toilette perfume may contain around 10% fragrance, and a body wash product around 1%, for example; the fragrance compounder, meanwhile, may be exposed to large quantities of that fragrance without dilution, and so the exposure is notably greater. The fragrance industry is therefore an unexplored area for occupational exposure studies, and there is strong justification for similar research in this area as described in the articles reviewed above.

1.3 Defining the research question (part 1)

As seen in section 1.2, extensive research has been carried out exploring occupational respiratory exposure in other industries. Similar research has not been undertaken in the fragrance industry, despite the hazard of respiratory exposure resulting from regular working procedures. Health surveillance (as recommended by COSHH [Home Office, 2002, Regulation 11]) using spirometry is useful in such a workplace environment in monitoring employees' respiratory health over time, and such a system is in place at the researcher's workplace, but there is a clear lack of published literature exploring the consequences of working in the industry.

The primary aim of the research planned and undertaken for this thesis was formally organised into a research question using the PECO method (population, exposure, comparison, outcome) (Richardson, Wilson, Nishikawa and Hayward, 1995; Dewey et al., 2011). The PECO method was selected instead of PICO as the factor to be investigated is an exposure, rather than an intervention.

Table 1.5 shows how the PECO method was used to define the research question.

Table 1.5: Formalising the research question using PECO		
P	**Population**	*fragrance industry employees*
E	**Exposure**	*occupational respiratory exposure to chemicals*
C	**Comparison**	*employees using chemicals compared to non-exposed control group*
O	**Outcome**	*change in lung function (measured using spirometry)*

Formal research question:

In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?

This research question gives the alternative and null hypotheses:

Research/alternative hypothesis: *In fragrance industry employees, occupational respiratory exposure to chemicals is linked to a statistically significant change in lung function as measured using spirometry.*

Null hypothesis: *In fragrance industry employees, occupational respiratory exposure to chemicals is not linked to a statistically significant change in lung function as measured using spirometry.*

Designing, undertaking and reporting a research study that aims to answer this question will form the primary arm of the research, referred to as 'part 1' (part 2 comprises questionnaire development, outlined in section 1.4 and detailed in chapters 4 and 5). Aims and objectives for both parts of the study will be outlined in section 1.5. Methodology of the research study will be covered in chapter 2.

1.4 Questionnaire development (part 2)

Part 2 of the study approaches the knowledge gap in the fragrance industry from the perspective of occupational health and pre-placement questionnaires and assessments.

Many pre-placement examinations and assessment procedures used currently are ineffective in assessing employees' fitness for work, and there is weak evidence to support their continued use (Madan & Williams, 2010; Madan & Williams, 2012; Mahmud et al., 2010; Hulshof, Verbeek, van Dijk, van der Weide & Braam, 1999). Within the fragrance industry, respiratory exposure is an occupational hazard, and health surveillance of employees is recommended (Home Office, 2002). This may take the form of periodic monitoring of employees' lung function with spirometric

assessments. Knowledge of an employee's lung health at the start of employment would inform the employer of the necessity of further measures for that employee, for example the use of face masks, or more frequent spirometric assessments.

Due to the Equality Act 2010 Section 60 (Home Office, 2010), however, it is now illegal for an employer to request any health-related information from a prospective employee prior to a formal offer of employment. This Act has two consequences relevant here:

1) 'pre-employment' questionnaires should now be referred to as 'pre-placement' questionnaires. Existing questionnaires considered later in this section were developed prior to the Act becoming law, and so these terms may be used interchangeably here.

2) as health information can now only be sought following an employment offer, it is crucial that a pre-placement questionnaire functions as a worthwhile tool, and is able to correctly identify potential relevant issues that can then be addressed.

The aim of part 2 of this research was to additionally use the spirometric data collected from participants, along with demographic and physical information collected on pre-assessment data collection sheets, to develop a pre-placement questionnaire that is predictive for lung function impairment. This questionnaire is intended to fulfil this function specifically within the fragrance industry, developed to be representative of its target population.

The process behind the development of the data collection sheets will be detailed in chapter 4 (part 2 methodology), and subsequent construction of the final pre-placement questionnaire will be covered in chapter 5 (part 2 results).

1.5 Aims and objectives

The production of fragrance mixtures for inclusion in perfumes and other fragranced products has developed from the simple burning of fragrant plant material to the industrial manufacturing processes and facilities used today. Production employees

in these modern facilities are exposed to the natural and synthetic chemicals used as fragrance ingredients, often in large quantities, and so this work falls within the scope of occupational health. What effect, if any, does respiratory exposure in this industry have on the health of the employee, and how can this be sensibly measured? This thesis is concerned with the investigation of this question, and has two overarching aims:

Primary aim (part 1): to investigate the effects of occupational respiratory exposure to chemicals in the fragrance industry on lung function, by answering the research question:

In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?

Secondary aim (part 2): to develop a pre-placement occupational health questionnaire that is predictive of reduced lung function, for use within the fragrance industry.

For clarification, the structure and terminology used to describe the work undertaken towards this thesis is shown in figure 1.2.
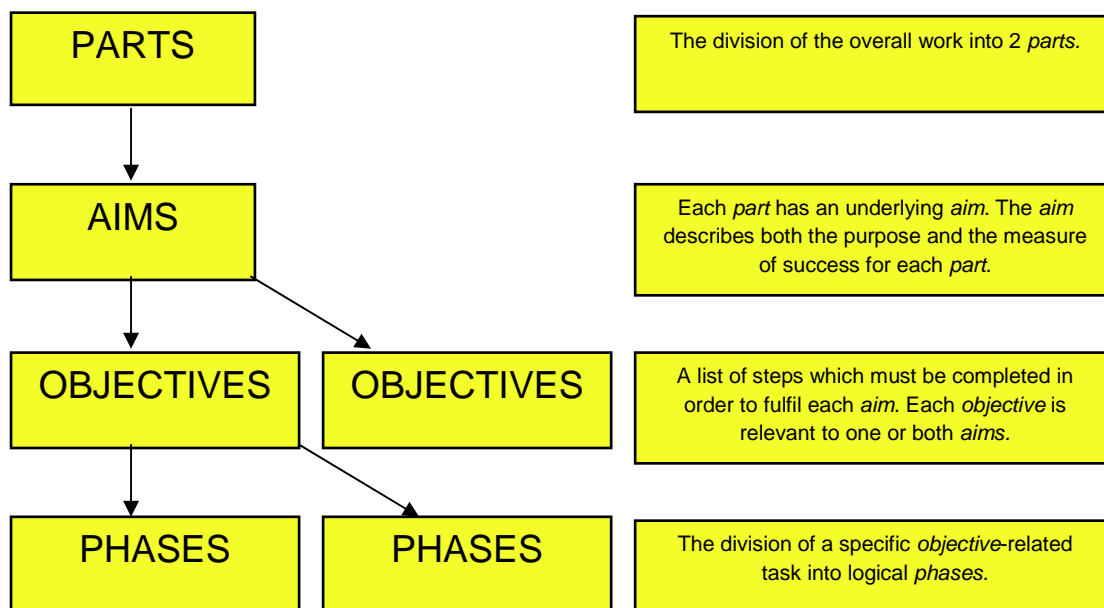
Figure 1.2: General structure and organisation of the research

Figure 1.3 shows a process map of how parts 1 and 2 will be undertaken as part of one cohesive body of work.


```
┌──────────────────────┐        ┌──────────────────────┐
│       PART 1         │        │       PART 2         │
│                      │        │                      │
│  Research question   │        │ Questionnaire development │
└──────────────────────┘        └──────────────────────┘
            │                               │
            ▼                               ▼
┌──────────────────────┐        ┌──────────────────────┐
│        AIM           │        │        AIM           │
│ to investigate the   │        │ to develop a pre-    │
│ effects of occupational│      │ placement occupational│
│ respiratory exposure │        │ health questionnaire │
│ to chemicals in the  │        │ that is predictive of│
│ fragrance industry   │        │ reduced lung function,│
│ on lung function     │        │ for use within the   │
│                      │        │ fragrance industry   │
└──────────────────────┘        └──────────────────────┘
            │                               │
            ▼                               ▼
        ┌───────────────────────────────────┐
        │        SPIROMETRIC DATA            │
        └───────────────────────────────────┘
            │                               │
            │                               ▼
            │              ┌────────────────────────┐
            │              │   DEMOGRAPHIC AND      │
            │              │    PHYSICAL DATA       │
            │              └────────────────────────┘
            ▼                               │
┌──────────────────────┐                    │
│  EXPLORE RESEARCH    │                    │
│     QUESTION         │                    │
└──────────────────────┘                    │
            │                               ▼
            ▼              ┌────────────────────────┐
      ┌───────────┐        │ PREDICTIVE QUESTIONNAIRE│
      │  RESULTS  │        │     DEVELOPMENT        │
      └───────────┘        └────────────────────────┘
            │                               │
            │                               ▼
            │              ┌────────────────────────┐
            │              │  FINAL QUESTIONNAIRE   │
            │              └────────────────────────┘
            │                               │
            ▼                               ▼
        ┌───────────────────────────────────┐
        │   DISCUSSION AND IMPLICATIONS      │
        └───────────────────────────────────┘
```

Figure 1.3: Process map showing parts 1 and 2 of the research

Table 1.6 shows the objectives for both study aims.

Table 1.6: Objectives relating to parts 1 and 2	
Objective number	**Objective description**
1	Professional training and experience: To gain formal training in spirometric testing and interpretation, and experience at conducting spirometric testing in the workplace.
2	To answer the research question: *In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?*
3	Statistical analysis: To undertake statistical analysis on data collected to explore the relationship between chemical exposure and lung function.
4	*Predictive questionnaire:* To develop a predictive pre-placement screening questionnaire using spirometric data obtained and demographic information from pre-assessment data collection sheets. *Sub-objective:* To critically evaluate existing evidence on factors potentially associated with reduction in lung function (to inform the development of pre-assessment data collection sheets).
5	Dissemination: To disseminate results via industry seminars/presentations and reports, and preparation of article(s) for publication.
6	Professional implications: To explore the implications of research findings for industry via: preparation of guidelines / recommendations as appropriate; making the predictive questionnaire available within the fragrance industry; suggestion of future research ideas arising from the research findings.

Objective 1

> Professional training and experience:
>
> To gain formal training in spirometric testing and interpretation, and experience at conducting spirometric testing in the workplace.

The research outcome, a change in lung function, will be measured using spirometry. To ensure competence of lung function testing during data collection, both formal training and significant prior experience with conducting spirometric assessments are necessary (Miller et al., 2005a).

I received formal training in spirometric assessments and interpretation of results in March 2010 at the Royal Brompton Hospital's Lung Function Unit, London (appendix entry 3). Immediately following this training, a health surveillance programme was implemented in the workplace, involving spirometric testing at two-month intervals (appendix entry 4). I am responsible for all aspects of organising and conducting this programme. Data collection for research purposes was scheduled to take place during October and November 2011, giving over 18 months personal experience in regular spirometric testing. Standardisation of testing was achieved by ensuring that all spirometric tests were conducted by the same trained and experienced individual (myself).

Objective 2

> To answer the research question:
>
> *In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?*

Design and methodology of the research study planned to answer this question will be reported in chapter 2.

Objective 3

Statistical analysis:

To undertake statistical analysis on data collected to explore the relationship between chemical exposure and lung function.

Statistical methods used in the analysis of the data will be detailed in chapter 2.

Objective 4

Predictive questionnaire:

To develop a predictive pre-placement screening questionnaire using spirometric data obtained and demographic information from pre-assessment data collection sheets.

Sub-objective:

To critically evaluate existing evidence on factors potentially associated with reduction in lung function (to inform the development of pre-assessment data collection sheets).

Chapter 4 contains the review of existing literature and examination of existing questionnaires. Information obtained through these processes was used to develop a data collection sheet (appendix entry 5). The methodology behind the development of a predictive pre-placement screening questionnaire to fulfil this objective will be covered in chapter 4.

Objective 5

Dissemination:

To disseminate results via industry seminars/presentations and reports, and preparation of article(s) for publication.

Disseminated material arising from the research was listed in the dissemination list (page xi). Future articles and presentations will be listed in chapter 5.

The questionnaire developed for part 2 will be made available to other fragrance companies. As future work, a presentation will be prepared on the development and intended use of the questionnaire to aid its release into industry; there will be interest

from RIFM and IFRA United Kingdom to receive this presentation. The results of part 2 will also be written up as an article and submitted for publication in a peer-reviewed journal.

Objective 6

> Professional implications:
>
> To explore the implications of research findings for industry via:
>
> preparation of guidelines/recommendations as appropriate;
>
> suggestion of future research ideas arising from the research findings.

Chapter 6 will explore the implications of the research findings. Considering the research question, the primary and immediate implication of the results will be:

If the research hypothesis is supported: industry will be made aware of a potential problem that could affect the well-being of their staff, and will have the justification to budget for improvements to ventilation and protective measures, for example.

If the null hypothesis is supported: existing measures used will have been shown to be sufficient. Industry will have justification for continuing to use existing measures.

The potential benefits of the predictive questionnaire will also be explored in chapter 6, along with specific ideas for future research leading on from and inspired by both parts of this research study.

Summary

This chapter has provided the setting, context, and justification for the research study, and defined the formal research question and the aims and objectives underlying the research.

Chapter 2 will follow the background, research question and objectives formalised in this chapter to give detailed methods and study design for part 1, followed by the reporting and discussion of the results in chapter 3.

Chapter 4 will detail the methodology behind the development of the predictive pre-placement questionnaire. Chapter 5 will report the results of questionnaire development and link to the completed questionnaire and accompanying scoring guide in the appendix.

Chapter 6 will then conclude by drawing together all elements of the research and results, the implications for industry, and future research possibilities arising from the study.

Chapter 7 will be dedicated to personal and professional reflection, including an evaluation of my progress towards the professional doctorate and the significant developmental steps that have occurred throughout the process.

The methodology for part 1, the primary aim of answering the research question, can now be detailed in chapter 2.

Chapter 2 Methodology, part 1

The aim of this chapter is to provide the methodology used to investigate the effects of occupational respiratory exposure to chemicals in the fragrance industry on lung function, and so answer the research question:

In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?

This will be achieved by detailing all aspects of study design, planning and organisation.

2.1 Study design

The outcome(s) were measured using numerical spirometric data, therefore the study was designed using quantitative methodology.

The type of study design used must provide the most appropriate and suitable method of answering the type of research question, and must also be feasible and practical in the intended setting. Using an inappropriate design not only wastes time and funding, but could also give misleading results and render the entire process meaningless (Petrie & Sabin, 2005, p.30). An understanding of the nature, benefits and disadvantages of each type of study is critical to the whole research process (Gordis, 2009, p.166), so consideration was given to each study type in turn. Three main types of study design can be used for quantitative research, as shown in table 2.1.

Table 2.1: Types of quantitative study design	
Type of study	**Example**
Observational, descriptive	Cross-sectional
	Case study / case report, case series
Observational, analytical	Case-control
	Cohort (prospective)
	Cohort (retrospective)
	Cross-sectional with controls
Experimental	Randomised controlled trial

As this study will be looking at occupational exposure rather than an intervention, an experimental design such as a randomised controlled trial would be unsuitable, as it would be unethical to purposely expose individuals to a hazard (Petrie & Sabin, 2005, p.30). The observational types of design will be considered in turn, enabling the selection of the most appropriate design (Crombie & Davies, 1996, pp.168-9).

● *Cross-sectional:* carrying out a 'snap-shot' study gives rapid results and is inexpensive. Although useful in determining prevalence, the lack of a control group means that a causal relationship between the exposure and outcome(s) of interest cannot be investigated (Mann, 2003; Monson, 1990, pp.144-147), and so this type of design would not be effective in answering the research question.

● *Case studies / case series:* while case studies are inexpensive and can give detailed information on the clinical progress of a disease or condition and response to treatment, this type of study is not suitable for investigating and answering formal research questions (Crombie & Davies, 1996, pp.79-84).

● *Case-control:* usually retrospective, this type of study matches a case group (those with the outcome) and a control group (those without the outcome) and compares historical exposure to the variable of interest between groups (Mann, 2003; Gordis, 2009, pp.177-178). This type of study is particularly effective when investigating rare diseases or conditions (Mann, 2003). A retrospective approach, however, can make

it difficult or impossible to control for confounding variables (Crombie & Davies, 1996, p.152; Mann, 2003). Also, a case-control study designed to answer this research question would require the recruitment of a sufficient number of industry employees *with* either a reduced lung function or a specific respiratory condition such as asthma, and a similar number of control employees *without* the outcome, and acquiring historical exposure data. This approach was felt to be impractical to answer this specific question.

● *Cohort study:* these studies typically require a large sample size and take place over a lengthy timescale, often several years (Gordis, 2009, p.169). While the idea of following a cohort of industry employees over many years to monitor lung function is an attractive one, it is not feasible given the time and budgetary constraints of this study.

● *Cohort study (retrospective):* this approach modifies the standard cohort study to use historical data already collected for other purposes (Mann, 2003; Gordis, 2009, pp.170-171). This has the advantage of being more rapid and less expensive than a prospective cohort study, although controlling for confounding variables can be difficult or impossible (Mann, 2003). It would be possible to use historical spirometric data from the researcher's workplace collected as part of the occupational health service; however, the limitation on demographic data would make controlling for confounding factors difficult. The main issue with this study type, however, would be population size; the population at a single fragrance production site would not be sufficient to conduct a viable study.

● *Cross-sectional with controls:* modifying a cross-sectional study design to add a control group (Monson, 1990, pp.144-147) elevates the design from a descriptive study to an analytical methodology. In the context of answering this specific research question, this design has the benefit of a basic 'case-control' structure, with the statistical analysis options this gives, and also the shorter timescale offered by a cross-sectional study. This was the most appropriate study methodology.

The selected design was therefore a **cross-sectional study with controls:**

• exposed group: employees using chemicals as part of their daily working routine (fragrance production employees such as compounders, and associated functions such as packers).

• non-exposed group (controls): employees not using chemicals as part of their daily working routine (office-based staff, e.g. customer services, finance, human resources, for example).

Recruiting a control group from within industry ensures that the study remains relevant to the fragrance industry, and that recruitment of a sufficient number of controls can realistically be achieved within the organisational requirements of the study. This also minimises potential selection bias resulting from the 'healthy worker effect' (Monson, 1990, p.114; Leonard, Kreckmann, Sakr & Symons, 2008; Shah, 2009; Le Moual, Kauffmann, Eisen & Kennedy, 2008).

2.2 Outcome measurements (spirometry)

The spirometric measurements used were forced expiratory volume in one second (FEV_1), forced vital capacity (FVC) and peak expiratory flow (PEF). These are standard measurements used when assessing and reporting on lung function (Berry, Bhagat, Ajelabi & Petrini, 2008; Downs et al., 2005; Jakubowski, Abramowska-Guzik, Szymczak & Trzcinka-Ochocka, 2004; Kezunovic, 2008; Kumar et al., 1995; Marcon et al., 2009; Osman & Pala, 2009; Quanjer et al., 1993; Wang, Avashia & Petsonk, 2009).

Measurements taken were converted to a percentage of the predicted values for each participant. The predicted values were taken from the European Community for Steel and Coal Working Party Report (Quanjer et al., 1993), these are the standards used in European spirometric assessments. Each participant's age, height and gender can be factored in, and a predicted value given based on these variables. Each outcome measurement can then be expressed as percentage-of-predicted (*%pred*). This method ensures standardisation of measurements for all outcome measures, and also accounts for three potential confounding factors at the data collection stage (age, height and gender).

A further correction factor was applied to the predicted figures for FEV_1 and FVC for participants of African ethnic origin, as recommended by Quanjer et al. (1993), to account for the proportionate difference in trunk length – and therefore lung size – relative to height in those individuals. An adjustment of 0.87 was made, i.e. predicted value x 0.87 to give a predicted value adjusted for ethnicity in addition to age, height and gender; this adjustment was made for 6 participants.

The outcome sought using spirometric measurements was a change in spirometric performance over the course of a working shift. Such cross-shift change has been used as a measurement tool in many similar studies in other industries, often referred to as cross-shift decline or cross-shift decrement. The term 'cross-shift change' is preferred here, as the outcome sought was any significant change in spirometric measurements, whether that change is a decline or an increase.

Reversible obstruction observed across a working shift in this context would be defined as work-related asthma. This may be an aggravation of a pre-existing condition (work-aggravated asthma), or directly induced by occupational exposure (occupational asthma) (Nicholson, Cullinan, Burge & Boyle, 2010, p.4; Vandenplas & Malo, 2003). If occupational asthma were to be observed in this study, it is unlikely to result from a sensitising reaction, as known respiratory sensitisers are not used in the production of fragrance compounds; if observed, this would almost certainly be irritant-induced. Distinguishing between the variant types of work-related asthma does not fall within the scope of this study, however, nor does clinical diagnosis.

Although spirometry is often used in health surveillance, these measurements can have a low sensitivity in detecting reversible airway obstruction, leading to false negatives (Nicholson et al, 2010, p.18, p.21). Serial peak flow readings may be more effective in detecting such obstruction; the minimum criteria required to achieve optimal diagnostic accuracy, however, is ≥4 readings per day for a period of at least 3 weeks (Nicholson et al, 2010, pp.21-22; Anees, Gannon, Huggins, Pantin & Burge, 2004; Malo et al, 1993). This is not feasible within the organisational constraints of this study. Cross-shift change as measured using spirometry was selected for this study, as used in a number of similar occupational studies (Mandryk, Alwis & Hocking, 1999; Abramson et al., 2001; Park et al., 2007; Raulf-Heimsoth et al., 2007; Fell et al., 2011).

A further point regarding spirometry is the risk of false positives arising from poor subject technique (Nicholson et al, 2010, p.18; Kraw & Tarlo, 1999). This can be prevented by ensuring that data collection is carried out by an experienced competent individual, and by taking repeated measurements. Ensuring that all data collection is carried out by the same individual (the researcher) using the same equipment and protocol will also minimise measurement bias (Hartman et al., 2002; Crombie & Davies, 1996, pp.259-260; Monson, 1990, p.138).

Measurements were taken from each participant by the same trained and competent individual (the researcher) to minimise measurement bias. The spirometry equipment used is detailed in table 2.2; this is the spirometer used by the researcher for occupational health assessments, selected for its ease of use, portability and its proven reliability (Dirksen, Madsen, Pedersen, Vedel, & Kok-Jensen, 1996; Otulana et al., 1990). The spirometer was returned to the manufacturer for calibration prior to data collection taking place, thus ensuring the reliability of the measurements taken.

Table 2.2: Details of the MicroPlus spirometer used for spirometric data collection	
Model:	MicroPlus
Type:	Flow spirometer – turbine
Portable / fixed:	Portable
Manufacturer:	Cardinal Health UK 232 Ltd., Quayside, Chatham Maritime, Kent, ME4 4QY
Supplier:	Williams Medical Supplies Ltd. Craiglas House, Maerdy Industrial Estate, Rhymney, Gwent, NP22 5PY
Measurements taken:	FEV_1 - forced expiratory volume in one second (litres) FVC - forced vital capacity (litres) FEV_1/FVC - ratio of FEV_1 to FVC PEF - peak expiratory flow (litres/min)
Calibration:	Once annually, by manufacturer

The procedure followed for spirometric data collection is as described in the spirometry measurement protocol used at the researcher's workplace (appendix entry 6); Johns & Pierce, 2007; Miller et al, 2005b).

2.3 Bias

Biases inherent to a study must be acknowledged and controlled in order for the study to produce valid results (Hartman, Forsen, Wallace & Neely, 2002; Crombie & Davies, 1996, pp.256-262; Monson, 1990, pp.34-37).

The types of bias relevant to this study are summarised in table 2.3, along with measures taken to minimise their effects.

Table 2.3: Types of bias	
Bias	**Measure(s) taken**
Sampling / selection bias	Selection of the most appropriate study design to answer the research question (section 2.1) (Hartman et al., 2002)
	Clearly defined eligibility and exclusion criteria prior to recruitment (section 2.6) (Hartman et al., 2002; Monson, 1990, p.35)
	Recruitment of control group (non-exposed) from the same industry
Measurement bias	Data collection methods clearly defined in advance, as part of the study design (section 2.7) (Hartman et al., 2002)
	The same (trained and competent) individual was responsible for spirometric measurements; procedure used was identical for exposed and control groups (Hartman et al., 2002; Crombie & Davies, 1996, pp.259-260; Monson, 1990, p.138)
	Same equipment was used for measurements; reliable, maintained, calibrated (Crombie & Davies, 1996, pp.259-260)
Recall bias	Questions (e.g. on smoking habits) on data collection sheet were written to be easy to understand and sensible; the data collection sheet was piloted pre-study to ensure ease of completion
Confounding	Relevant information on potential confounding factors was acquired via data collection sheets and/or during assessments (section 2.7) (Monson, 1990, pp.34-35)
	Potential confounding factors were adjusted for using appropriate statistical analysis methods (section 2.8)
	Use of percentage-of-predicted values controlled for certain potential confounders (age, height, gender) (Quanjer et al., 1993)

2.4 Sample size

The minimum sample size required for the study was calculated as shown in table 2.4, below (also see appendix entry 7).

Table 2.4: Minimum sample size required for study			
Power	**Significance**	**Effect size**	**Sample size**
80%	5%	7% or greater*	**108**
80%	5%	6% or greater	**126**
90%	5%	6% or greater	**168**

*i.e. the cross-shift decline measured in an individual must be 7% or greater to be considered important.

Sample size calculations were performed by University of Portsmouth statistician, Dr. Reuben Ogollah. The effect size of clinical significance for cross-shift change in spirometric measurements was set at ≥6%, to be greater than the 5% variance limit for acceptable repeatability criteria (Miller et al, 2005b; Quanjer et al, 1993). Minimum sample size for 80% power and 5% significance was calculated as 126. Recruitment gave an initial sample size of 125 (prior to subsequent withdrawals and exclusions, see section 2.6), so a post-hoc sample size calculation was performed by the statistician using an effect size of ≥7%, which gave a lower minimum sample size of 108.

Sample sizes in similar cross-sectional respiratory studies in other industries ranged from 75 (Fishwick et al, 2004) to 2639 (Musk et al, 2000). Given the initial recruitment of 125 participants, a final sample size of ≥108 was an achievable target. Details of the phased recruitment strategy are given in section 2.6.

2.5 Ethics and governance

Ethical review

Ethical approval was sought from the Research Ethics and Peer Review Committee, School of Health Sciences and Social Work (SHSSW), University of Portsmouth. Formal approved was granted in July 2011 (appendix entry 8).

Ethics

Ethical issues to consider when planning this study were:

● confidentiality: measures undertaken to ensure confidentiality (Department of Health, 2005, pp.30-32) are outlined below.

- *anonymisation*: each participating company was allocated a reference number (site 1, site 2 etc.). Company names or other identifying characteristics such as location were not revealed to other parties, and are not stated in the presentation or dissemination of results. Participants were each allocated a reference number, and these numbers were used for electronic data entry. It is not possible to identify individuals from these numbers.

- *data storage (electronic)*: for the duration of the study, all electronic data acquired from study participants will be stored on a personal laptop computer that is password-protected. Following the completion, presentation, dissemination and defence of the study, all such electronic data will be deleted.

- *data storage (hard copy)*: for the duration of the study, all completed spirometry data-entry forms, data collection sheets and other material such as appointment schedules will be stored in a locked cabinet to which only the researcher has a key. No other individual shall have access to this material. Following the completion, presentation, dissemination and defence of the study, all such material will be either destroyed or returned to the participant, by individual preference.

Figure 2.1 shows how confidentiality was maintained.
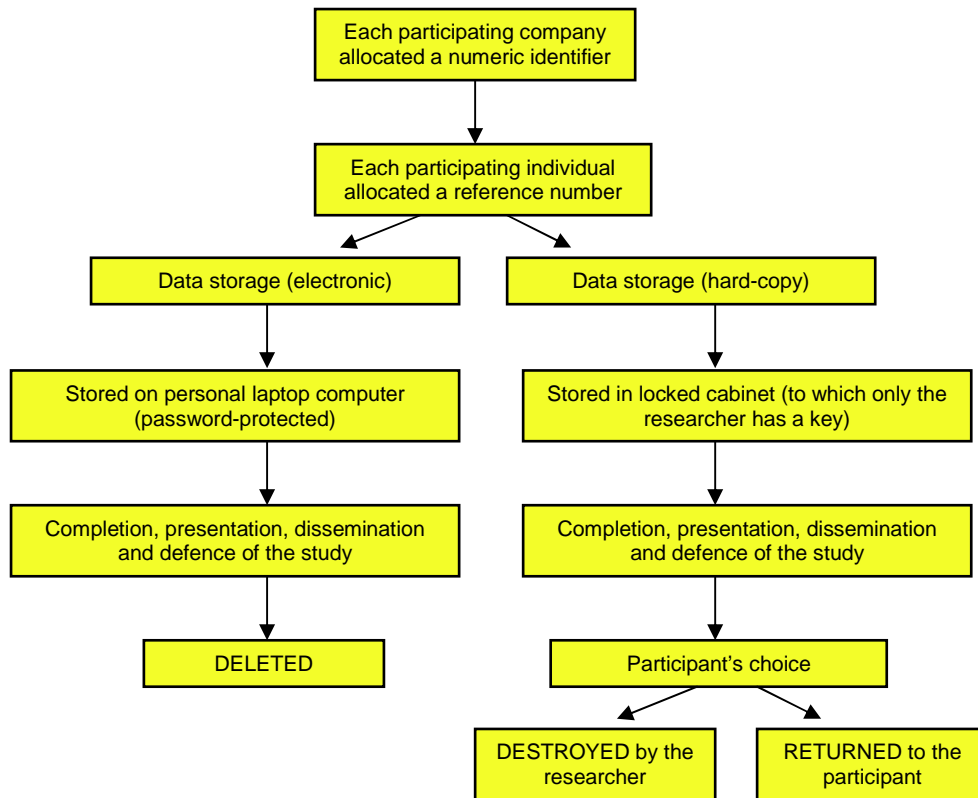
Figure 2.1: Confidentiality process map

● ensuring free and informed consent: an information sheet (appendix entry 9) was prepared and given to suitable employees to allow informed consent. Individuals expressing an interest were then given a consent form (appendix entry 10) and data collection sheet (appendix entry 5). Both the employee information sheet and consent form clearly state that the participant may withdraw from the study at any time without giving a reason. Free consent was ensured at the beginning of the data collection appointment, when each participant was advised verbally that participation was voluntary and they were under no obligation (or pressure from their employer) to proceed further.

● worrying employees: it was possible that some employees may have become worried by the implied risks resulting from their occupational exposure. Any queries of this nature were discussed confidentially during appointments; indeed, many participants were reassured by this novel research taking place within their industry, and understood that the research was beneficial to them as a workforce.

● worrying employers: it was also possible that employers may have been reluctant to participate due to a fear of the consequences of a negative relationship between exposure and lung function being found. A presentation was given by the researcher to a meeting of the International Fragrance Association, United Kingdom (IFRA-UK) Executive Committee, to provide information on the research prior to formal invitations. It was made clear that if a negative relationship was found, this would suggest that improvements were necessary, and those improvements would improve the health of the workforce and would show concrete evidence to enforcing bodies (e.g. Health and Safety Executive) that exposure was being investigated and acted upon. Ultimately, however, this may have been a factor in the decision of some of the invited companies not to participate.

● conflict of interest: all material relating to the research study was given University of Portsmouth headers, and it was made clear to invited companies that for the purposes of the study, the researcher should be considered as a researcher affiliated with the university, rather than an employee of one particular company. A confidentiality agreement was also prepared (appendix entry 11), and was signed by a representative from each participating company.

● dealing with an issue/referral: any spirometric results which suggested a restricted lung function would at first be discussed confidentially with the individual. A confidential letter would then be provided by the researcher summarising the results, for the individual to discuss with their general practitioner. The individual would also be offered confidential follow-up contact with the researcher to further discuss the issue.

Governance

Effective research governance requires that research is conducted according to general principles of good practice, ensuring the quality of the research and the safety of participants (Department of Health, 2005). The responsibilities of the researcher's employer as the employing organisation and the sole funder of the study are outlined in table 2.5 (adapted from Department of Health, 2005, pp.23-24; text marked in italic are direct quotations).

Table 2.5: Responsibilities and actions of the researcher's workplace towards research governance		
	Responsibility	**Action (individual)**
Employing organisation	*Ensuring researchers understand and discharge their responsibilities*	Regular discussions and progress updates with researcher (AC*, BW**)
	Ensuring studies are properly designed and submitted for independent review	Checked that ethical review was sought and approved (AC)
	Ensuring studies are managed…as agreed	Regular discussions and progress updates with researcher (AC, BW)
Funder / sponsor	*Assessing the scientific quality of the research as proposed*	Discussions with researcher during planning stages (AC)
	Establishing the value for money of the research as proposed	Assessing and approving funding and expenses requests (AC, GE***)
	Considering the suitability of the research environment	Discussions with researcher during planning stages, following site visits (AC, BW)
	Confirming that everything is ready for the research to begin	Progress updates, providing funds for equipment and sundries, confirming travel arrangements etc. (AC, GE)

*Anne Connet, Regulatory Manager, CPL Aromas, Brixworth (workplace supervisor).

**Brian White, Q-SHE Manager, CPL Aromas, Brixworth (workplace supervisor).

***George Ewen, Production Director, CPL Aromas, Brixworth (head of establishment).

2.6 Recruitment

The study population was employees working within the fragrance industry, so all fragrance companies with a production site in the UK were invited to participate. Individual recruitment then took place in those companies agreeing to take part. Conducting a multi-site study ensured that a sufficient sample size could be achieved, and also ensured that the population was representative of the UK fragrance industry as a whole.

Recruitment of participants was achieved via a phased process, as shown in figure 2.2.


```
                        ┌──────────────────────────────────────────────┐
                        │            PHASE 1: AWARENESS                 │
                        │      Presentation to IFRA-UK* (Mar 2011)      │
                        │   Invitation packs sent to employers (May 2011)│
                        │  Follow-up contact via telephone and email    │
                        │                (Jun/Aug 2011)                 │
                        └──────────────────────────────────────────────┘

┌─────────────────────┐   ┌──────────────────────────┐   ┌──────────────────┐
│ 5 companies agree   │ ← │ Company willing to       │ → │ Company declines │
│ to take part;       │   │ participate              │   │                  │
│ Total population =398│   └──────────────────────────┘   └──────────────────┘
└─────────────────────┘

                ┌──────────────────────────────────────────────────────────┐
                │        PHASE 2: RECRUITMENT OF COMPANIES                  │
                │ Site visit with company contact to discuss requirements   │
                │ and individual recruitment.                               │
                │ Collect signed acceptance form and confidentiality        │
                │ agreement (Jul/Aug 2011)                                  │
                └──────────────────────────────────────────────────────────┘

                ┌──────────────────────────────────────────────────────────┐
                │        PHASE 3: RECRUITMENT OF INDIVIDUALS                │
                │ Company contact distributes information sheets to suitable │
                │ employees (Aug/Sep 2011)                                  │
                └──────────────────────────────────────────────────────────┘

┌───────────┐   ┌──────────────────────────┐   ┌──────────────────┐
│ n = 125   │ ← │ Employee willing to      │ → │ Employee declines│
└───────────┘   │ participate              │   └──────────────────┘
                └──────────────────────────┘

                ┌──────────────────────────────────────────────────────────┐
                │ Company contact distributes consent forms and data        │
                │ collection sheets (Sep/Oct 2011)                          │
                └──────────────────────────────────────────────────────────┘

                ┌──────────────────────────────────────────────────────────┐
                │      PHASE 4: EXCLUSIONS / WITHDRAWALS                    │
                │ Site visits for data collection appointments (Oct/Nov 2011)│
                └──────────────────────────────────────────────────────────┘

┌───────────┐ ┌──────────────────┐   ┌──────────────────┐  ┌──────────────┐
│ n = 115   │←│ Employee willing │   │ Employee no longer│→ │ WITHDRAWN=10 │
└───────────┘ │ to participate   │   │ willing to       │  └──────────────┘
              └──────────────────┘   │ participate      │
                                      └──────────────────┘

              ┌──────────────────────────────────────────────────────────┐
              │ 1st appointment, beginning of shift: contraindications    │
              │ for spirometry checked                                    │
              └──────────────────────────────────────────────────────────┘

┌───────────┐ ┌──────────────────┐   ┌──────────────────┐  ┌──────────────┐
│ FINAL     │←│ No contraindica- │   │ One or more      │→ │ EXCLUDED = 3 │
│ SAMPLE    │ │ tions            │   │ contraindications│  └──────────────┘
│ SIZE:     │ └──────────────────┘   └──────────────────┘
│ n = 112   │
└───────────┘
```
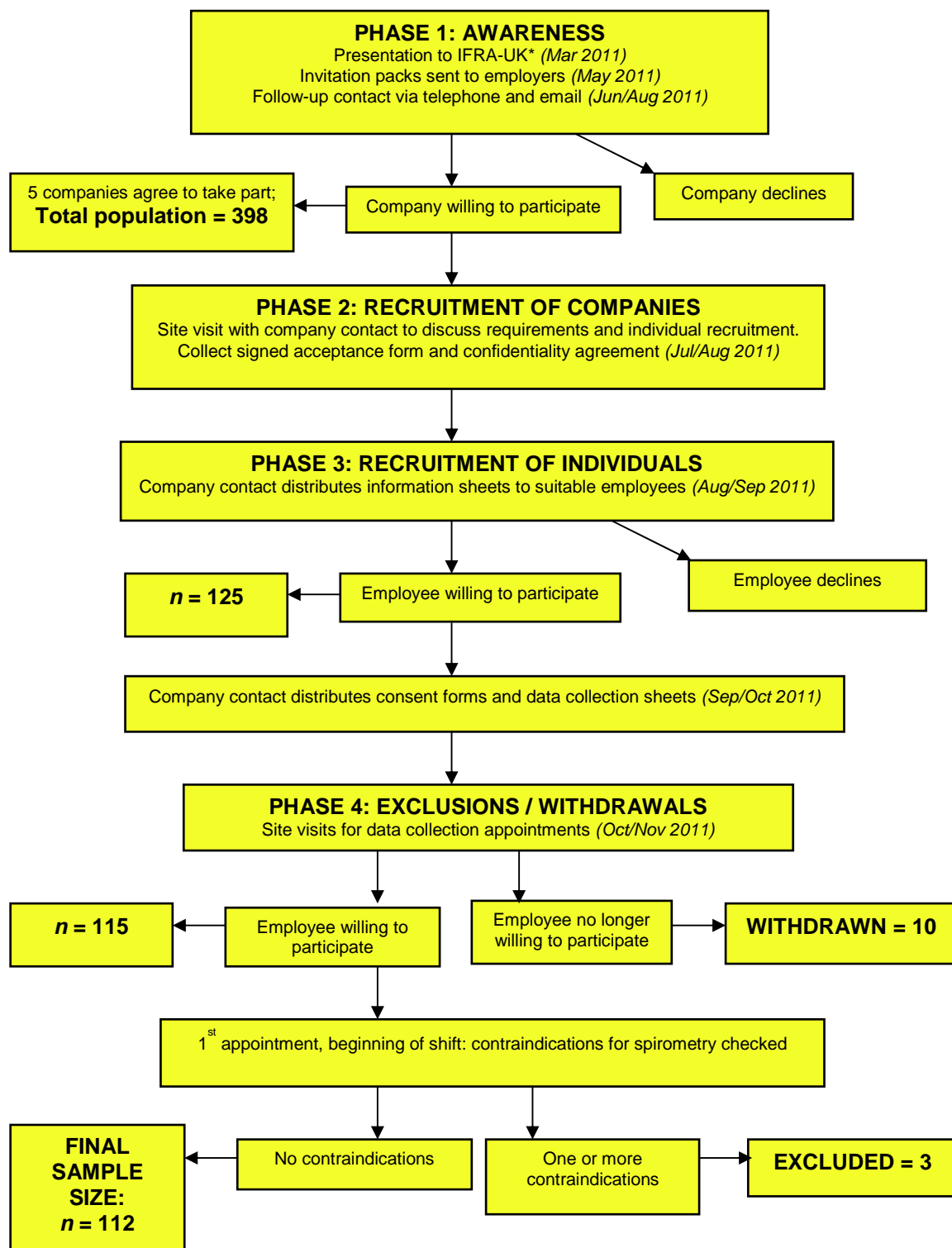
Figure 2.2: Phased recruitment strategy

*International Fragrance Association, United Kingdom

Recruitment phase 1: Awareness

Phase 1 was intended to promote awareness of the aims, justification and methodology of the study in advance of formally inviting companies to participate. This involved:

• giving a presentation to a meeting of the International Fragrance Association, United Kingdom (IFRA-UK) Executive Committee

• sending official invitation packs to suitable companies (appendix entry 12).

Recruitment phase 2: Recruitment of companies

The purpose of phase 2 was to acquire definitive signed agreements from participating companies. This involved:

• repeated follow-up of invitations via telephone and email

• establishing contact with an individual from each company to sign relevant forms and assist in individual recruitment

• return of signed acceptance forms (appendix entry 13) and confidentiality agreements from participating companies.

Recruitment phase 3: Recruitment of individuals

The purpose of phase 3 was to finalise a list of participants from each site and arrange data collection appointments. This involved:

• arranging site visits with the contact at each company to discuss requirements and individual recruitment

• instructing the company contacts to distribute employee information sheets (appendix entry 9) to all suitable employees

• instructing the company contacts to distribute informed consent form (appendix entry 10) and data collection sheets (see section 2.7) to individuals expressing an interest and giving initial agreement to participate

• liaising with company contacts to acquire participant lists and arrange an appointment schedule for data collection.

Recruitment phase 4: Exclusions and withdrawals

Withdrawals: of the total number of individuals who were initially willing to take part (125), 10 subsequently decided to withdraw from the study prior to assessments taking place.

Exclusions on medical grounds: contraindications for performing the spirometric procedure were used as exclusion criteria. Examples of such contraindications are recent surgery, pneumothorax, heart attack, stroke, aneurysm, or glaucoma (Cooper, 2011; Miller et al, 2005a). Each participant was asked about these prior to the first (pre-shift) spirometric assessment being performed, and any giving a positive response to at least one contraindication were excluded. Three individuals were excluded from the study in this manner.

Ten companies were identified as suitable for participation and approached to take part in the study. Of these, five companies agreed to participate. Individual recruitment over the five sites as described above gave a final sample size of 112.

The comparison of response rates between groups (Table 2.6) shows that the response rate was higher in the exposed group but the difference did not reach the standard level of statistical significance (p = 0.066).

Table 2.6: Cross-tabulation showing comparison of response rate between groups							
		Response rate			Pearson Chi-square		
		Participants	Non-participants	Total	Value	df	p-value
Group	Exposed	60 (32.6%)	124	184	3.38	1	0.066
	Control	52 (24.3%)	162	214			
	Total	112 (28.1%)	286	398			

2.7 Data collection

Spirometry

Spirometric assessments were conducted on each participant prior to beginning a working shift and at the end of a working shift, with such a shift consisting of ≥6 hours. A cross-shift change was then calculated from the pre-shift and post-shift measurement.

Figure 2.3 shows the spirometric data collection process.
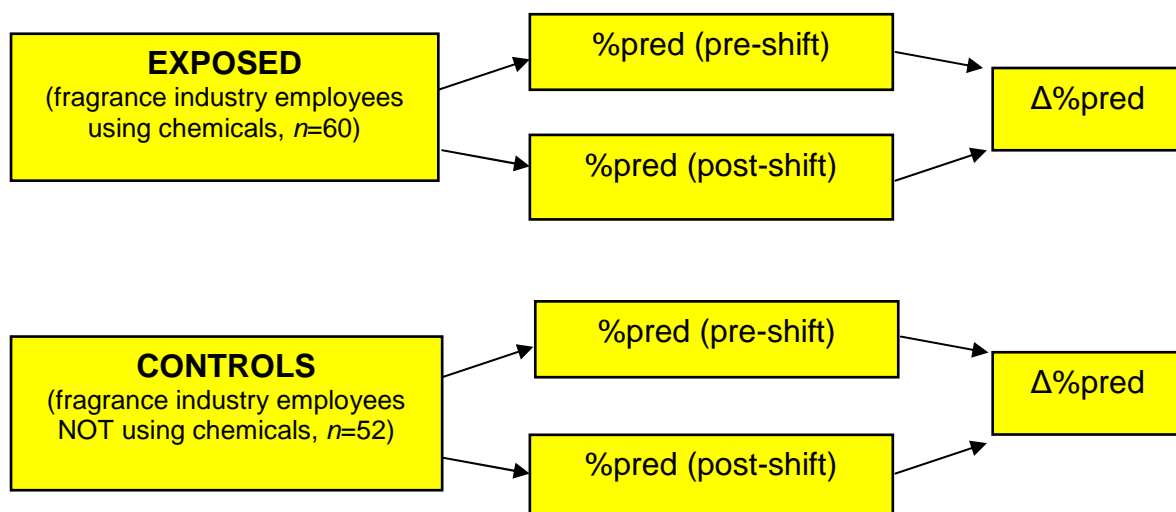
Figure 2.3: Spirometric data collection process

All assessments were conducted by the researcher over a six week period of site visits during October and November 2011. This was as narrow a time window as could be arranged for organisational reasons, as the researcher was required to be personally present to conduct the assessments during each site visit.

Potential confounding factors

Potential confounding factors (table 2.6) were selected using the following criteria:

● potentially associated with the outcome (change in lung function), *and either*:

● physical data – a physical factor that can be measured rapidly and non-invasively by the researcher during data collection appointments, *or*:

● demographic data – lifestyle or historical information that can be recorded by a participant on a questionnaire or form.

Table 2.7: Potential confounding factors		
Factor	**Information acquired**	**Literature**
Smoking	Questionnaire/form*	Vollmer et al., 2000; Downs et al., 2005; Urrutia et al., 2005; Clennell et al., 2008
Personal history of respiratory problems	Questionnaire/form*	Hersh et al., 2011; McCloskey et al., 2001; Sly, 2011; Tennant, Gibson & Pearce, 2008
Family history of respiratory problems	Questionnaire/form*	
Body mass index (BMI)	Measured during appointment+	Wood, Attia, McElduff, McEvoy & Gibson, 2010; Thyagarajan et al., 2008; Eisner et al., 2007

*information provided by participants on data collection sheets

+calculated by the researcher from physical data recorded during assessments

Physical data

Physical data was measured and recorded by the researcher during the pre-shift spirometric appointments. Height was measured using a stadiometer; participants were asked to remove shoes and caps. Weight was measured using a digital scale; participants were asked to remove shoes and protective clothing such as high-visibility vests and jackets. Body mass index (BMI) was calculated from standing height and weight (BMI = weight[kg] / height[m]^2[National Heart, Lung and Blood Institute, 1998]).

Spirometric data and physical data were recorded on a results form, which the participant was asked to sign (appendix entry 14).

2.8 Statistical analysis

The statistical package Predictive Analytics SoftWare Statistics (PASW [Predictive Analytics SoftWare] Statistics version 18.0 for Windows, release 18.0.0 [July 30, 2009]) was used for all statistical calculations. An electronic PASW data file was created containing spirometric data and data on potential confounding factors.

Analysis of covariance (ANCOVA) was used to compare each outcome measure between the exposed and control groups. The ANCOVA model was fitted as described in table 2.24 below, following the advice of University of Portsmouth statistician, Dr. Reuben Ogollah. Modelling the analysis in this way – using the post-shift measurement as the response variable and the pre-shift measurement as a covariate – accounts for variability in the baseline measurement (Robins et al., 1997; Christiani et al., 1994; personal communication, March 02, 2012). Further analysis can be conducted using the potential confounding factors identified earlier as additional covariates.

Table 2.8: Modelling the statistical analysis	
Analysis:	**ANCOVA (unadjusted)**
Response variable:	FEV_1* post-shift %predicted
Fixed factor:	Case or control
Covariate:	FEV_1* baseline (pre-shift) %predicted
Analysis:	**ANCOVA (adjusted)**
Response variable:	FEV_1* post-shift %predicted
Fixed factor:	Case or control
Covariates:	FEV_1* baseline (pre-shift) %predicted
	Smoking
	Personal history of respiratory problems
	Family history of respiratory problems
	Body mass index

*FEV_1 is used as an example here; the same procedure was carried out for the other outcome measures, FVC and PEF.

Summary

This chapter has detailed all aspects of the research methodology used to answer the research question formalised in chapter 1. The results of the research study conducted in accordance with this methodology are reported in the next chapter, chapter 3.

Chapter 3 Results and discussion, part 1

The aim of this chapter is to answer the research question defined in chapter 1.

Research question: *In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?*

This will be achieved by:

● exploring the demographics of the study participants;

● performing analysis of covariance (ANCOVA) using the spirometric data;

● discussing the findings in relation to the research question.

3.1 Demographics

Demographics – results

Gender of the exposed group was almost exclusively male (96.7% male vs. 3.3% female), while in the control group gender was close to equal distribution (51.9% male vs. 48.1% female) (table 3.1).

Age of the participants was well-matched across the study groups, with a mean age of 43.6 (range 21-65) for the exposed group and 43.9 (range 22-66) for the controls (table 3.1), with a total mean age of 43.7 years (range 21-66) for the whole study population. The difference in means between groups was not significant.

The exposed group were significantly taller than the controls, with mean heights of 1.76m (SD 0.06) and 1.71m (SD 0.09), respectively ($p = 0.004$) (table 3.1).

There was no significant difference in weight and body mass index between groups. Mean weight was 81.5kg (SD 13.2) for exposed and 81.6kg (SD 17.2) for controls. Mean body mass index was 26.5 (SD 4.5) for exposed and 27.7 (SD 4.9) for controls.

Table 3.1: Characteristics of the study participants		Exposed	Control
Subjects, *n*		60	52
Gender	Male, *n* (%)	58 (96.7)	27 (51.9)
	Female, *n* (%)	2 (3.3)	25 (48.1)
Mean age, *years** (SD)		43.6 (10.4)	43.9 (11.9)
Height, *m*+ (SD)		1.76 (0.06)	1.71 (0.09)
Weight, *kg** (SD)		81.5 (13.2)	81.6 (17.2)
Body mass index, *weight(kg)/height(m)*^{2}* (SD)		26.5 (4.5)	27.7 (4.9)
Smoking status	Non-smoker, *n* (%)	23 (38.3)	26 (50.0)
	Former smoker, *n* (%)	15 (25.0)	15 (28.8)
	Smoker, *n* (%)	22 (36.7)	11 (21.2)
Personal history of respiratory problems, *n* (%)		13 (21.7)	14 (26.9)
Family history of respiratory problems, *n* (%)		20 (33.3)	15 (28.8)

*non-significant (p=>0.05)

+p = 0.004

Demographics – discussion

The gender distribution in the exposed group is a population characteristic of the exposed population as a whole, as few women were observed to be working in the factory (exposed) areas of the participating companies.

This unequal gender distribution is likely to be the cause of the significant difference in mean heights between groups, with the exposed group being significantly taller (p = 0.004). This difference in height has in turn affected the difference in mean body mass index between groups (as body mass index is calculated from height and weight), although this was not significant. Both group means were within the same category, 'overweight' (body mass index score of 25.0-29.9 [National Heart, Lung and Blood Institute, 1998]).

Using percentage-of-predicted (%pred) values for the spirometric outcome measures prevented the introduction of bias resulting from the significant difference in height between groups, as these %pred values account for age, height and gender. The unequal gender distribution between groups is therefore also accounted for.

3.2 Statistical analysis

Statistical analysis – results (cross-shift change and ANCOVA)

The research question requires comparison of spirometric measurements between the exposed and control groups. Table 3.2 shows the unadjusted mean cross-shift change (%predicted) for each outcome measurement and the differences between groups.

Table 3.2: Mean cross-shift change for spirometric outcome measurements, comparison between groups			
	Exposed	**Control**	**Difference (95%CI)**
Mean cross-shift change, FEV$_1$ %predicted* (SD)	0.22 (4.58)	-0.16 (4.00)	0.38 (-1.24 – 2.00)[+]
Mean cross-shift change, FVC %predicted* (SD)	-1.13 (6.66)	-0.60 (4.67)	-0.53 (-2.72 – 1.66)[+]
Mean cross-shift change, PEF %predicted* (SD)	1.43 (8.45)	0.44 (8.76)	0.99 (-2.24 – 4.21)[+]

*Unadjusted

[+]non-significant (p=>0.05)

These differences were not seen to be significant; it should be noted, however, that in analysing mean cross-shift change no adjustment has been made for the pre-shift baseline measurements. There was variance, albeit non-significant, in these initial baseline measurements, and so they must be adjusted for in the same manner as the defined potential confounding factors. (Differences between mean baseline measurements were not significant, although the difference in PEF approached significance [p = 0.064].)

Further detailed analysis using analysis of covariance (ANVOCA) allowed for the appropriate adjustments to be made, initially for the baseline measurements only, and then in conjunction with the additional potential confounding factors.

Table 3.3 shows ANCOVA results for each outcome measure, comparing mean post-shift measurements between groups. (Note that values in the 'unadjusted' column have been adjusted only for the baseline pre-shift measurements.)

Table 3.3: Analysis of covariance (ANCOVA) results, comparison between groups					
Outcome variable	Mean post-shift measurement, %pred (SD)	Unadjusted*		Adjusted[+]	
		F value (df)	P-value	F value (df)	P-value
FEV$_1$ cross-shift change					
Control, n=52	99.0 (12.9)	0.080 (1,109)	0.778	0.127 (1,105)	0.722
Exposed, n=60	98.0 (14.5)				
FVC cross-shift change					
Control, n=52	107.8 (14.3)	0.019 (1,109)	0.890	0.022 (1,105)	0.883
Exposed, n=60	105.9 (14.2)				
PEF cross-shift change					
Control, n=52	103.4 (15.6)	0.014 (1,109)	0.906	0.176 (1,105)	0.676
Exposed, n=60	98.6 (16.8)				

*Adjusted for the pre-shift (baseline) measurements only

[+]Adjusted for the pre-shift (baseline) measurements as well as BMI, smoking status, personal history of respiratory problems and family history of respiratory problems

Potential confounding factors – results

The potential confounding factors selected for the study were smoking status, personal history and family history of respiratory problems, and body mass index.

None of the potential confounding factors were seen to have a significant effect on the outcome measures (table 3.4).

The effect of personal history of respiratory problems on FVC measurements was the closest to, but did not reach, statistical significance ($p = 0.097$).

Table 3.4: Effects of potential confounding factors on each outcome measure*			
Potential confounding factor	FEV_1 cross-shift change	FVC cross-shift change	PEF cross-shift change
Smoking status	$p = 0.648$	$p = 0.257$	$p = 0.361$
Personal history of respiratory problems	$p = 0.445$	$p = 0.097$	$p = 0.400$
Family history of respiratory problems	$p = 0.415$	$p = 0.227$	$p = 0.208$
Body mass index (BMI)	$p = 0.514$	$p = 0.964$	$p = 0.448$

*p-values taken from adjusted ANCOVA results

With smoking status, there were differences between groups in current smokers (36.7% in exposed vs. 21.2% in controls) and non-smokers (38.3% in exposed vs. 50.0% in controls). There was a smaller difference in former smokers (25.0% in exposed vs. 28.8% in controls). Chi-square (Pearson) of 3.30 ($p = 0.192$) indicated that the difference in smoking status between groups was not significant (table 3.5).

Table 3.5: Cross-tabulation showing comparison of smoking status between groups

		Smoking status				Pearson Chi-square		
		Non-smoker	Former smoker	Smoker	Total	Value	df	p-value
Group	Exposed	23	15	22	60	3.30	2	0.192
	Control	26	15	11	52			
	Total	49	30	33	112			

A greater proportion of the control group (26.9%, vs. 21.7% of exposed) declared a personal history of respiratory problems. The reverse was the case with declaration of a family history of respiratory problems (33.3% of exposed, vs. 28.8% of controls). These differences were not significant: Chi-square (Pearson) statistic for personal history was 0.42 (p = 0.517), and 0.26 (p = 0.609) for family history (table 3.6).

Table 3.6: Cross-tabulation showing comparison of history of respiratory problems between groups

		Personal history				Pearson Chi-square		
		Personal history	No personal history	Total		Value	df	p-value
Group	Exposed	13 (21.7%)	47	60		0.42	1	0.517
	Control	14 (26.9%)	38	52				
	Total	27	85	112				

		Family history				Pearson Chi-square		
		Family history	No personal history	Total		Value	df	p-value
Group	Exposed	20 (33.3%)	40	60		0.26	1	0.609
	Control	15 (28.8%)	37	52				
	Total	35	77	112				

Statistical analysis – discussion (including potential confounding factors)

Forced expiratory volume in 1 second (FEV$_1$) cross-shift change

Mean post-shift measurements were marginally lower for the exposed group (98.0%predicted against 99.0%predicted for controls). Adjusting for the baseline measurements showed that this difference was not statistically significant (unadjusted p = 0.778); further adjustment for potential confounding factors gave an adjusted p-value of 0.722.

Forced vital capacity (FVC) cross-shift change

Mean post-shift measurements were marginally lower for the exposed group (105.9%predicted against 107.8%predicted for controls). Adjusting for the baseline measurements showed that this difference was not statistically significant (unadjusted p = 0.890); further adjustment for potential confounding factors gave an adjusted p-value of 0.883.

Peak expiratory flow (PEF) cross-shift change

Mean post-shift measurements were lower for the exposed group (98.6%predicted against 103.4%predicted for controls). This difference between means was the largest of the three outcome measures. This is accounted for by the difference in baseline PEF measurements, which approached significance (p = 0.064). Adjusting for the baseline measurements showed that this difference was not statistically significant (unadjusted p = 0.906); further adjustment for potential confounding factors gave an adjusted p-value of 0.676.

Statistical analysis of the data acquired for the study has shown no significant effects of occupational respiratory exposure on the spirometric performance of the study population.

ANCOVA analysis showed no significant effects in all spirometric outcome measures used. This is in direct contrast to the results of similar studies in other industries with occupational respiratory exposure, as seen in the literature review included in chapter 1. Significant reductions in spirometric measurements were observed in the wood-working industry (Osman & Pala, 2009), farming and agriculture (Rylander & Carvalheiro, 2006), metalworking and smelting (Fishwick et al., 2004; Johnsen et al., 2008) and in hairdressers (Hashemi et al., 2010). Sample size ($n = 112$) may account for the lack of significant findings in comparison to other, larger studies ($n = 656$, Osman & Pala, 2009; $n = 3924$, Johnsen et al., 2008). Many studies were, however, of a similar or smaller sample size ($n = 100$, Hashemi et al., 2010; $n = 82$, Rylander & Carvalheiro, 2006; $n = 75$, Fishwick et al., 2004). The lack of a significant effect in this study may instead be accounted for by the nature of the occupational hazards within the industry and the effectiveness of the protective measures in place. Such measures are clearly prescribed by law in the UK and subject to strict enforcement by a single body, the Health and Safety Executive (Home Office, 2002; Home Office, 1974), and so the measures are seen to be standardised in principle across the industry.

The assumption cannot be made that a lack of effect signifies a lack of hazards. Although there is a strong argument that respiratory exposure from fragrance production carries far less risk than industries such as construction (Ghasemkhani et al., 2006; Moshammer et al., 2007), welding (Fishwick et al., 2004) or even hospital cleaning (Kogevinas et al., 2007; Bello et al., 2009), many fragrance chemicals do pose a known risk to health in the absence of any protective measures. Table 3.7 shows the risk phrases relevant to respiratory health and the number of fragrance chemicals each risk phrase applies to.

Table 3.7: Hazard classifications relating to respiratory exposure	
Risk phrases (R-phrases)*	Number of applicable chemical substances used at CPL Aromas[+]
R37 Irritating to respiratory system	49
R20 Harmful by inhalation	31
R23 Toxic by inhalation	2
R26 Very toxic by inhalation	0
R42 May cause sensitisation by inhalation	0

*Home Office, 2009

[+]Used as example of a typical fragrance manufacturer

Two substances are classified as *'Toxic by inhalation'*; the procedure for using one of these substances (cresylic acid) is included in the appendix (appendix entry 15) to demonstrate the strict control measures in place where appropriate.

The lack of a significant effect in this study may suggest that protective measures in place in fragrance manufacturing workplaces – such as the example above – are sufficient in preventing reduction of employees' lung function during working hours.

To further explore this, a multi-industry study directly comparing relative risk between fragrance production and other industries, similar to that conducted by Kogevinas et al. (2007), would be of great interest.

A degree of unavoidable selection bias may have theoretically influenced the results, and must be acknowledged. Employees suffering a current episode of airways obstruction may have been absent from work and so not available to participate in the study, resulting in sampling bias due to a healthy worker effect. Furthermore, it is reasonable to assume that any individuals who suffer any respiratory condition may have previously left the industry, or chosen a different occupation altogether, and this may have led to survivorship bias. These selection biases may have resulted in the study population being biased towards those without any known respiratory conditions. Potential non-response bias resulting from a varying response rate was

not seen to be important, as the difference in response rate between groups was not statistically significant (Chi-square [Pearson] of 3.38, p = 0.066; see table 2.6, section 2.6).

Potential confounding factors had no significant effect on outcome measures, in contrast to previous research. Smoking has been shown to significantly affect lung function in many previously published studies (Vollmer et al., 2000; Downs et al., 2005; Urrutia et al., 2005; Clennell et al., 2008); the lack of a significant effect here is of interest, and may suggest an area for potential future research. A larger study, or one focussed specifically on smoking as the variable of interest, may provide further explanation as to why smoking was not seen to affect the outcome, as might reasonably be expected from previous findings. This may be a result of the population size; the study population here was sufficient to investigate a binary variable (i.e. exposed vs. non-exposed), but not to investigate smoking as the primary variable of interest, as the allocation of three categories (current, former and non-smoker) may not leave a sufficient number in each group. A larger population size would allow the further exploration of the effects of smoking. For example, the above studies used considerably larger sample sizes than this study, from $n = 1792$ (Downs et al., 2005) to $n = 3387$ (Clennell et al., 2008). The study by Vollmer et al. (2000) was particularly large as this was a meta-analysis pooling the results of 8 cross-sectional studies (total $n = 40,733$); a reduction in FEV_1 due to smoking was observed, although no control groups were used.

Body mass index (BMI) has been shown to affect lung function in previous studies (Wood, Attia, McElduff, McEvoy & Gibson, 2010; Thyagarajan et al., 2008), but was not seen to have a significant effect here. This may be due to the population size not allowing a large enough variance of the BMI measure to reveal any significant effects, although there was a reasonable spread along the range of values, with the only category not represented being 'underweight'. Alternatively, it may be the case that BMI is not the most useful physical factor in terms of its effects on lung function, and an alternative such as sitting height may be more appropriate.

Personal and family history of respiratory problems did not have a significant effect on the outcome measures. Of all the potential confounding factors, the factor which came closest to achieving significance was personal history of respiratory problems and its effect on FVC ($p = 0.097$). Personal history of childhood lower respiratory tract infections was previously observed to have a negative impact on adult lung function (Tennant, Gibson & Pearce, 2008) and childhood asthma prevalence (Sly, 2011). The lack of significance in this study may be due to sample size; the study by Tennant et al. (2008) used a sample size of $n = 412$, for example. Alternatively, a degree of recall bias is unavoidable when requesting historical information from participants, and this may have been a factor.

An additional potential confounder was the length of time each participant had spent working in the industry. Participants remaining in the industry for longer periods of time may be less likely to suffer from respiratory conditions due to survivorship bias, or alternatively, may be more likely to suffer the effects of increasing years of exposure. The results may have been confounded if the length of employment showed a statistically significant difference between groups.

Table 3.8 shows the comparison of means between groups. The difference was not statistically significant ($p = 0.273$).

Table 3.8: Mean time working in fragrance industry (years), comparison between groups			
	Exposed	**Control**	**P-value**
Mean length of time working in fragrance industry (years) (SD)	13.7 (9.8)	15.8 (10.1)	0.273

Summary

Point summary (part 1)
● Using statistical analysis to answer the research question, no significant effects of occupational respiratory exposure were observed on the spirometric performance of the study population. The alternative hypothesis must be rejected, and the null hypothesis must be accepted: *In fragrance industry employees, occupational respiratory exposure to chemicals is not linked to a statistically significant change in lung function as measured using spirometry.*
● Smoking status, body mass index, personal and family history of respiratory problems were not observed to significantly affect the outcome measurements. The effect of personal history on FVC was the closest to – but did not reach – a statistically significant effect size.
● Acceptance of the null hypothesis suggests that protective measures in place in fragrance manufacturing workplaces are sufficient in minimising occupational risk to respiratory health, and so are effective in preventing reduction of employees' lung function during working hours.

This chapter has reported the results of the study designed to answer the research question, and shown that the null hypothesis must be accepted. Chapters 4 and 5 will report the methodology and results of the second part of this body of work, the development of the predictive pre-placement questionnaire. The results of both parts will be further discussed and summarised in chapter 6.

Chapter 4 Methodology, part 2 (questionnaire development)

The aim of this chapter is to provide the methodology behind the development of a pre-placement predictive questionnaire. This will be achieved by:

● describing the phased process of creating a data collection sheet (informed by published literature and existing questionnaires) to acquire information towards the development of a predictive questionnaire;

● describing the process used to develop the predictive questionnaire from the spirometric and demographic information acquired.

4.1 Rationale

The aim of part 2 of this research is to additionally use the spirometric data collected from participants, along with demographic and physical data, to develop a pre-placement questionnaire that is predictive for lung function impairment. This questionnaire is intended to fulfil this function specifically within the fragrance industry, developed to be representative of its target population.

The pre-placement questionnaire was developed by exploring spirometric data alongside demographic and physical data collected from the participants and using these to select questions for inclusion on the final questionnaire and develop an appropriate weighting system. A phased approach was used in the development of the pre-placement questionnaire (figure 4.1).

FEV_1 pre-shift measurements collected for part 1 were used as the spirometric data for questionnaire development. The collection of demographic and physical data for use towards questionnaire development required the construction of data collection sheets, informed by published literature and existing questionnaires. The phased methodology used to develop the final pre-placement questionnaire is outlined in subsequent sections.
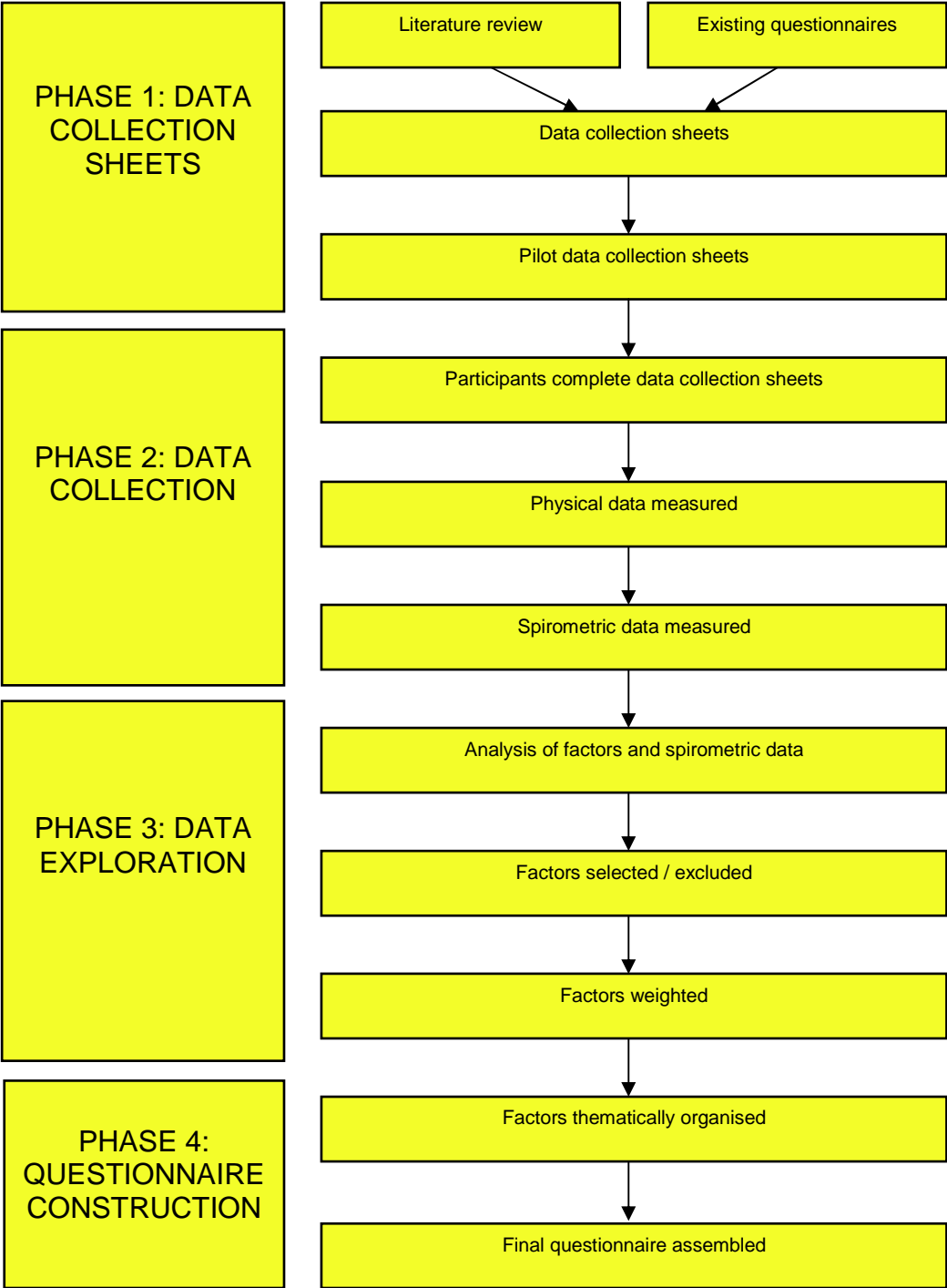
Figure 4.1: Phased strategy for questionnaire development

4.2 Data collection sheets (questionnaire development phase 1)

The purpose of phase 1 (figure 4.1) was to construct data collection sheets in order to collect demographic data from study participants. A literature review was conducted to inform development of the sheets by critically evaluating existing research and identifying factors which were observed to influence lung function.

Literature review

Factors with an observed or potential influence on lung function: a review of the literature

Methods

Data collection

Search strategy

A systematic search was conducted using relevant keywords combined into search strings as shown in table 4.1.

Table 4.1: Keywords and search strings used in systematic search				
Keywords:	factor / factors	cause	trigger	
Search string:	factor* OR cause OR trigger			
Purpose:	synonyms for underlying causal factor being investigated			
Keywords:	Influence	impact	affect	effect
Search string:	Influence OR impact OR affect OR effect			
Purpose:	Synonyms for effect of the causal factor being investigated			
Key-words:	lung function	spirometry	spirometric	FEV[+]
Search string:	"lung function" OR spirometr* OR fev*			
Purpose:	measurements used in assessing respiratory effects			

[+]forced expiratory volume. Commonly measured and expressed as FEV_1, (forced expiratory volume in one second), alternatives such as $FEV_{0.4}$ are occasionally used.

Search strings were combined using the Boolean operators AND and/or OR in order to broaden or narrow the search as necessary. The search terms above were used for an initial search, with subsequent refinements as necessary to give sufficient yet manageable results. Table 4.2 shows the databases used for the literature search, refined search terminology and the number of results retrieved.

Table 4.2: Search strategy, showing databases and search terms used, alongside initial and relevant results			
Database	**Refined search terms**	**Initial results**	**Relevant results**
SSCI (Social Sciences Citation Index)	(factor* OR cause OR trigger) in Topic AND (influence OR impact OR affect OR effect) in Topic AND ("lung function" OR spirometr* OR fev) in Title	323	**19**
PubMed	(influence OR affect OR effect) AND "lung function" in Title	428	**10**
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	(factor* OR cause OR trigger) AND (influence OR impact OR affect OR effect) AND ("lung function" OR spirometr* OR fev) in Abstract	180	**7**
Cochrane Reviews	(factor* OR cause OR trigger) AND (influence OR impact OR affect OR effect) in Title, Abstract or Keywords, AND ("lung function" OR spirometr* OR fev) in Record Title	121	**3**
Science Direct	(factor* OR cause OR trigger) AND (influence OR impact OR affect OR effect) AND ("lung function" OR spirometr* OR fev) in Abstract	427	**7** **(duplicates)**

Selection

The following inclusion criteria were used to select relevant articles from initial results:

• must be written in the English language;

• must provide statistically significant evidence for a factor with an influence on lung function;

- the causal factor investigated must be either:

  - information that can be accurately recalled by a study participant (e.g. smoking habits, childhood illness), or:

  - data that can be non-invasively measured by a researcher (e.g. body mass index);

- quality of study design was appraised using appraisal checklists developed by the Critical Appraisal Skills Programme (CASP) (Public Health Resource Unit, 2004a; Public Health Resource Unit, 2004b); studies considered to be poorly designed were excluded (CASP checklists are included as appendix entries 1 and 2).

The total number of relevant articles included in this review was 39.

Data analysis

Factors identified from selected articles were organised into groups, to allow evidence for each factor to be evaluated concurrently. The grouping method used was taken and adapted from a thematic analysis process (Braun & Clarke, 2006). Although typically used for qualitative research analysis, this method was appropriate in this case, facilitating the organisation of identified substances into sub-groups and larger overarching 'theme' groups.

The factors identified from the selected articles were organised into four 'theme' groups, which will be considered in turn: *lifestyle factors and lung function; environmental factors and lung function; occupation and lung function;* and *physical factors and lung function*.

Results
1. Lifestyle factors and lung function
Sub-category: smoking

Table 4.3 summarises information on the factor(s) allocated to this sub-category.

Table 4.3: Summary of studies, smoking and lung function

Exposure / factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Smoking & ethnicity	Retro cohort (Berry, Bhagat, Ajelabi & Petrini, 2008)	n=216	Self-reported	Lung function decline, FEV_1, FVC	No difference in results when ethnic reference equations used
	Pooling of cross-sectional analyses (Vollmer et al., 2000)	8 studies, total n=40733	Self-reported	Lung function decline, FEV_1	No difference between black and white smokers; Difference between whites and Asians/Pacific Islanders (men), p = <0.05
Smoking & gender	Cohort (Downs et al., 2005)	n=1792	Self-reported	Lung function decline, FEV_1	Both genders showed significant mean annual decline (p =<0.001), females showed greater decline; female quitters showed less mean annual decline than persistent smokers (p = 0.05), not sig. in males (p = 0.49)
Smoking	Cohort (Belousova, Haby, Xuan & Peat, 1997)	n=1499	Self-reported	Lung function decline, FEV_1, PEFR, $FEF_{25-75\%}$	FEV_1 decline not significant (p = 0.53); PEFR sig. decline (p = <0.05); $FEF_{25-75\%}$ sig. decline (p = <0.05)
	Cohort (Jaakkola, Ernst, Jaakkola, N'gan'ga & Becklake, 1991)	n=391	Self-reported	Lung function decline, FEV_1	Significant decline (p = 0.04)
	Retro cohort (Wang, Avashia & Petsonk, 2009)	n=1884	Self-reported	Lung function decline, FEV_1	Significant decline in males (p = <0.0001); no sig. decline in females
	Cohort (Clennell et al., 2008	n=3387	Self-reported	Lung function decline, FEV_1	Decline significantly faster in current smokers vs. never smokers (8.4 mL/y faster, 95%CI -12.0 - -5.0)
	Cross-sectional (Urrutia et al., 2005)	n=2647	Self-reported	Lung function decline, FEV_1	Significant decline, p = 0.03 (10-20 cigarettes/day), p = <0.01 (>20 cigarettes/day)
Initiation <15 years	Cohort (Apostol et al., 2002)	n=3901	Self-reported	Lung function decline, FEV_1	Significant decline (p = 0.01); not sig. after adjusting for current smoking

Smoking status was observed to have a negative influence on lung function in a number of studies (Vollmer et al., 2000; Downs et al., 2005; Belousova et al., 1997; Jaakkola et al., 1991; Wang et al., 2009; Clennell et al., 2008; Urrutia et al., 2005; Apostol et al., 2002).

A small retrospective cohort study (n = 216) compared the effects of smoking on lung function between two ethnic groups (Berry et al., 2008). A difference between means of 0.39L for forced expiratory volume in one second (FEV_1) (p = 0.002) and 0.59L for forced vital capacity (FVC) (p = 0.001) was found in African-American smokers vs. white smokers. There were, however, no statistically significant differences when the data were converted to percentage-of-predicted (%pred) values using equations that allow racial differences to be accounted for. This is in line with guidance for interpreting lung function results (Quanjer et al., 1993), advising that subjects of African ethnicity would be expected to give proportionally reduced data; the accepted range for this difference is 12-15% for FEV_1 and FVC (Quanjer et al., 1993; Collen et al., 2010). Berry et al. (2008) assumed a difference of 15%, and found a difference of 14.3% and 13.8% for FEV_1 and FVC, respectively. Although such racial differences are generally accepted, another study (Vollmer et al., 2000) found no significant difference between black smokers and white smokers; a significant difference in smoking-related FEV_1 decline was detected, however, between whites and Asians/Pacific Islanders (-10 mL/year ± 1.0 vs. -4 mL/year ± 2.0 for >10 cigarettes/day, p = <0.05). It is important to note that all participants in both studies were current smokers; it is unfortunate that Berry et al. and Vollmer et al. did not include a non-smoking group in order to more thoroughly explore the difference between races in the effects of smoking.

A large (n = 9651) 11-year cohort study (Downs et al., 2005) showed that female smokers experience a greater mean annual decline in FEV_1 than men (-13.8mL vs. -10.4mL per pack per day). Also, women who ceased smoking before the end of the study experienced less annual decline than persistent smokers (p = 0.05), an effect not seen in male participants (p = 0.49). The authors concluded that lung function recovers faster in women who cease smoking than men.

A study exploring factors affecting lung function (Belousova et al., 1997) found that current smoking (vs. non-smoking) adversely affected peak expiratory flow rate (PEFR) ($p = <0.05$) and forced expiratory flow between 25% and 75% of FVC ($FEF_{25-75\%}$) ($p = <0.05$) measurements. A decline was observed in FEV_1, but not to a significant level ($p = 0.053$). The study population, however, was exclusively white Australians, so these results can only be generalised to the same ethnic group. Current smoking was found to negatively affect FEV_1 in a number of studies (Jaakkola et al., 1991; Wang et al., 2009; Clennell et al., 2008; Urrutia et al., 2005; Apostol et al., 2002). The study by Wang et al. (2009) found a significant effect in men ($n = 1721$, $p = <0.0001$), but not in women ($n = 163$). The small proportion of women in the study may account for this gender difference. Urrutia et al. (2005) found that the degree of effect increased with the number of cigarettes smoked per day: 10-20/day corresponds to a change of -83mL FEV_1 ($p = 0.03$), and >20/day a change of -177mL FEV_1 ($p = <0.01$). Apostol et al. (2002) found that smoking initiation at less than 15 years of age appeared to be significant for greater decline in FEV_1 ($p = 0.01$), but the decline did not remain significant after adjusting for current smoking.

A common problem with these studies is that the data on smoking habits is self-reported, thereby introducing the possibility of recall bias. None of the above authors comment on this bias, however a small number use reasonable steps to minimise it, such as interviewer-administered questionnaires (Downs et al., 2005; Jaakkola et al., 1991), and providing clear definitions of categories of smoking habit (Downs et al., 2005; Urrutia et al., 2005).

Sub-category: weight

Table 4.4 summarises information on the factor(s) allocated to this sub-category.

Table 4.4: Summary of studies, weight and lung function

Exposure / factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Weight-related (weight gain)	Retro cohort (Wang et al., 2009)	n=1884	Measured	Lung function decline, FEV_1	Significant decline, 5.43mL per pound gained (p = <0.0001)
	Cohort (Marcon et al., 2009)	n=638	Measured	Lung function decline, FEV_1	Significant decline, 20mL/y (95% CI 10-30) (males) and 7mL/y (95% CI 1-11) (females) per kg gained
Weight-related (weight loss)	Randomized controlled study (Stenius-Aarniala et al.,2000)	n=38	Measured	Lung function change in asthmatics, FEV_1, FVC	FEV_1 improved by 7.2%predicted (p = 0.009); FVC improved by 8.6%predicted(p = <0.0001)
Weight-related (BMI & proportion of dietary fat intake)	Cohort (Wood et al., 2010)	n=195	Measured, self-reported	Lung function decline, FEV_1, FVC	BMI associated with significant FVC decline in males (-3.9%pred, p = 0.05); proportion of dietary fat intake associated with sig. FEV_1 decline in males (-4.8%pred, p = 0.05); no sig. decline in females
Weight-related ('traditional' diet)	Cross-sectional (McKeever et al., 2010)	n=12648	Self-reported	Lung function decline, FEV_1	Significant decline (-94.4mL, 95% CI –123.4 - -65.5mL, p = <0.001)
Weight-related (waist-hip ratio, WHR)	Cross-sectional (Harik-Khan, Wise & Fleg, 2001a)	n=1634	Measured	Lung function decline, FEV_1, FVC	Significant FEV_1 decline in males (p = 0.0001); significant FVC decline in males (p = 0.0005); significant FVC decline in females (p = 0.02)

Weight gain negatively affected FEV_1 in two studies. A decline of 5.43mL per pound gained (p = <0.0001) was observed (Wang et al., 2009), while a study in asthmatics found that a gain of 1 kilogram was associated with a decline of 20mL/y and 7mL/y in men and women, respectively. (Marcon et al., 2009). Conversely, a reduction in weight (a loss of 14.5% body weight compared to 0.3% in controls) was associated with an increase in FEV_1 of 7.2%pred (p = 0.009) and FVC of 8.6%pred (p = <0.0001) measurements in asthmatics (Stenius-Aarniala et al., 2000).

A greater body mass index (BMI) and proportion of dietary fat intake were significantly associated with a reduction in FVC (-3.9%pred, p = 0.05) and FEV_1 (-4.8%pred, p = 0.05), respectively, in men but not in women (Wood et al., 2010). The consumption of a 'traditional' diet (defined as high intake of meat and potatoes and low intake of soy and cereal) was also associated with a reduction in FEV_1 of 94.4mL (95% CI –123.4 – -65.5mL, p = <0.001) (McKeever et al., 2010). Both these articles use self-reported data on food intake, however, introducing potential recall bias.

Body-fat distribution, measured by waist-to-hip ratio (WHR), was inversely associated with FEV_1 in men (p = 0.0001) but not women, and with FVC (p = 0.0005 for men, p = 0.02 in women) (Harik-Khan et al., 2001a). Overall WHR is therefore a more important predictor of reduced lung function in men than women in this study.

Sub-category: socio-economic status (SES)

Table 4.5 summarises information on the factor(s) allocated to this sub-category.

Table 4.5: Summary of studies, socio-economic status (SES) and lung function

Exposure / factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Socio-economic	Cross-sectional (Adedoyin, Erhabor, Olajide & Anifowose, 2010)	n=1930	Self-reported	Lung function decline, FEV_1, FVC, PEF	Significant FEV_1 decline (0.23mL, p = <0.01); sig. FVC decline (0.25mL, p = <0.01); sig. PEF decline (25L/s, p = <0.01)
	Cross-sectional (Raju, Prasad, Ramana, Balakrishna & Murthy, 2005)	n=2616	Reported by parents of subjects	Lung function decline (5-15 years), FEV_1, FVC	Significant decline in FEV_1 and FVC (p = 0.001 for both); decline greater in males than females
	Cohort (Johannessen, Eagan, Omenaas, Bakke & Gulsvik, 2010)	n=1644	Self-reported	Lung function decline, FEV_1, FVC	Significant decline associated with socioeconomic status in males; significant decline associated with marital status in females
Socio-economic (level of education)	Cohort (Tabak, Spijkerman, Verschuren & Smit, 2009)	n=5705	Self-reported	Lung function decline, FEV_1	Significant decline in females (p = <0.01), but not in males
	Cross-sectional (Trupin et al., 2010)	n=176	Self-reported	Lung function decline in asthmatics, FEV_1	Borderline significant decline (p = 0.05)

Socio-economic status (SES), as defined by a variety of criteria, was also shown to be associated with lung function. A study conducted on a population of Nigerians (Adedoyin et al., 2010) showed that SES assessed by occupation, educational level and family income was associated with a reduction of FEV_1 (0.23L mean difference high SES vs. low SES, p = <0.01), FVC (0.25L mean difference high SES vs. low SES, p = <0.01), and peak expiratory flow (PEF) (25L/s mean difference high SES vs. low SES, p = <0.01).

SES as assessed by family income in Indian children 5-15 years (Raju et al., 2005) showed a reduction in lung function measurements in the low income group compared to the high income group. In the oldest children, difference in FEV_1 and FVC (high income group vs. low income group) was greater in boys (0.52L and 0.56L, respectively) than in girls (0.27L and 0.35L, respectively).

Two cohort studies found gender differences in the effects of SES (Johannessen et al., 2010; Tabak et al., 2009). Lung function decline in men (FEV_1 and FVC) was more strongly associated with a low SES, while for women decline was associated with marital status (Johannessen et al., 2010). Unmarried females were observed to have a smaller decline in FEV_1 and FVC than married and widowed females, an effect not seen in men. Conversely, a low educational level did not affect lung function decline in men, but was significantly associated with FEV_1 decline in females in a larger study (Tabak et al., 2009). A smaller cross-sectional study (Trupin et al., 2010) found that FEV_1 was lower in those with high school education or less vs. some college education (p = 0.05).

With one exception (Trupin et al., 2010), all studies in this sub-group use self-reported data on socio-economic factors. Trupin et al. (2010) used telephone interviews to acquire this data.

2. Environmental factors and lung function

Sub-category: distance of home from roadway

Table 4.6 summarises information on the factor(s) allocated to this sub-category.

Table 4.6: Summary of studies, distance of home from roadway and lung function					
Exposure / factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Distance of home from roadway	Cross-sectional (Trupin et al., 2010)	n=176	Mapped by researchers	Lung function change in asthmatics, FEV_1	Significant increase proportionate with increase in distance from roadway (p = 0.001)
	Cohort (Balmes et al., 2009)	n=176	Mapped by researchers	Lung function change in asthmatics, FEV_1	Significant increase proportionate with increase in distance from roadway (p = 0.04); sig. increase proportionate with increase in distance from major roadway (p = 0.02)
	Cross-sectional (Kan et al., 2007)	n=15792	Mapped by researchers	Lung function decline, FEV_1, FVC	Significant decline in FVC in females (p=0.030); no sig. decline for males

All studies considered here investigated the effects of air pollution resulting from traffic exhaust by categorising the distance of the home from the nearest major road. A gender difference was observed in a cross-sectional study with a large population of >15000 (Kan et al., 2007), with distance from major road of <150m associated with a significant reduction in FVC in women (-24.2mL, p = 0.030), but not in men (p = 0.548). Reduction in FEV_1 was not significant for women or men (p = 0.099 and p = 0.693, respectively).

In studies on two similar populations of asthmatics, FEV_1 measured as percentage-of-predicted (%pred) was shown to significantly increase in proportion with home distance from roadway in two studies (p = 0.001 [Trupin et al., 2010]; p = 0.04 [Balmes et al., 2009]). Balmes et al. (2009) also found a significant increase

associated with distance from *major* roadway, defined as interstate or state highways (p = 0.02).

Sub-category: childhood respiratory illness

Table 4.7 summarises information on the factor(s) allocated to this sub-category.

Table 4.7: Summary of studies, childhood respiratory illness and lung function					
Exposure / factor	**Type of study**	**Sample size**	**Measure (exposure)**	**Measure (outcome)**	**Results / significance**
Childhood respiratory illness	Cohort (Johnston, Strachan & Anderson, 1998)	n=1392	Historical	Lung function decline, FEV_1, FVC	Pneumonia associated with significant FEV_1 decline (p = 0.006) and FVC decline (p = 0.001); whooping cough associated with significant FVC decline (p = 0.04)

Only one study (Johnston et al., 1998) investigating the effects of contracting a lung condition such as pneumonia or whooping cough (pertussis) during childhood on lung function in adulthood was retrieved. Pneumonia was associated with a reduction in adult FEV_1 (p = 0.006) and FVC (p = 0.001), and whooping cough a reduction in FVC (p = 0.04) (Johnston et al., 1998). No significant reduction in FEV_1 was associated with whooping cough. Recall bias is an issue with this factor however, as these results presume that the historical diagnoses of these diseases are accurate.

3. Occupation and lung function

Occupational exposures that can potentially lead to a reduction in lung function in the employee are many and varied, from a hypersensitivity reaction leading to occupational asthma (Baran & Teul, 2007; Hoy et al., 2007), to the irritant effect of the agent on lung tissue (Johnsen et al., 2008; Moshammer et al., 2007).

Sub-category: respirable dust / coal dust

Table 4.8 summarises information on the factor(s) allocated to this sub-category.

Table 4.8: Summary of studies, exposure to respirable dust / coal dust and lung function

Exposure / factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
Respirable dust (silica / ceramic / cement)	Cohort (Bakke, Ulvestad, Stewart & Eduard, 2004)	n=651	Personal exposure sampling	Lung function decline, FEV_1, FVC	Decline in FVC, silica dust (p = <0.001); decline in FEV_1, NO_2 exhaust (p = <0.001)
	Cross-sectional (Cowie et al., 2001)	n=774	Historical / exposure estimates	Lung function decline, FEV_1, FVC	Decline in FEV_1 and FVC in male smokers (p = <0.05); decline in FEV_1 and FVC in females (p = <0.05)
	Cross-sectional (Noor, Yap, Zolkepli & Faridah, 2000)	n=132	Measured	Lung function decline, FEV_1, FVC	Decline in FEV_1 in 30-40 year old employees (p = <0.05)
	Cross-sectional (Jaakkola, Sripaiboonkij & Jaakkola, 2011)	n=308	Self-reported	Lung function decline, FEV_1, FVC	Decline in FEV_1 (p = 0.01) and FVC (p = 0.005) associated with silica dust
Brown coal dust	Retro cohort (Finocchiaro, Lark, Keating, Ugoni & Abramson, 1997)	n=448	Classified by occupation	Lung function decline, FEV_1	Significant decline only in mixed vs. high exposure groups (p = 0.008)
	Cohort (Carta, Aru, Barbieri, Avataneo & Casula, 1996)	n=909	Personal exposure sampling	Lung function decline, FEV_1	Significant decline, p-value not stated
	Cross-sectional (Lewis, Bennett, Richards & Britton, 1996)	n=1853	Classified by occupation	Lung function decline, FEV_1	Decline in FEV_1 (p = <0.001)

A number of studies investigated the effects of dust inhalation in the construction and mining industries. A six-year cohort study on 651 tunnel construction personnel (Bakke et al., 2004) found a significant reduction in FVC associated with exposure to α-quartz (silica) dust (p = <0.001). The most powerful association with FEV_1 decline was not with respirable dust, however, but with exposure to the nitrogen dioxide (p = <0.001) resulting from blasting and machinery exhausts. Silica dust was also observed, in the form of tile dust in a ceramic tile facility, to affect FEV_1 (p = 0.01) and FVC (p = 0.005), with a larger adverse effect in current smokers (Jaakkola et al., 2011). Exposure data was self-reported, however, and so exposure levels were not measured or estimated.

Ceramic fibres and respirable dust were associated with a reduction in FEV_1 and FVC (p = <0.05) (Cowie et al., 2001) in men, but this was only seen in current smokers. Women also experienced a significant decline in FEV_1 and FVC (p = <0.05), but this group was not separated into smokers and non-smokers, and so smoking cannot be ruled out as a confounding factor.

Cement dust exposure was not associated with a significant reduction in FEV_1 or FVC using data from the entire study population (*n* = 132) of cement factory employees (Noor et al., 2000). Selecting only employees 30-40 years old, however (*n* = 77), showed a reduction in FEV_1 in non-smoking employees (-0.30L, p = <0.05) and smoking employees (-0.27L, p = <0.05), compared to non-smoking controls. No significant decline was observed in FVC. There were also significant declines associated with high dust exposure vs. low exposure in FEV_1 (-0.35L, p = <0.05) and FVC (-0.22L, p = <0.05).

Exposure to brown coal dust from mining was investigated for a possible association with lung function in three studies. The smallest of the three studies, an Australian retrospective cohort study (*n* = 448, Finocchiaro et al., 1997), did not find a significant decline in FEV_1 comparing low exposure to high exposure groups. A decline in FEV_1 was observed, but was only significant (p = 0.008) in mixed vs. high exposure groups. Smoking was also shown to have a significant effect on FEV_1 (p = 0.02) in comparison to non-smoking.

A larger Italian study (*n* = 909, Carta et al., 1996) found that the difference in FEV_1 decline between exposure groups was significant after adjusting for smoking (p-

value not stated), although absolute spirometric values are not shown, and the data generally is not presented with clarity. There is also the lack of a true control group with no dust exposure in this and the study by Finocchiaro et al. (1997).

The largest of the three studies was a British cross-sectional study ($n = 1853$, Lewis et al., 1996) using a control group from outside the mining industry. A significant decline in FEV_1 was found after adjusting for smoking (-155mL, $p = <0.001$). When data were refined to participants aged 45 years and under, a greater decline was observed (-251mL, $p = <0.001$).

Sub-category: farming / laboratory animals

Table 4.9 summarises information on the factor(s) allocated to this sub-category.

Table 4.9: Summary of studies, exposure to farming / laboratory animals and lung function					
Exposure / factor	**Type of study**	**Sample size**	**Measure (exposure)**	**Measure (outcome)**	**Results / significance**
Farming	Cohort (Venier et al., 2006)	$n=215$	Self-reported	Lung function decline, FEV_1, VC	Significant decline in FEV_1 ($p = <0.05$) and VC ($p = 0.01$) associated with traditional vs. modern farming methods and equipment
Laboratory animals	Retro cohort (Portengen, Hollander, Doekes, de Meer & Heederik, 2003)	$n=319$	Historical	Lung function decline, FEV_1, FVC	Significant decline in FEV_1 ($p = <0.05$) and FVC ($p = <0.01$) only in subjects with existing sensitization

The modernisation of dairy farming methods was investigated for its effect on lung function decline (Venier et al., 2006), testing the hypothesis that advanced methods and improved ventilation may result in significantly improved spirometric values. The authors cite micro-organisms within stored hay as the significant exposure for small dairy farmers. FEV_1 annual decline and vital capacity (VC) were reduced in traditional farm workers in comparison to those using modern techniques and equipment ($p = < 0.05$ and < 0.01, respectively).

Working with laboratory animals was associated with a significant decline in lung function only in individuals with an existing sensitisation to the animal they work with (Portengen et al., 2003). Mean annual decline of FEV_1 and FVC in these subjects was -83mL/y (p = <0.05) and -148mL/y (p = <0.01), respectively.

Sub-category: second-hand smoke (SHS)

Table 4.10 summarises information on the factor(s) allocated to this sub-category.

Table 4.10: Summary of studies, exposure to second-hand smoke (SHS) and lung function					
Exposure / factor	**Type of study**	**Sample size**	**Measure (exposure)**	**Measure (outcome)**	**Results / significance**
Second-hand smoke	Randomised controlled study (Flouris et al., 2009)	n=16	1 hour's controlled exposure	Lung function decline, FEV_1	Significant immediate decline (p = <0.05), return to baseline after 3 hours post-exposure
	Cross-sectional (Janson et al., 2001)	n=7882	Structured interview	Lung function decline, FEV_1	Significant decline when exposed ≥8 hours/day (p = 0.01)

Second-hand smoke (SHS) was included in this section as this is considered to be an occupational exposure, rather than a direct lifestyle choice such as personal smoking.

One hour's exposure to SHS was observed (Flouris et al., 2009) to reduce FEV_1 with immediate testing (0.5L reduction from pre-exposure measurements, p = <0.05), but with a return to baseline at 3 hours following exposure. Another study (Janson et al., 2001) showed that SHS had a significant negative effect on FEV_1 only if exposure was ≥8 hours/day (p = 0.01), otherwise there was no significant association with lung function.

4. Physical factors and lung function

Sub-category: upper body segment (UBS) / sitting height (SiH)

Table 4.11 summarises information on the factor(s) allocated to this sub-category.

Table 4.11: Summary of studies, upper body segment (UBS) / sitting height (SiH) and lung function

Factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
UBS and/or SiH	Cross-sectional (Whitrow & Harding, 2007)	n=3294	Measured (UBS)	Effect of factor on racial differences in lung function (FEV$_1$, FVC)	UBS shown to account for 41-51% of racial difference in adolescents (Black African/Caribbean vs. white)
	Cross-sectional (Harik-Khan, Muller & Wise, 2004)	n=1462	Measured (SiH)	Effect of factor on racial differences in lung function (FEV$_1$, FVC)	SiH shown to account for 42-53% of racial difference in children (African-American vs. white American)
	Cross-sectional (Harik-Khan, Fleg, Muller & Wise, 2001b)	n=1242	Measured (SiH)	Effect of factor on racial differences in lung function (FEV$_1$, FVC)	SiH shown to account for 35-39% of racial difference (African-American vs. white American)

The racial difference in lung function (Quanjer et al., 1993; Collen et al., 2010) may be related to a variance in trunk size (Hsi, Hsu and Jenkins, 1983; Hankinson, Odencrantz and Fedan, 1999); this can be explored through body compartmentation, measuring certain physical characteristics and investigating these as associative factors. Body compartmentation measurements include standing height (SH), sitting height (SiH), femur leg length (LL), and upper body segmentation (UBS).

In a cross-sectional study on African-Americans and white Americans, (Harik-Khan et al., 2001b) replacing SH with SiH for regression analyses was observed to account for 35-39% of the racial difference in FEV$_1$ and FVC. SiH was also shown to be a more important predictor of difference than socio-economic factors such as education level (2-4.7% reduction in difference) and poverty index (2.5-7.5%). A similar study comparing African-American and white American children (Harik-Khan et al., 2004) found that SiH accounted for 42-53% of the racial difference in FEV$_1$ and FVC.

A study in UK adolescents (Whitrow & Harding, 2007) also supported these results, observing that upper body segment (UBS) – a measurement analogous to SiH –

again accounted for a greater amount of the racial difference in FEV_1 and FVC than other physical measurements and socio-economic measures.

Sub-category: low birth weight (LBW) and lung function

Table 4.12 summarises information on the factor(s) allocated to this sub-category.

Table 4.12: Summary of studies, low birth weight (LBW) and lung function					
Factor	Type of study	Sample size	Measure (exposure)	Measure (outcome)	Results / significance
LBW	Cohort (Hoo et al., 2004)	n=80	Measured	Effect of factor (vs. appropriate for gestation birth weight) on infant lung function ($FEV_{0.4}$)	Significant reduction of 9% (95% CI 2–16%, p = <0.05)
	Retro cohort (Laerum et al., 2004)	n=1683	Historical	Effect of factor (vs. appropriate for gestation birth weight) on adult lung function (FEV_1%pred, FVC%pred)	No significant effect observed after adjustment for confounders
	Cohort (Edwards, Osman, Godden, Campbell & Douglas, 2003)	n=323	Historical	Effect of factor (vs. appropriate for gestation birth weight) on adult lung function (FEV_1, FVC)	Positive association with birth weight (p = 0.01)

Low birth weight (LBW) may be associated with reduced adult lung function due to the effects on lung development and growth (Stick, 2000; Stein et al., 1997; Shaheen, Sterne, Tucker, Florey, 1998). This was shown to have an effect on lung function in both infants and adults. LBW was associated with 9%, 8% and 4% reductions in $FEV_{0.4}$, $FEF_{75\%}$ and FVC, respectively, in infants aged ~9 months (Hoo et al., 2004). A study measuring lung function in 381 adults aged 45-50 years (Edwards et al., 2003) with LBW found that both FEV_1 and FVC show a positive association with birth weight, i.e. lung function increases with birth weight (adjusted p = 0.01 for trend).

A larger (*n* = 1683) historical cohort study on 1683 adults (Laerum et al., 2004) showed an initial associated decline, but after adjusting for confounders such as BMI and smoking, no significant effects were seen on FEV_1(%pred) or FVC(%pred).

Conclusions

The factors identified from this review are summarised in table 4.13.

The purpose of this review was to inform the development of data collection sheets, by examining existing research to identify factors which are observed to influence lung function.

The following information was selected for inclusion on the data collection sheets, based on the evidence from previous research of an association with lung function:

• *smoking habits* (age of initiation was not seen to be relevant so this was not included on the sheet) (Vollmer et al., 2000; Downs et al., 2005; Belousova et al., 1997; Jaakkola et al., 1991; Wang et al., 2009; Clennell et al., 2008; Urrutia et al., 2005; Apostol et al., 2002)

• *socio-economic status* (educational level, household income, marital status) (Adedoyin et al., 2010; Raju et al., 2005; Johannessen et al., 2010; Tabak et al., 2009; Trupin et al., 2010)

• *distance from nearest major road* of family home (defined as the nearest regularly-used main road or 'A-road') (Kan et al., 2007; Trupin et al., 2010; Balmes et al., 2009)

• reported history of childhood respiratory illness (e.g. pneumonia, whooping cough) (Johnston et al., 1998)

• *previous occupation* (any work involving exposure to respiratory irritants or sensitisers) (Baran & Teul, 2007; Hoy et al., 2007; Johnsen et al., 2008; Moshammer et al., 2007; Bakke et al., 2004; Jaakkola et al., 2011; Cowie et al., 2001; Noor et al., 2000; Lewis et al., 1996; Venier et al., 2006; Portengen et al., 2003; Delclos et al., 2006)

Table 4.13: Summary of factors identified as associated with lung function

Factor	Lung function measure	Evidence of effect?	Comments
Smoking	FEV_1, FVC, PEFR, $FEF_{25-75\%}$	Yes	• effect is dosage-related (Urrutia et al., 2005) • greater decline in women; women quitters recover faster (Downs et al., 2005) • initiation age not significant (Apostol et al., 2002)
Weight-related factors	FEV_1, FVC	Yes	• body mass index not significant in women (Wood et al., 2010)
Socio-economic status	FEV_1, FVC, PEF	Yes	• marital status only significant in women (Johannessen et al., 2010)
Distance from (major) roads	FEV_1, FVC	Yes	• more important factor for asthmatics (Trupin et al., 2010; Balmes et al., 2009)
Childhood respiratory illness	FEV_1, FVC	Yes	
Occupational dust exposure	FEV_1, FVC	Yes	• significant results for construction, mining, silica & cement dust (Bakke et al., 2004; Carta et al., 1996; Cowie et al., 2001; Finocchiaro et al., 1997; Jaakkola et al., 2011; Lewis et al., 1996; Noor et al., 2000)
Farming exposure	FEV_1, VC	Yes	
Lab. animals exposure	FEV_1, FVC	Yes	• only significant with existing sensitisation (Portengen et al., 2003)
Second-hand smoke	FEV_1	Mixed	• significant if exposure ≥ 8 hours/day (Janson et al., 2001) • significant short-term effects (Flouris et al., 2009)
Sitting height / Upper body segment	FEV_1, FVC	Yes	
Low birth weight	FEV_1, $FEV_{0.4}$, FVC, FEF	Mixed	

- *birth weight* (Stick, 2000; Stein et al., 1997; Shaheen et al., 1998; Hoo et al., 2004; Edwards et al., 2003).

The following measurements were taken during the spirometric assessment appointment with each participant, as previous research has provided supporting evidence of an association with lung function:

- *weight* and *height* of the participant, to calculate *body mass index* (Wang et al., 2009; Marcon et al., 2009; Stenius-Aarniala et al., 2000; Wood et al., 2010; Harik-Khan et al., 2001a)

- *sitting height* and *upper body segment* (Hsi, Hsu and Jenkins, 1983; Hankinson, Odencrantz and Fedan, 1999; Harik-Khan et al., 2001b; Harik-Khan et al., 2004; Whitrow & Harding, 2007).

Existing questionnaires

Occupational health questionnaires

Questionnaires already in use for occupational health relating to respiratory issues are summarised in table 4.14 below and the following text.

Table 4.14: Questions asked relating to respiratory health on existing occupational health questionnaires			
Subject of question	**Category**	**Document reference**	**Validation**
Previous chest disease / illness	Medical / symptoms	Serco Occupational Health, 2010;	N/S*
		Medical Research Council, 1986	Yes
History of allergy / asthma symptoms	Medical / symptoms	Serco Occupational Health, 2010;	N/S
		Wieslander, Norback, Janson & Edling, 1997;	Yes
		Delclos et al., 2006	Yes
Chest problems, e.g. breathlessness, wheeze, cough	Medical / symptoms	Health & Safety Executive, n.d.[a];	N/S
		Wieslander et al., 1997;	Yes
		Medical Research Council, 1986	Yes
Interruption of sleep	Medical / symptoms	Medical Research Council, 1986	Yes
Exposure in previous job(s)	Employment	Serco Occupational Health, 2010;	N/S
		Delclos et al., 2006;	Yes
		Medical Research Council, 1986	Yes
Chest problems in relation to previous job	Employment	Health & Safety Executive, n.d.[a]	N/S
Smoking status	Lifestyle	Serco Occupational Health, 2010;	N/S
		Medical Research Council, 1986	Yes
Exercise habits - type and frequency	Physical activity	Serco Occupational Health, 2010	N/S
Non-occupational exposure	Additional information	Delclos et al., 2006	Yes

*not stated

The majority of questions regarding respiratory health concern existing symptoms and problems (Serco Occupational Health, 2010; Wieslander et al., 1997; Delclos et al., 2006; Health and Safety Executive, n.d.[a]; Medical Research Council, 1986). These range from simple yes/no questions (example 1, below) to requests for more detailed information (example 2, below).

Example 1:

"Have you had a chest disease at any time e.g. asthma, bronchitis, pleurisy, tuberculosis?

Do you have any allergies or allergic conditions, e.g. hay fever…?" (Serco Occupational Health, 2010)

Example 2:

"Do you feel shortness of breath when you walk fast on flat land or slight inclines?

Have you felt wheezing in the chest during the night during the last two years?" (Wieslander et al., 1997)

Questions on previous chest disease/illness (e.g. example 1, above) (Serco Occupational Health, 2010; Medical Research Council, 1986) do not specifically ask about childhood respiratory illnesses such as pneumonia and pertussis (whooping cough), when there is some evidence that such illnesses can adversely affect adult lung function (Johnston et al., 1998).

Information on previous occupational exposure is also requested. The user is asked to declare if they have ever worked with specific substances, e.g. asbestos, isocyanates or wood dust (Serco Occupational Health, 2010; Medical Research Council, 1986). The questionnaire used by Delclos et al. (2006) for health service workers is particularly exhaustive in this regard, with a checklist of dozens of substances, including ammonia, gluteraldehyde, acetaldehyde, chloramines, formaldehyde, nitric oxide, toluene and pesticides. Delclos et al. (2006) also ask about non-occupational exposure, through metalworking and woodworking hobbies, for example.

Only one questionnaire (Serco Occupational Health, 2010) requests information on exercise habits (example 3, below):

Example 3:

"Do you take any form of regular physical exercise?" (Serco Occupational Health, 2010)

There is evidence that reduction in weight is associated with an improvement in lung function (Wang et al., 2009; Marcon et al., 2009; Jubber, 2004; Wood et al., 2010), suggesting further exploration of this area; it should be noted, however, that Serco (2010) do request height and weight, from which body mass index (BMI) can be calculated.

Smoking details are requested on the Serco and Medical Research Council questionnaires (Serco Occupational Health, 2010; Medical Research Council, 1986) with questions asked to ascertain quantity smoked per day, and time since quitting for ex-smokers. The Medical Research Council questionnaire additionally asks the following (example 4):

Example 4:

"How old were you when you started smoking regularly?

Do you smoke any other forms of tobacco?" (Medical Research Council, 1986)

It should be noted, however, that age of smoking initiation does not tend to be a significant factor, as this is usually confounded by current smoking status (Apostol et al., 2002).

Existing respiratory questionnaires not used for occupational health purposes are summarised in table 4.15 below and the following text.

Table 4.15: Questions asked relating to respiratory health on non-occupational health questionnaires			
Subject of question	**Category**	**Document reference**	**Validation**
Asthma symptoms: limitation of regular activities / interruption of sleep; breathlessness, wheeze, cough	Medical / symptoms	QualityMetric Incorporated, 2002; Asthma UK, 2010	Yes N/S
Asthma - frequency of inhaler use	Medical / symptoms	QualityMetric Incorporated, 2002; Asthma UK, 2010	Yes N/S
Asthma history / history of allergy	Medical / symptoms	Asthma UK, 2010	N/S
Asthma / chronic obstructive pulmonary disease / other lung disease Yes/No	Medical / symptoms	Stanford University, 2008	Yes
Chest problems, e.g. breathlessness, wheeze, cough	Medical / symptoms	British Lung Foundation, 2011; Stanford University, 2008; Yawn et al., 2010; Jones, Quirk & Baveystock, 1991	N/S Yes Yes Yes
Chest problems in relation to limitation of regular activities	Medical / symptoms	Jones et al., 1991	Yes
Chest problems in relation to employment	Employment	Jones et al., 1991	Yes
Smoking status	Lifestyle	British Lung Foundation, 2011; Yawn et al., 2010	N/S Yes
Exercise habits - type and frequency	Physical activity	Stanford University, 2008	Yes

As with occupational questionnaires, existing symptoms and problems comprise the majority of questions; it should be noted, however, that many non-occupational questionnaires are tailored to existing sufferers (QualityMetric Incorporated, 2002; Asthma UK, 2010). For example, the Asthma Control Test (QualityMetric Incorporated, 2002) uses a scoring system to rate the user's control of existing asthma symptoms (example 5, below).

Example 5:

"During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning?

- o *4 or more times a week*
- o *2-3 nights a week*
- o *Once a week*
- o *Once or twice*
- o *Not at all"* (QualityMetric Incorporated, 2002)

The use of a 5-point response scale is of interest here. A study evaluating the use of a questionnaire as a diagnostic tool for chronic obstructive pulmonary disease (COPD) (Hanania et al., 2010) found that such 5-point scaled responses were significantly more accurate than yes/no answers at predicting airflow obstruction ($p=<0.05$).

The Stanford Questionnaire (Stanford University, 2008) uses both yes/no and multiple scaled responses (examples 6 & 7, below).

Example 6:

"Please indicate below which chronic condition(s) you have:

- ❑ *Asthma*
- ❑ *Emphysema or COPD"* (Stanford University, 2008)

> *Example 7:*
>
> *"In general, would you say your health is:*
>
>   *(Circle one)*
>
> *Excellent………………1*
>
> *Very good……………..2*
>
> *Good…………………..3*
>
> *Fair……………………4*
>
> *Poor…………..……...5"* (Stanford University, 2008)

Example 6 presumes that the user is aware of an existing condition, and is not intended to predict the future development of such a condition; example 7, meanwhile, is so generalised as to be functionally meaningless. This questionnaire also asks the user to rate their shortness of breath over the previous two weeks on a scale from 0 (no shortness of breath) to 10 (severe shortness of breath). A more effective line of questioning would ascertain the specific activities that leave the user breathless (example 2, above, example 8, below).

> *Example 8:*
>
> *"Do you experience shortness of breath upon physical exertion (walking up a flight of stairs or walking up an incline without stopping to rest)?"* (Yawn et al., 2010)

The St. George's Respiratory Questionnaire (Jones et al., 1991) is particularly exhaustive in this area, listing a wide variety of activities in relation to breathlessness, coughing and wheezing.

Smoking details (quantity and duration) are requested on the questionnaire developed by Yawn et al. (2010). The British Lung Foundation questionnaire (British Lung Foundation, 2011) merely asks if the user is a smoker, non-smoker or ex-smoker.

Reviews

A research report was conducted by the Institute of Occupational Medicine on behalf of the Health and Safety Executive (Miller, Graham, Creely, Cowie & Soutar, 2003) to examine questionnaire predictors for occupational asthma. The findings are summarised in table 4.16.

Table 4.16: Questionnaire predictors of occupational asthma identified by Miller et al. (2003)		
Subject of question	**Category**	**Document reference**
Asthma history **(childhood)***	Medical / symptoms	Miller et al., 2003
Asthma symptoms, e.g. breathlessness, wheeze, cough	Medical / symptoms	Miller et al., 2003
Exposure in previous job(s) **to allergen(s) or irritant/reactive chemicals***	Employment	Miller et al., 2003
Previous occupation	Employment	Miller et al., 2003
Smoking status	Lifestyle	Miller et al., 2003

*questions or further details *additional* to those listed in tables 4.14 and 4.15 are marked in bold text

The report by Miller et al. (2003) concluded that in terms of occupational asthma, there are no agreed standards as to which predictive questions are most effective. The factors found to be most strongly associated with clinically-assessed occupational asthma were previous occupational exposure to allergens or irritant reactive chemicals, and childhood asthma. Many questionnaires request asthma history, but Miller et al. (2003) specifically highlight the importance of asthma in childhood.

For previous occupational exposure, a checklist can be provided on a questionnaire in the style of that used by Delclos et al. (2006), ensuring that substances with known respiratory hazards (review, chapter 1, section 1.2) are included.

Other relevant factors not otherwise observed on existing questionnaires, but identified from the literature review previously in this section, were childhood

respiratory disease, socio-economic status, distance of home from nearest major road, and birth weight.

Data collection sheet construction

For any questionnaire-type document to be effective in its purpose, it must be clear and straightforward, sensibly organised, and the questions must be structured in the appropriate manner to acquire the desired information (Peterson, 2000, pp.13-27, 101-102).

The factors identified from the literature review and existing questionnaires were arranged by theme into sections (table 4.17).

A brief introductory paragraph was included at the beginning of the sheet to state its purpose, provide confidentiality assurance, and to request that the participant answers all questions (Peterson, 2000, pp.102-106; Gillham, 2007, pp.37-39).

With the exception of birth weight, questions were structured as closed-end questions, limiting responses to a defined set of options. This was done to ensure meaningful responses and so facilitate statistical analysis, and also for ease of completion by participants (Bradburn, Seymour & Wansink, 2004, pp.151-152; Peterson, 2000, pp.38-39).

For certain questions rating scale responses were used. For example, 'exercise habits' was arranged as a 5-point scale, with option 1 (never exercise) as the 'worst' option, and option 5 (exercise every day) as the 'best'. A Likert-type scale such as this, limited to 5 points for simplicity, was the most effective way of acquiring meaningful and useful data for this type of question (Peterson, 2000, p.75; Gillham, 2007, pp.31-32; Hanania et al., 2010). All 5-point sets of responses were constructed in this way, 'negative' at option 1 to 'positive' at option 5.

Groupings of the questions into sections is summarised in table 4.17; the completed data collection sheet is included in the appendix (appendix entry 5).

Table 4.17: Grouping of questions asked on data collection sheet	
Section 1: Personal information	Name, date-of-birth, gender
	Birth weight
	Exercise habits (1-5 scale)
Section 2: Socio-economic information	Marital status
	Educational level
	Household income (1-5 scale)
	Distance of home from major road (1-5 scale)
Section 3: Smoking history	Smoking status
Section 4: Asthma & other chest conditions	Asthma & allergies, personal and family history
	Other chest problems, personal and family history
	Childhood chest illness
	Symptoms: Breathlessness (1-5 scale)
	Wheezing (1-5 scale)
	Coughing (1-5 scale)
	Limitation of regular activities (1-5 scale)
	Interruption of sleep (1-5 scale)
Section 5: Previous occupational exposure	List of relevant substances
	Previous employment, list of relevant industries
Section 6: Previous non-occupational exposure	List of hobbies involving relevant substances

The completed data collection sheet was piloted during August 2011. Six individuals from CPL Aromas were selected, ensuring variance in department, role, age and gender. The individuals were asked to complete the sheet with no prior explanation as to the questions asked or the purpose of the sheet. The completed sheets were returned to the researcher and checked, with all sheets correctly completed. The individuals were invited to comment on ease-of-completion, order and structure, and suggested improvements; feedback received was exclusively positive, and no

improvements to the sheet were necessary. Individuals were also asked to measure the time taken to complete the sheet; times ranged from 8 to 15 minutes.

The completed and piloted data collection sheet was distributed to study participants during phase 3 of recruitment, detailed earlier in this chapter.

4.3 Data collection (questionnaire development phase 2)

The purpose of phase 2 (figure 4.1) was to collect the spirometric data, demographic data and physical data from the study participants.

Spirometric data

Spirometric assessments were performed as detailed in chapter 2; FEV_1 pre-shift measurements were used.

Demographic data

Completed data collection sheets were handed to the researcher during the pre-shift spirometric appointments.

Physical data

Physical data was measured and recorded by the researcher during the pre-shift spirometric appointments. Height was measured using a stadiometer; participants were asked to remove shoes and caps. Weight was measured using a digital scale; participants were asked to remove shoes and protective clothing such as high-visibility vests and jackets. Sitting height (SiH) was also measured using the stadiometer and a standard stool, and upper body segment (UBS) calculated from this (UBS = SiH minus stool height). Body mass index (BMI) was calculated from standing height and weight (BMI = weight[kg] / height[m]^2).

Spirometric data and physical data were recorded on a results form, which the participant was asked to sign (appendix entry 14).

4.4 Data exploration (questionnaire development phase 3)

Phase 3 (figure 4.1) involved the analysis of each demographic and physical factor for any effect on the spirometric outcome measures. Those factors observed to have an effect were selected for progression to phase 4.

The statistical package Predictive Analytics SoftWare Statistics (PASW [Predictive Analytics SoftWare] Statistics version 18.0 for Windows, release 18.0.0 [July 30, 2009]) was used for all statistical calculations. Demographic and physical data were added to the spirometric data contained on the electronic PASW data file created for part 1.

Statistical analysis was used to analyse the effects of each predictor variable on the spirometric outcome measurements. Pre-shift (baseline) FEV_1 measurements (%predicted) were used as the dependent variable. Building the model for statistical analysis is summarised in figure 4.2.

Item reduction occurred in two stages: first, the exclusion of predictor variables where frequency of endorsement had resulted in an incomplete spread of responses (for example, variables with 1-5 responses where only responses 4 and 5 were given); these variables were excluded from further analysis.

Simple linear regression was performed for the remaining predictor variables. For the second stage of item reduction, similar predictors were checked for correlation using Pearson correlation for continuous predictors, and chi-square test for categorical variables; where correlation was significant between two similar predictors ($p = $ <0.05), one predictor was selected as the most relevant based on effect size, and the other was seen as redundant and was excluded. All remaining significant* predictors were then fitted in a multiple linear regression model to give adjusted values. The unstandardised coefficient (B) was taken as a measure of effect size (Hosmer & Lemeshow, 2001, pp.3-30, pp.32-42).

*Statistical significance for progression to the multiple linear regression model was set at $p = $ <0.2, as recommended by Hosmer and Lemeshow (2001, p.88, pp.106-118), Menard (2001, pp.64-66) and Montgomery, Peck and Vining (2006, pp.281-283.
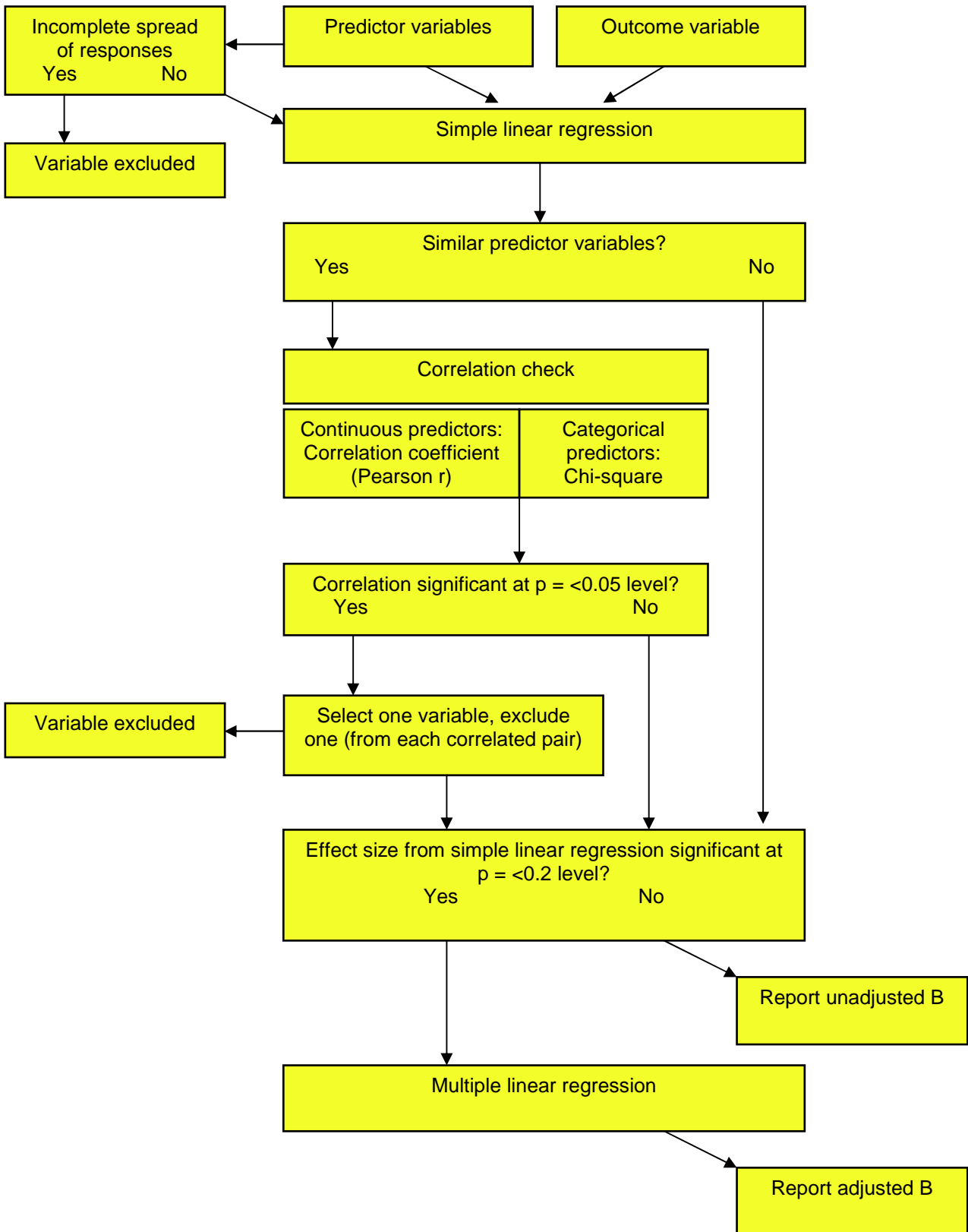
Figure 4.2: Building the model for statistical analysis using simple and multiple linear regression

4.5 Questionnaire construction (questionnaire development phase 4)

Factors selected from phase 3 for progression to phase 4 (figure 4.1) were thematically organised, allocated an appropriate weighting, and used to construct the final questionnaire.

A weighting score was then allocated to each variable response, based on:

• unstandardised coefficient (B) (adjusted where appropriate)

• distance from lowest or highest observed values (continuous variables)

• distance from reference category (categorical variables)

• direct of effect on FEV_1 (positive or negative).

The questions relating to the remaining variables were organised into groups and collated as the final questionnaire, using the data collection sheet (appendix entry 5) as a template.

Chapter 5 will present the results of phases 3 and 4 of questionnaire development.

Summary

This chapter has detailed the methodology behind the development of the data collection sheet, and how the information acquired will be used alongside spirometric data to develop a predictive pre-placement questionnaire. The development of this final questionnaire – phases 3 and 4 of the development process outlined above – will be reported in chapter 5.

Chapter 5 Results, part 2 (questionnaire development)

The aim of this chapter is to complete development of the predictive pre-placement questionnaire.

This will be achieved by:

● reporting the results of data exploration (phase 3 of questionnaire development);

● reporting the results of questionnaire construction (phase 4 of questionnaire development);

● performing internal validity checks on the finished questionnaire and associated weighting system.

5.1 Data exploration (questionnaire development phase 3)

Phase 3 involved the analysis of each variable for effect size on the outcome measure, pre-shift FEV_1. The stages of data exploration were performed as described in chapter 4.

The first stage of item reduction resulted in the exclusion of 6 variables, as shown in table 5.1.

Table 5.1: Item reduction: incomplete responses					
Variable excluded	**Frequency of endorsement**				
Breathlessness (scale 1-5)	1:	2:	3:	4:	5:
	0	0	11.6%	26.8%	61.6%
Wheezing (scale 1-5)	1:	2:	3:	4:	5:
	0	0	2.7%	3.6%	93.8%
Limitation of activities (scale 1-5)	1:	2:	3:	4:	5:
	0	0	0	10.7%	89.3%
Interruption of sleep (scale 1-5)	1:	2:	3:	4:	5:
	0	0	4.5%	5.4%	90.2%
Personal non-asthmatic chest problem Yes/No	Yes:			No:	
	2.7%			97.3%	
Family history, non-asthmatic chest problem Yes/No	Yes:			No:	
	5.4%			94.6%	

The frequency of endorsement for these variables shows an incomplete spread of responses, and so there is insufficient variance in the responses to support a meaningful analysis of the data. These variables were therefore excluded from further analysis.

Simple linear regression was then performed for each remaining variable, to show effect size using the unstandardised coefficient (B), as shown in table 5.2.

Table 5.2: Linear regression showing effect size of predictor variables on pre-shift FEV$_1$ measurements

Variable	Unadjusted (simple linear regression)	
	B (95%CI)	p-value
Birth weight, kg	1.10 (-5.53 – 7.72)	0.741
Smoking status	-2.06 (-5.22 – 1.09)	0.198
Upper body segment (UBS), m	23.53 (-41.91 – 88.97)	0.478
Body mass index, by group	1.43 (-2.12 – 4.99)	0.426
Marital status	5.12 (0.05 – 10.19)	0.048
Educational level	-1.18 (-3.97 – 1.61)	0.403
Exercise frequency (scale 1-5)	-1.96 (-4.36 – 0.44)	0.108
Household income (scale 1-5)	-2.17 (-5.87 – 1.52)	0.247
Distance of home from major road (scale 1-5)	0.88 (-1.51 – 3.27)	0.466
Coughing (scale 1-5)	1.46 (-1.26 – 4.19)	0.288
Personal history of asthma Yes/No	4.28 (-5.56 – 14.11)	0.391
Family history of asthma Yes/No	0.88 (-5.06 – 6.82)	0.769
Childhood history of asthma Yes/No	-1.14 (-8.62 – 6.33)	0.762
Personal history of hayfever Yes/No	0.47 (-5.98 – 6.91)	0.886
Family history of hayfever Yes/No	-1.79 (-7.30 – 3.71)	0.520
Childhood respiratory illness Yes/No	1.05 (-8.82 – 10.91)	0.833
Previous occupational exposure to at least 1 of chemicals listed Yes/No	-4.02 (-9.49 – 1.44)	0.147
Previous employment in at least 1 of listed jobs Yes/No	0.58 (-4.93 – 6.10)	0.835

Further item reduction was performed by checking similar predictor variables for correlation; all relevant variables were categorical, so chi-square tests were used. Where correlation was significant (p = <0.05), one predictor was selected as the most relevant based on effect size, and the other was seen as redundant and was excluded. This resulted in the exclusion of a further 3 variables, as shown in table 5.3.

Table 5.3: Item reduction: correlation check and item redundancy		
Variables	**Chi-square (p-value)**	**Variable selected**
Personal history of asthma Yes/No *vs.* Childhood history of asthma Yes/No	12.39 (<0.001)	Personal history of asthma Yes/No
Personal history of hayfever Yes/No *vs.* Family history of hayfever Yes/No	23.56 (<0.001)	Personal history of hayfever Yes/No
Previous occupational exposure to at least 1 of chemicals listed Yes/No *vs.* Previous employment in at least 1 of listed jobs Yes/No	9.00 (0.003)	Previous employment in at least 1 of listed jobs Yes/No

All remaining predictors that reached the level of significance recommended by Hosmer and Lemeshow (2001, p.88, pp.106-118), Menard (2001, pp.64-66) and Montgomery et al (2006, pp.281-283. for regression model building (p = <0.2) were then fitted in a multiple linear regression model to give adjusted values (table 5.4).

Table 5.4: Linear regression showing effect size of predictor variables on pre-shift FEV$_1$ measurements (including adjusted figures)

Variable	Unadjusted (simple linear regression)		Adjusted* (multiple linear regression)	
	B (95%CI)	p-value	B (95%CI)	p-value
Birth weight, kg	1.10 (-5.53 – 7.72)	0.741	———————————	
Smoking status	-2.06 (-5.22 – 1.09)	0.198	-2.18 (-5.38 – 1.02)	0.180
Upper body segment (UBS), m	23.53 (-41.91 – 88.97)	0.478	———————————	
Body mass index, by group	1.43 (-2.12 – 4.99)	0.426	———————————	
Marital status	5.12 (0.05 – 10.19)	0.048	3.73 (-1.55 – 9.02)	0.164
Educational level	-1.18 (-3.97 – 1.61)	0.403	———————————	
Exercise frequency (scale 1-5)	-1.96 (-4.36 – 0.44)	0.108	-1.80 (-4.31 – 0.70)	0.156
Household income (scale 1-5)	-2.17 (-5.87 – 1.52)	0.247	———————————	
Distance of home from major road (scale 1-5)	0.88 (-1.51 – 3.27)	0.466	———————————	
Coughing (scale 1-5)	1.46 (-1.26 – 4.19)	0.288	———————————	
Personal history of asthma Yes/No	4.28 (-5.56 – 14.11)	0.391	———————————	
Family history of asthma Yes/No	0.88 (-5.06 – 6.82)	0.769	———————————	
Personal history of hayfever Yes/No	0.47 (-5.98 – 6.91)	0.886	———————————	
Childhood respiratory illness Yes/No	1.05 (-8.82 – 10.91)	0.833	———————————	
Previous employment in at least 1 of listed jobs Yes/No	0.58 (-4.93 – 6.10)	0.835	———————————	

*Adjusted for smoking status, marital status and exercise frequency

The variables and associated effect sizes (B) as shown in table 5.4 were selected for progression to phase 4.

5.2 Questionnaire construction (questionnaire development phase 4)

The weightings allocated to each variable response score are shown in table 5.5 (continuous variables) and table 5.6 (categorical variables), along with the maximum possible score for each variable.

Table 5.5: Weighting system allocating scores to continuous variables				
Variable	**Mean (lowest value, highest value)**	**Effect direction***	**Score**	**Maximum possible score+**
Birth weight, kg	3.25 (0.82, 5.06)	Positive	For each kg below highest observed value, score 1.10	4.24 x 1.10 = 4.66
Upper body segment, m	0.87 (0.77, 0.96)	Positive	For each m below highest observed value, score 23.53	0.19 x 23.53 = 4.47

*Effect on pre-shift FEV_1 measurements

+Based on lowest value

The maximum possible score for continuous variables was calculated using the unstandardised coefficient (B), the direction of effect (on FEV_1), and the lowest and highest observed values. For example, for birth weight, the effect direction is positive, so that FEV_1 increases as birth weight increases. The highest observed value was 5.06kg, so for each unit (kg) below this value, the value of B should be added to the score. The lowest observed value was 0.82kg, and so the maximum possible score was calculated thus:

Maximum score (for birth weight) = (highest – lowest values) x B

$$= (5.06kg – 0.82kg) \text{ x } 1.10$$

$$= 4.24 \text{ x } 1.10 = \textbf{4.66}.$$

Table 5.6: Weighting system allocating scores to categorical variables

Variable	Reference category	Effect direction*	Score			Maximum score[+]
Smoking status	Non-smoker	Negative	Non-smoker: 0 Former smoker: 2.18 Smoker: 4.36			4.36
Body mass index, by group	Normal weight	Positive	Normal weight: 2.86 Overweight: 1.43 Obese: 0			2.86
Marital status	Single	Positive	Single: 7.46 Married: 3.73 Divorced/Widowed: 0			7.46
Educational level	GCSE or equivalent	Negative	GCSE equiv.: 0 A-level equiv.: 1.18 Degree equiv.: 2.36 Post-grad: 3.54			3.54
Exercise frequency (scale 1-5)	Response 1 (lowest)	Negative	1: 0 4: 5.40	2: 1.80 5: 7.20	3: 3.60	7.20
Household income (scale 1-5)	Response 1 (lowest)	Negative	1: 0 4: 6.51	2: 2.17 5: 8.68	3: 4.34	8.68
Distance of home from major road (scale 1-5)	Response 1 (lowest)	Positive	1: 3.52 4: 0.88	2: 2.64 5: 0	3: 1.76	3.52
Coughing (scale 1-5)	Response 1 (worst symptom)	Positive	1: 5.84 4: 1.46	2: 4.38 5: 0	3: 2.92	5.84
Personal history of asthma Y/N	Yes	Positive	Yes: 4.28	No: 0		4.28
Family history of asthma Y/N	Yes	Positive	Yes: 0.88	No: 0		0.88
Personal history of hayfever Y/N	Yes	Positive	Yes: 0.47	No: 0		0.47
Childhood respiratory illness Y/N	Yes	Positive	Yes: 1.05	No: 0		1.05
Previous employment in 1 of listed jobs Y/N	Yes	Positive	Yes: 0.58	No: 0		0.58

*Effect on pre-shift FEV_1 measurements

[+]Based on lowest response value

The maximum possible score for categorical variables was calculated using the unstandardised coefficient (B), the direction of effect (on FEV_1), and distance from the reference category.

For example, for smoking status, the effect direction is negative, so that FEV_1 would be expected to decrease from *non-smoker* to *former smoker* to *smoker*. Non-smoker is therefore the reference category; for each unit away from the reference category, the unstandardised coefficient (B) should be scored. The maximum score would be for *smoker*, and would be calculated thus:

Maximum score (for smoking status) = distance from reference category x B

$$= 2 \times 2.18$$

$$= \mathbf{4.36}.$$

The total maximum score (the 'worst' score in terms of expected FEV_1 performance) for all variables is as follows:

- maximum score, continuous variables = 9.13

- maximum score, categorical variables = 50.72

- total maximum score = 9.13 + 50.72 = 59.85.

Each participant's scores should be totalled, and the total score then converted into a percentage of the maximum possible score.

The questions relating to the remaining variables were organised into groups as follows, and the final questionnaire was constructed, using the data collection sheet developed for phase 1 (appendix entry 5) as a template.

- *Personal Information*

- birth weight, kg

- upper body segment *(measure height, sitting height and stool height)*

- body mass index, by group *(measure height and weight)*

- smoking status

- exercise frequency (scale 1-5)

- *Socio-economic information*

- marital status

- educational level

- household income (scale 1-5)

- distance of home from major road (scale 1-5)

- *Symptoms and history*

- coughing (scale 1-5)

- personal history of asthma Y/N

- family history of asthma Y/N

- personal history of hayfever Y/N

- childhood respiratory illness Y/N

- previous employment in 1 of listed jobs Y/N

The final questionnaire is included in the appendix (appendix entry 16), along with a scoring guide for the assessor (appendix entry 17).

5.3 Internal validity checks

The questionnaires were completed using data from 5 randomly selected study participants. Scores were calculated and compared to the FEV_1 pre-shift measurements (table 5.7).

Table 5.7: Questionnaire scores of randomly-selected study participants compared to FEV_1 pre-shift measurements			
Participant code	Questionnaire score	% of maximum possible score	FEV_1 pre-shift, %predicted*
055	23.3	38.9	92.4
010	23.1	38.6	88.8
104	23.7	39.6	76.6
052	24.1	40.3	73.1
102	33.0	55.1	67.6

*Shown in descending order of FEV_1 pre-shift measurements

The questionnaire scores correlate well with FEV_1 measurements. Based on these findings, a questionnaire score of ≥ 40.0% corresponds well with FEV_1 measurement of <80%predicted, regarded as the lower limit of 'normal' in the interpretation of lung function measurements (Celli et al., 2004; Pellegrino et al., 2005).

As a further validity check, the questionnaires were piloted by 4 new employees at the researcher's workplace; these individuals did not take part in the original research study. Spirometry measurements were performed using the study protocol outlined in chapter 2.

Questionnaire scores were calculated and compared to FEV_1 pre-shift measurements (table 5.8).

Table 5.8: Questionnaire scores of new employees compared to FEV$_1$ pre-shift measurements		
Questionnaire score	**% of maximum possible score**	**FEV$_1$ pre-shift, %predicted***
18.8	31.4	110.0
30.0	50.1	104.6
35.2	58.8	96.2
37.8	63.2	89.7

*Shown in descending order of FEV$_1$ pre-shift measurements

Again the questionnaire scores correlate well with FEV$_1$ measurements. As the questionnaire score increases, the FEV$_1$ measurement (%pred) decreases. The suggested threshold of a questionnaire score ≥ 40.0% of the maximum does not apply here, however, suggesting that although correlation is good, further testing and validation is necessary to establish the appropriate threshold for the questionnaire score to suggest an FEV$_1$ of <80%predicted.

This is encouraging for the future validation of the questionnaire, and suggests that this may indeed be a useful tool for occupational health screening.

Summary

This chapter has concluded the phases of questionnaire development, leading to the completed questionnaire as included in the appendix (appendix entry 16). Internal validity checks have thus far supported the questionnaire as a useful screening tool for employees within the fragrance industry. The results of both parts of the study will be further discussed and summarised in chapter 6.

Chapter 6 Final discussion

The aim of this chapter is to further discuss the findings of both parts of the study, in the context of current practice and the implications for future practice.

This will be achieved by:

● discussing the results of the controlled research study (part 1) in the context of current health and safety legislation and practice;

● summarising the implications of part 1 for future practice;

● discussing the predictive questionnaire developed for part 2, and its potential for future use;

● summarising the limitations of both parts of the study;

● summarising future research arising from this study.

● 6.1 Introduction

This thesis set out to investigate occupational respiratory exposure within the fragrance industry and its effects on lung function from two perspectives: firstly, with a controlled study comparing spirometric results between 'exposed' and 'control' groups; and secondly, from an occupational health perspective, with the development of a pre-placement questionnaire.

The research study was a novel investigation in terms of setting, background and population; occupational studies using spirometry to assess the effects of exposure are common in other industries (Baran & Teul, 2007; Bello et al., 2009; Fishwick et al., 2004; Ghasemkhani et al., 2006; Hashemi et al., 2010; Johnsen et al., 2008; Kezunovic, 2008; Kogevinas et al., 2007; Moshammer et al., 2007; Osman & Pala, 2009; Rylander & Carvalheiro, 2006; Suuronen et al., 2008), but within the fragrance industry no meaningful previous attempt has been made to use this type of study to assess employees. (The exceptions are two Russian studies published too long ago to be of any current relevance [Galperina et al., 1986; Xuev, 1964]. The annual updating of usage restrictions and prohibitions within the industry [RIFM Expert Panel, 2011], combined with the development of strict health and safety procedures prescribed and enforced by legislation [Home Office, 1974; Home Office, 2002], mean that these studies are not relevant to current occupational exposure.) This

research study can therefore be seen as the first step in the development of a body of work focussing on employees within the fragrance industry.

The pre-placement questionnaire was developed to address the concerns of Madan and Williams (2010, 2012) and others (Mahmud et al., 2010; Hulshof et al., 1999) that many occupational health questionnaires are not fit-for-purpose and do not provide any meaningful information that can be used effectively by occupational health practitioners. These concerns are particularly relevant in the UK with the introduction of the Equality Act 2010 (Home Office, 2010), prohibiting the employer from requesting health-related information prior to an offer of employment being made. In this context, the questionnaire can function as an effective tool within the fragrance industry. It should be seen as a tool that is intended for the benefit of both employer and employee.

● 6.2 Discussion, part 1

The results of the study conducted to answer the research question have shown that no significant effects on lung function were observed resulting from occupational exposure within the fragrance industry. This is in contrast to research conducted in other industries, where respiratory effects of occupational exposure were observed (Fishwick et al., 2004; Hashemi et al., 2010; Johnsen et al., 2008; Osman & Pala, 2009; Rylander & Carvalheiro, 2006). The lack of previous research within the fragrance industry – an advantage in terms of justifying the need for this research – is in this context a disadvantage, as there are simply no directly comparable studies within industry. The specific challenge for this study, then, is in relating its findings to current guidelines and practice, the principles of establishing a safe, healthy working environment set out by the Health and Safety Executive (Health & Safety Executive, 2012, pp.5-8), and placing it as the *beginning* of a body of work on occupational exposure within the industry.

The Health and Safety Executive (HSE) is the public body responsible for regulating and enforcing all matters pertaining to occupational health and safety in Great Britain (Health & Safety Executive, 2012; Home Office, 1974). Their core aim is summarised below:

"Our mission is the prevention of death, injury and ill health to those at work and those affected by work activities." (Health & Safety Executive, 2012, p.7.)

The HSE also runs campaigns and programmes targeted at specific areas, such as the Disease Reduction Programme. The aims of this programme are to reduce incidence of occupational asthma, and to develop risk reduction measures for work-related respiratory conditions (Health & Safety Executive, 2008).

In terms of the legal requirements set out by UK legislation, the UK fragrance industry conforms to the statutes and guidelines set out in the Health and Safety at Work Act 1974 (Home Office, 1974) to ensure that the workplace is as safe as is practicably possible, and risks are assessed and either eliminated, reduced or managed. This is supported by the study findings, whereby a lack of significant effect on lung function suggests that protective measures in the workplace are sufficient in managing the risks posed by occupational exposure. The findings could also be used to support budgetary justification of the maintenance and upkeep of facilities and equipment and the supply of appropriate personal protective equipment – the results show that the budget allocated to health and safety has a clear benefit in preventing ill health.

Research within industry on occupational exposure and health (and resulting improvements to practice or guidelines) not only conforms to the general mission statement above, but also to specific initiatives such as the Disease Reduction Programme. Such research is also relevant to one of the HSE's stated key objectives from their most recent Annual Report:

"Clarifying ownership of risk and improving compliance:

Motivate others in the health and safety system to address their responsibilities in a common sense and proportionate manner and contribute to improving health and safety performance." (Health & Safety Executive, 2012, p.16.)

The research study conducted here can be seen as extremely pertinent to this objective; by initiating, funding and supporting this research, the UK industry has proved willing to take 'ownership' of respiratory issues in relation to occupational exposure, and take further steps to ensure employees' occupational health beyond

what is prescribed by law. The preparation for the research has also shown how straightforward it can be to establish, maintain and run a spirometric health surveillance system in the workplace, in line with the principles set out in Regulation 11 of the COSHH Regulations (Home Office, 2002). This can be achieved in-house with minimal equipment and training costs, and the workload handled by a small number of willing personnel in addition to their usual duties. This will be a recommendation for industry arising from this research. In relation to this, the HSE has prepared a number of freely available industry-specific guideline documents advising on COSHH; for example, for the woodworking industry (Health & Safety Executive, n.d.[b]). There is no such specific guidance for the fragrance industry. A guidance document endorsed by the HSE providing specific guidance for the industry would be of great value, and this will also be a recommendation arising from the research – this will be formally suggested to the HSE. Such a document could be prepared by collaboration with health and safety representatives from UK fragrance companies, in the spirit of co-operation fostered by this study.

The lack of similar industry-specific research makes it all the more imperative that the work of this study is continued, both in terms of a direct follow-up and in expanding the study. Repeating the study with the same cohort of individuals would allow the assessment of any changes to lung function over time, and would be of great interest, although there is a danger that loss-to-follow-up may leave the sample size too small to generate statistically relevant results or introduce attrition bias (Crombie & Davies, 1996, p.118). The study could also be expanded to include the fragrance companies who declined to participate. The successful completion of this initial research and dissemination of results may help to convince these companies to take part in future research. There is also the possibility that overseas divisions could be supported to conduct similar research, and so contribute to a global data-set. Larger studies conducted in this way would provide a greater sample size and so increase the statistical power of any findings. Such future research could be seen as continuing the work of this study, and building up a body of work specific to this industry.

● 6.3 Discussion, part 2

The questionnaire developed for part 2 is intended to function as a score based predictive tool used in conjunction with a questionnaire for employees within the fragrance industry, by providing a numerical score that is predictive for potential respiratory problems. The need for such a tool has increased in recent years with the passing of the Equality Act 2010, with the result that employers are no longer able to request health-related information prior to a formal offer of employment (Home Office, 2010). Any pre-placement procedure must therefore be effective in terms of assessing the needs of the employee, and must also be conducted rapidly. Occupational health screening questionnaires are, however, of little benefit in providing concrete, useful information to the employer in terms of predicting adverse health outcomes and/or assessing employees' needs (Madan & Williams, 2010; Madan & Williams, 2012; Mahmud et al., 2010; Hulshof et al., 1999).

Madan and Williams (2012) conclude that:

"There is little evidence that pre-employment health screening by questionnaire is effective in determining future health or occupational outcomes for prospective employees." (Madan & Williams, 2012.)

The challenge, then, lay in developing a screening questionnaire that is effective, and provides a clear result that can be used in predicting occupational outcomes and so aid in the pre-placement assessment of employees. The questionnaire (appendix entry 16) was informed by the literature and existing questionnaires before being developed and finalised from the study data. An accumulated score is calculated from the responses, with a higher score expected to predict a lower FEV_1 performance.

Two internal validity checks on the final questionnaire showed a correlation between questionnaire score and FEV_1, with a high score correlating with reduced FEV_1 results.

Interestingly, there was disparity in terms of establishing a threshold point for potential respiratory issues. The first check suggested that a score threshold of ≥40.0% of maximum predicts an FEV_1 of <80%predicted. The second check,

conducted with new employee data, found that the score threshold would be >60% of maximum before FEV_1 <80%predicted is approached. These were conducted with a small number of people, however (check 1 $n = 5$, check 2 $n = 4$), and were intended as a rapid initial check on the functionality of the questionnaire, and to show that score does negatively correlate with FEV_1. Further external validation is necessary to establish the threshold score relating to FEV_1 <80%predicted before the questionnaire can be made available for widespread use.

The questionnaire will be externally validated using spirometric results from fragrance industry employees not involved with the original research. This will be achieved by visiting the companies that declined to take part, and using the results of both parts of the study and the clear benefits offered by the questionnaire to justify their involvement with the validation process. External validation does not form part of this thesis, and is part of the suggested future research.

Following external validation, the questionnaire would be offered to all fragrance companies within the UK. It should be given to any new employees for completion following an offer of employment. A score calculated as above the threshold point would be predictive of potential respiratory issues. Responses of the employer to such a score may include:

● a more detailed risk assessment;

● a specific risk assessment relating to respiratory exposure;

● increased protective measures made available to the employee;

● periodic scheduled appointments with occupational health / health and safety / human resources;

● and/or spirometric assessments (more frequent if these are already in place).

In this way the questionnaire may provide a predictive tool which could be used to fulfil the need identified by Madan and Williams (2010, 2012) for an effective predictive tool that provides useful information to the employer for the benefit of both employer and employee. As an industry-specific tool, generated from data

representative of UK fragrance industry employees, a limitation of the questionnaire is that it is only valid for use in that industry. The process used to develop the questionnaire, however, could be used as a model to develop similar tools in other areas. For example, if the research conducted for part 1 was followed up and extended to represent the global fragrance industry, regional questionnaires could be developed alongside this. This model could also be followed in other industries where chemical use or dust presents an occupational exposure hazard, and questionnaires developed specific to those industries.

6.4 Implications in the field and recommendations for future practice

Based on the results of this study, health and safety measures in place within the fragrance industry are sufficient but must be maintained as a minimum. Although no significant respiratory effects resulting from occupational exposure were found in this study, occupational risks do exist in the fragrance industry, and so the industry would benefit from further research. Future research with a larger sample size would give confidence that the results reported here give a representative view of employees in the industry, and that sufficient protective measures are in place.

A COSHH guide specific to the fragrance industry should be prepared and made available via the HSE. This will be suggested to the HSE. The guide could be prepared as a collaborative effort within the UK industry and endorsed by the HSE.

Spirometric occupational health surveillance is of great benefit to staff and employers. Where this does not take place, this should be implemented as a matter of priority. Providing this service in-house is straightforward and inexpensive; guidance will be offered where necessary on the process of setting up and maintaining such a service.

The challenge of effectively assessing employees' occupational needs whilst complying with the Equality Act 2010 (Home Office, 2010) can be met with the use of a pre-placement questionnaire, albeit one that is specifically designed and created to yield useful information, rather than a generic form. The questionnaire developed here is an example of this. Once externally validated, the questionnaire will function

as a predictive tool for potential lung function issues in employees of the fragrance industry, aiding in the pre-placement and risk assessment processes. The wider implications of this, taking into account the conclusions of Madan and Williams (2010, 2012) that many occupational health questionnaires are not useful or effective, are that specific tools such as this should be the standard method of pre-placement assessment, where feasible. Where a specific risk or hazard is evident in a workplace, and health-related information can be effectively used to support risk management for the employee, a tool designed to gather that information can be more effective than a generic form. It is critical, however, for the potential cost implications of implementing any such tool to be defined as part of the development and/or validation process. Further to this, the development model used to generate the questionnaire can be followed in other global regions of the industry and/or other industries with occupational respiratory hazards, thus creating tools that are specific to the region or to a particular industry.

● 6.5 Limitations of the study

The two chief limitations of the research study concern sample size and the limited population represented by the participants.

The sample size of 112 was sufficient to meet the minimum sample required for statistical analysis (108). Although this does compare favourably with some studies in other industries ($n = 100$, Hashemi et al., 2010; $n = 82$, Rylander & Carvalheiro, 2006; $n = 75$, Fishwick et al., 2004), many studies which found significant effects using spirometry had significantly larger populations ($n = 656$, Osman & Pala, 2009; $n = 3924$, Johnsen et al., 2008). It must be acknowledged that a larger sample size for this study may have, in theory, been necessary in order to observe any effects of occupational exposure, if such effects exist, or to eliminate any concerns in this area. The sample size was the result of the lack of participation of certain UK fragrance companies during the recruitment process. Whilst this was disappointing, it was not expected that all invited companies would agree to participate. The offer to participate in follow-up research studies will be supported by the work undertaken

thus far, and it is hoped that this will result in a larger study population being available.

The other chief limitation of the study is that the results are representative of the study population – UK fragrance industry employees – and should not be extrapolated to represent other global regions. This was the intention of the study design, however, to conduct the research at sites within the UK, as a global study would have been impractical at this stage in terms of budgetary and time constraints. As has been stated previously, this work can be followed up using the study methodology to conduct similar research in other global locations.

An additional limitation is that no exposure monitoring was conducted at the sites visited for data collection, as analysis of personal exposure data did not form part of the research methodology. The collection of personal exposure monitoring data will be investigated for feasibility in further studies.

The existing limitations of the predictive questionnaire tool are that it remains to be externally validated within industry, and that a threshold score corresponding to FEV_1 <80%predicted has not yet been established. External validation will provide further support of its effectiveness, and also allow a threshold score to be defined. The questionnaire is also limited in that it is representative of the UK fragrance industry population, although this is its intended purpose.

Finally, as has been discussed above, an issue with the research study is that there are no directly comparable studies conducted within industry to compare these results to. Strictly speaking, this is not a limitation of the study itself, rather a limitation of the available literature, and this research aims to begin the process of filling this knowledge gap. This can be seen as the greatest strength of this research, a truly novel piece of work in an under-investigated area, breaking ground in the fragrance industry and produced with the willing co-operation of parties that have long been competitors. This research is indeed the beginning of a body of work focussed on the industry, and will be continued and expanded with the ongoing collaborative support of the industry.

● 6.6 Overall conclusions

No significant effects of occupational respiratory exposure on the spirometric performance of the study population were observed. The study population was representative of employees of the UK fragrance industry. This suggests that protective measures in place in the fragrance industry are sufficient in minimising occupational risk to respiratory health, and so are effective in preventing reduction of employees' lung function during working hours. This conforms to the requirements of health and safety legislation and to the stated aims of the Health and Safety Executive, and such protective measures must be maintained as a minimum. It would be useful, however, to replicate this study with a larger population. A larger future study using the same methodology would determine if sample size was truly a limitation of this study.

The potential confounding factors adjusted for using statistical analysis were: smoking status; body mass index; personal history of respiratory problems; and family history of respiratory problems. These factors were not observed to significantly affect the outcome measurements. A larger future study may also allow further exploration of the effects of these potential confounders, particularly smoking status.

Using spirometric, physical and demographic data from this study population, a pre-placement occupational health questionnaire was developed as a predictive tool for potential lung function problems in fragrance industry employees. External validation and determination of the threshold score representing an FEV_1 of ≤80% is required before the questionnaire can be released for widespread use. Once validated, the questionnaire can be used as an effective tool to provide meaningful and useful information as part of a pre-placement assessment. This tool may provide the means to comply with relevant legislation prohibiting health-related questions prior to the offer of employment, while ensuring that the needs of the employee are known and can be met. The development model used to create the questionnaire could be followed to generate region-specific or industry-specific questionnaires.

Occupational exposure within the fragrance industry is an unexplored area for research. The lack of previously published research in this area may be due to

concerns of the employers that any negative findings would expose them to litigation, compensation claims or enforcement notices. This may also be a factor in the decision of some companies to decline to participate in the study. The reverse is the case, however; participation in studies such as this demonstrates that companies are actively supporting occupational research, and that they are attentive to employees' occupational health needs. Engaging in cross-industry collaboration to support the finding of definitive research results leaves companies in a far stronger position of defence. This is a particularly salient point when considering that a great deal of similar research has been carried out in other industries.

This study is the first step in a novel area of research. The research can – and should – be followed-up and expanded upon.

● 6.7 Future dissemination

Disseminated material arising from the research was listed in the dissemination list (page xi). Articles yet to be published and future presentations are listed below.

● *Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study.*

Article, submitted for publication to *Occupational Medicine.*

● *The development of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry.*

Article, to be submitted for publication.

● *The validation of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry.*

Article, to be submitted for publication.

● *Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study.*

Presentation, to be given to:

International Fragrance Association United Kingdom (IFRA-UK) Executive Committee, London; UK fragrance companies.

● *The development, validation and use of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry.*

Presentation, to be given to:

International Fragrance Association United Kingdom (IFRA-UK) Executive Committee, London; UK fragrance companies.

● 6.8 Future studies

Future areas of research arising from this study and the discussion of the findings are summarised below:

● participants of the research study could be directly followed-up at a later date using the same data collection and analysis methodology (Monson, 1990, p.61, pp.144-147), in order to investigate changes to lung function over time (this would be considered as a cohort study, albeit with a relatively small population);

● regional studies could be conducted globally using the same research methodology, to give results representative of the region;

● following completion of further global regional studies, a global meta-study could compare and/or combine results from those regional studies;

● a multi-industry study directly comparing relative risk of lung function effects from occupational exposure within the fragrance industry to that in other industries, in the style of the research conducted by Kogevinas et al. (2007), would be of interest;

● dermatological effects of occupational exposure within the fragrance industry also remain unexplored, this is another potential area for future research;

● development of a COSHH guidance document endorsed by the HSE providing specific guidance for the fragrance industry;

● advice and guidance to other parties as necessary on the benefits of an in-house spirometry assessment service and the procedure and requirements for establishing such a service (this could be via informal consultation or the creation of a guidance document);

● validation of the predictive questionnaire within the fragrance industry is necessary before its subsequent use in pre-placement assessments;

● further global region-specific questionnaires could be developed, following the questionnaire development methodology used here as a model.

Summary

This chapter has summarised the findings of both parts of the study, placing them in the context of current practice and considering the implications for future practice. Limitations of the study were acknowledged, and future research ideas arising from these findings were proposed.

Chapter 7 will begin with an assessment of the objectives outlined in chapter 1 and how these have been fulfilled, and will then be dedicated to personal and professional reflection, including an evaluation of progress towards the professional doctorate and the significant developmental steps that have occurred throughout the process.

Chapter 7 Reflection

The aim of this chapter is to revisit the objectives outlined in chapter 1, and to give a reflective account of personal and professional development throughout the course.

This will be achieved by:

● assessing the work undertaken against the defined objectives, and identifying any future work arising;

● reflecting on previous learning prior to the course;

● presenting a SWAIN analysis conducted at the beginning of the course;

● considering critical events in the context of strengths and weaknesses identified and/or addressed;

● conducting an up-to-date SWAIN analysis.

● 7.1 Assessment of objectives

The work undertaken in planning, undertaking and reporting the results of the study was assessed against each formal objective outlined in chapter 1.

Objective 1

Professional training and experience:	
To gain formal training in spirometric testing and interpretation, and experience at conducting spirometric testing in the workplace.	
Achieved by:	*Links:*
● receiving formal training;	● appendix entry 3
● running spirometric health surveillance programme in the workplace.	● appendix entry 4

Tasks remaining / follow-up:

● continue with workplace spirometric assessments;

● keep up-to-date with developments in spirometric equipment, testing and/or interpretation via relevant literature, network of contacts, and refresher courses where appropriate.

Objective 2

To answer the research question:	
In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a statistically significant change in lung function as measured using spirometry?	
Achieved by:	*Links:*
● designing an appropriate research methodology;	● chapter 2, research methodology
● conducting the study according to the methodology;	● chapter 3, results (part 1)
● reporting and discussing the results of the study.	● chapter 3, results (part 1) ● chapter 6, section 6.2, discussion (part 1)

Tasks remaining / follow-up:

● dissemination of results through published articles and presentations (see objective 5).

Objective 3

Statistical analysis:	
To undertake statistical analysis on data collected to explore the relationship between chemical exposure and lung function.	
Achieved by:	*Links:*
● consulting with a statistician to ascertain the most appropriate methods of analysis;	● chapter 2, section 2.8, statistical analysis
● performing analysis and reporting results.	● chapter 3, results (part 1)

Tasks remaining / follow-up: none.

Objective 4

Predictive questionnaire:

To develop a predictive pre-placement screening questionnaire using spirometric data obtained and demographic information from pre-assessment data collection sheets.

Sub-objective:

To critically evaluate existing evidence on factors potentially associated with reduction in lung function (to inform the development of pre-assessment data collection sheets).

Achieved by:	*Links:*
● clearly defining the phased development process;	● chapter 4, questionnaire development methodology
● conducting a literature review; ● reviewing existing questionnaires; ● developing an appropriate data collection sheet informed by the literature;	● chapter 4, literature review and review of existing questionnaires ● appendix entry 5 (data collection sheet)
● performing data analysis using appropriate methods; ● developing the final questionnaire and accompanying scoring guide.	● chapter 5, results (part 2) ● appendix entry 16 (final questionnaire) ● appendix entry 17 (scoring guide)

Tasks remaining / follow-up:

● external validation of questionnaire;

● release of questionnaire to industry and support for its use where appropriate.

Objective 5

Dissemination:
To disseminate results via industry seminars/presentations and reports, and preparation of article(s) for publication.

Achieved by:	*Links:*
● delivering presentations to industry and associated organisations;	● Dissemination list (page xi)
● submitting an article for publication;	● Dissemination list (page xi) Dix, G.R. (2012). Assessing the impact of journals: A review of journals in the field of respiratory research, in the context of industrial occupational health. *Occ Health [at Work], 8*(5), 30-33.
● preparing a summary report and poster to participating companies;	● Dissemination list (page xi)
● poster presentation outside industry (European Respiratory Society Annual Congress).	● Dissemination list (page xi) ● appendix entry 18

Tasks remaining / follow-up: (also see chapter 6, section 6.7, future dissemination)

● articles for journal publication:

> *Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study*;

> *The development of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry*;

> *The validation of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry*;

● presentations to be developed:

> *Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study*;

The development, validation and use of a pre-placement occupational health questionnaire that is predictive for potential lung function problems, for use within the UK fragrance industry.

Objective 6

Professional implications:	
To explore the implications of research findings for industry via:	
preparation of guidelines/recommendations as appropriate;	
making the predictive questionnaire available within the fragrance industry;	
suggestion of future research ideas arising from the research findings.	
Achieved by:	*Links:*
● reporting and discussing the results of the study and their implications;	● chapter 3, results (part 1) ● chapter 6, section 6.2, discussion (part 1) ● chapter 6, section 6.4, implications in the field and recommendations for future practice
● discussing the potential use, value and limitations of the final questionnaire;	● chapter 6, section 6.3, discussion (part 2) ● chapter 6, section 6.4, implications in the field and recommendations for future practice
● suggesting future ideas for research following and expanding this work.	● chapter 6, section 6.8, future studies

Tasks remaining / follow-up: (also see chapter 6, section 6.8, future studies)

● development of a COSHH guidance document endorsed by the HSE providing specific guidance for the fragrance industry;

● advice and guidance to other parties as necessary on the benefits of an in-house spirometry assessment service and the procedure and requirements for establishing such a service;

● validation of the predictive questionnaire, followed by its dissemination throughout the fragrance industry.

● 7.2 Professional and personal reflection

Introduction

A key element of the professional doctorate programme is a reflective account of the professional and personal development that has occurred throughout the course. Reflection on the experiences underpinning that development allows the consolidation of what has been learnt, and enables further development from future experiential learning (Kolb, 1984, pp.27-29, p.38; Moon, 1999, p.21, p.161). In this way, learning is seen as an ongoing process with its own values and impact, rather than merely a necessary step towards a defined outcome (Kolb, 1984, pp.26-29).

This reflective account begins with a consideration of learning and experiences prior to undertaking the professional doctorate and a SWAIN analysis (strengths, weaknesses, aspirations, interests and needs [Hall & Marsh, 2000, p.34, pp.46-47; O'Neill & Pennington, 1992, pp.35-41; UK Centre for Bioscience, 2010, pp.10-11]) conducted at this point in time. SWAIN analysis was preferred over alternatives such as SWOT analysis (strengths, weaknesses, opportunities, threats [Johnson, Scholes & Whittington, 2008, p.119, pp.569-570; Mullins, 2007, pp.545-546]) as I felt this would facilitate a more comprehensive evaluation of personal attributes and lead to the clear identification of 'needs' in order to achieve aspirations and identify and/or overcome weaknesses. In this way, SWAIN can be truly effective in using reflection as a mechanism towards further self-development (Moon, 1999, p.77).

Components of the SWAIN analysis will then be considered in more detail, reflecting on the changes resulting from experiential learning during the course of the doctorate programme. A current SWAIN analysis conducted as I approach the end of the professional doctorate will then be used to demonstrate the developmental changes that have occurred.

Previous learning

To be effective, any assessment of personal development requirements must include a consideration of previous learning experiences, and what the individual has taken forward from those experiences (Boud, Keogh & Walker, 1985, p.7).

Academic learning

My academic qualifications prior to beginning the professional doctorate were an honours degree (BSc Hons Biology) from the Open University, and a post-graduate diploma (PGDip Medical Toxicology) from Cardiff University. Both of these courses were undertaken via distance learning. The advantage of this format was being able to work full-time whilst studying. Undertaking these qualifications developed the following personal attributes, which I would consider to be strengths:

● *adaptability* – the modular structure of the Open University courses led to an overlap of subjects at times, requiring the ability to switch between subjects while ensuring sufficient attention was given to each.

● *organising and prioritising workloads* – periods of high workloads caused by overlap of Open University courses required the prioritisation of tasks and assignments. To achieve this, I would 'break up' the workloads into sections and assign each a time-bound deadline based on priority. This system worked well and so was also used when undertaking the post-graduate diploma.

● *remote / independent working* – both courses were undertaken as a distance learner, which promoted the development of self-organisation strategies as in the example above. Support was available in both cases, but this was barely used, as I did not feel that responses were timely, and I preferred to overcome any obstacles through my own investigation and comprehension. These periods developed and cemented my inclination for self-reliance and a determination to achieve things without outside assistance.

The successful completion of these qualifications gave me a tremendous sense of achievement and self-satisfaction. I felt rewarded, and somewhat vindicated, as

these experiences proved to me that hard work unquestionably leads to rewards. This is a basic personal principle that I have carried forward.

One of the strengths identified, however, had the potential to become a self-limiting factor, and so must be considered as a weakness:

● *reluctance to involve / depend on others* – while self-reliance had served me well to this point, I realised this was also a weakness which could impact my progression through the professional doctorate course. The course would involve developing doctoral level skills which were completely new to me, such as complicated statistical analysis methods, writing for publication, and formally reviewing published literature. It was likely that I would need support throughout the course, and so I resolved to actively minimise the effects of this personality trait by seeking support and interacting as much as possible with my study group and tutors/supervisors.

Work-based learning

I had been employed in the Regulatory department at CPL Aromas for almost three years when I began the professional doctorate course. Intensive learning had been required on the regulations and directives relevant to fragrance production, sale and use and their practical implementation using specialised software. Working in Regulatory requires a balance of short-, mid- and long-term priority tasks, the priorities of which change frequently. This work-based learning therefore supported the strengths of *adaptability*, and *organising and prioritising workloads*. The management structure in the department is relatively informal and flexible, and I am generally left to manage my own workload; this is my preferred way of working, and has further supported the strength of *independent working*. On reflection, however, this has also supported the weakness of a *reluctance to involve / depend on others*; this is unlikely to become an issue in the working environment, but as mentioned above, it was a weakness that needed to be actively worked on during the professional doctorate course.

It is notable that, prior to the professional doctorate course, academic and work-based learning were not integrated in any way, and any effects they had on personal

development occurred separately from each other, even when those effects were similar. The professional doctorate course was selected as one of its underlying principles is its relevance to, and interaction with, the student's workplace. This would therefore enable true experiential learning, by linking academic and work-based learning to achieve personal development (Kolb, 1984, p.4).

SWAIN analysis 1

Table 7.1 presents a SWAIN analysis conducted prior to beginning the professional doctorate, identifying the strengths, weaknesses, aspirations and interests relevant to the successful completion of the course. The final section, 'needs', outlines the actions necessary to build on strengths, overcome or minimise weaknesses, achieve aspirations and stimulate interests.

Table 7.1: SWAIN analysis, prior to undertaking the professional doctorate	
STRENGTHS	**WEAKNESSES**
● adaptability ● prioritising / organising workloads ● remote / independent working ● broad knowledge base ● drive and ambition for progression ● work ethic, professionalism	● reluctance to involve and/or depend on others ● lack of experience writing and studying at doctoral level ● lack of experience delivering presentations ● limited understanding and experience of formal statistical analysis methods ● lack of specialised knowledge and competency in area of research interest
ASPIRATIONS	**INTERESTS**
● professional development ● increased professional recognition and respect in industry ● academic development to doctoral level ● development of specialised knowledge base	● chemical industry ● employee health and well-being ● respiratory exposure, lung function / spirometry
NEEDS	
● to conceive, plan and undertake a research project relevant to the workplace, interests, and academic requirements ● to have support from employer: study days, time allowed for planning and conducting research ● to select appropriate first supervisor; foster good relations through tutorials / progress updates, discussion of problems and successes, asking for assistance when required ● to ask for assistance / support from tutors when required ● to foster good relations with peer group through regular contact; ask for and offer support when needed ● to gain experience of statistical analysis methods and understanding of which methods are appropriate for different data manipulation requirements ● to gain experience delivering presentations ● to gain experience writing and reviewing at doctoral level, via progression through doctorate unit assignments ● to successfully write, submit and publish research article(s) in an appropriate journal ● to undertake formal spirometry training and gain experience in conducting and interpreting spirometric tests.	

The following sections reflect on the points identified in the SWAIN analysis above, and examine the progression from this initial analysis to one conducted as I approach the end of the professional doctorate process.

Critical events and effects on strengths and weaknesses

The first SWAIN analysis (table 7.1) identified personal strengths that would be necessary for progression through the professional doctorate course, and weaknesses that needed to be addressed. The 'needs' in table 7.1 were designed not only to aid general progression through the course, but also to minimise or eliminate specific weaknesses identified. Thus weaknesses can be addressed with experiential learning and reflection on critical 'events', either by being transformed through experience into strengths, or by a lessening of their effects. This development planning and reflection was conducted with Kolb's reflective learning cycle (Kolb, 1984, pp.20-22) in mind, whereby reflection on concrete experience leads to new ideas and concepts which can be used to inform further experiences and further reflection, and so on.

Relevant events are given below with a brief commentary on their effects on personal development.

● *Event: Presentations* (see dissemination list, page xi)

- research proposal presentations to university peer group and tutors (x2)

- research proposal presentations to industry (x2)

- presentation of preliminary results to industry-associated bodies (x2)

- poster presentation, European Respiratory Society

Prior to the course, I had no experience writing or delivering presentations. This lack of experience was clear from the feedback received after giving the first presentation to the study group and tutors (22/01/2010), suggesting that I appeared nervous and did not engage with the audience effectively (appendix entry 19). Between this and the second presentation (11/02/2011), I had delivered several presentations as training material at work. This experience, combined with an increased subject knowledge and being more comfortable among the study group, gave me the confidence to deliver the second presentation much more effectively, and this was reflected in the feedback, which was greatly improved (appendix entry 20). Subsequent presentations – proposing my planned research and delivering preliminary results – built upon this experience, and I now feel I can count presentation skills as a strength. Of particular satisfaction was being personally invited to New Jersey, USA, to present the results of the study to the Research Institute for Fragrance Materials (RIFM); the audience was relatively hostile, and the presentation essentially became a defence of my research, which I was able to deal with without losing confidence or becoming nervous. I would not have been able to deal with such an experience prior to the course.

Attribute affected:	Transformed to:
Lack of experience presenting (W)*	Presentation skills (S)*

*S = strength; W = weakness

● *Event: Statistical analysis*

    - statistics assignment for unit 2, *Advanced Research Techniques*

    - statistical analysis on research study results

    - statistical analysis for questionnaire development

Formal methods of statistical analysis were unfamiliar to me prior to the course, and I anticipated that such methods would be required in the analysis of my research data. Unit 2 of the course, *Advanced Research Techniques*, gave me the opportunity to learn the various methods of statistical analysis and to practice using those methods on the sample data sets provided. For the assignments for this unit, we were given the choice of completing either quantitative or qualitative analysis to an advanced 'specialist' level; although I had enjoyed the qualitative component of the unit, I selected the former, as I felt this would be of more value to me later during the research phase of the course.

Although I felt competent in using statistical methods in analysing my research data, I felt that the advice of a statistician was required to be certain of the appropriate methods to use, and I had several consultations with the University of Portsmouth statistician, Dr. Reuben Ogollah. My prior experience gave me the confidence to discuss my requirements with Reuben without having to cover the basics, and to use his advice to come to a considered conclusion as to the appropriate methods to use.

Attribute affected:	*Transformed to:*
Lack of statistical analysis knowledge (W)*	Competence with statistical analysis methods (S)*

*S = strength; W = weakness

● *Event: Writing for publication* (see dissemination list, page xi)

 - acceptance of an article for journal publication

Writing succinctly to the standard required at doctoral level was not only necessary for the course unit assignments, but also useful for the preparation of articles for journal publication. An expectation of the professional doctorate course is the writing up of results for publication in an appropriate journal, so this was a weakness that had to be addressed. Completion of the unit assignments, and guidance and feedback on writing, helped me build these skills and gain confidence in this area. I was particularly pleased with an assignment written for unit 3, *Publication and Dissemination*, and I took the advice of both Dr. Isobel Ryder and Prof. Graham Mills who both suggested that I should submit the piece as an article for journal publication. The article was a journal review, focussing on how a journal's effectiveness in disseminating results and information can be measured, with particular emphasis on dissemination into the industrial occupational health field. This was published in the journal *Occupational Health [at Work]* (see dissemination list, page xi).

Publishing this article felt like a definitive step forward for me, and shows that the experience writing unit assignments has had a clear developmental effect on my writing skills. I now look forward to writing up my research results as articles for publication.

Attribute affected:	*Transformed to:*
Lack of experience writing at doctoral level (W)*	Writing at an appropriate level (S)*

*S = strength; W = weakness

- *Event: Spirometry training and experience*

  - formal training in spirometric assessment and interpretation

  - experience in performing spirometric tests in the workplace

In addition to developing the skills and confidence to perform spirometric testing, formal training and substantial subsequent experience in conducting workplace health surveillance testing has stimulated the development of specialised knowledge in this area. This is turn has increased the professional respect I receive in the workplace, and it is rewarding to know that employees trust me with confidential information and are keen to follow my advice. The confidence gained from conducting tests and overseeing the health surveillance programme was of critical importance during the data collection phase of my research, when I visited unfamiliar sites and tested new people; I was able to put these participants at ease and ensure good test performances, due to my previous experiences.

Attribute affected:	Transformed to:
Lack of specialised knowledge (W)*	Specialised knowledge base & competency in spirometric testing (S)*

*S = strength; W = weakness

● Event: *Conducting research study*

      - planning a feasible research study

      - data collection

      - reporting of results

The successful completion of this 'event' encompasses the development and utilisation of all the strengths mentioned previously. Although the research study was not conducted with the aim of addressing any single identified weakness, the weaknesses given above did need to be addressed for the research to be successfully conducted and reported.

This has led to the development of a strength that was not the result of a weakness identified in table 7.1 and subsequently transformed. The research study was the result of a great deal of planning and pre-emptive measures (spirometry experience, for example), and almost 3 years have passed between the initial proposal (quarter 1, 2010), and the writing up and submission of this thesis (quarter 4, 2012). As a result, I can now count *planning long-term projects* as a strength.

Attribute affected:	*Strength developed:*
_____	Planning long-term projects (S)*

*S = strength

● Event: *Study group days and tutorials*

      - formal and informal study days with peer group

      - regular communication with peer group

      - tutorials with first supervisor and regular contact for support and advice

A critical weakness arising from the first SWAIN analysis was my reluctance to involve or depend on others. Although this relates to a strength – independent working – I was aware that this may have become a liability during the professional doctorate course, as it was almost certain that I would need some form of support. Taking advantage of the formal study sessions, I gradually became friends with others in the study group, and this greatly assisted my progression through the course. I feel fortunate to be a member of a group with similar interests and needs, although our professional interests are often very different. I have felt truly comfortable with the group, both face-to-face and via remote contact. It is testament to the strength of our peer bond that if I ask a question or ask for support via email, I know that *someone* will respond swiftly. I have found this network of support to be invaluable, both directly (for example, proof-reading of my draft work) and indirectly, knowing that others in the group are undertaking similar tasks and are under similar pressures. I hope to remain in contact with members of the group long after the course has been completed.

The support I have received from Dr. Isobel Ryder has also been critical to my progress through the course, both as a unit tutor and as a first supervisor for my research. I have come to rely on Dr. Ryder in many ways, and I have made a conscious effort to accept this and not to be hesitant in accepting the support offered. It was Dr. Ryder who facilitated my entry onto the professional doctorate course, and she has been an ever-present source of support since.

I do feel that I still have a preference for independent working, but I realise that this is a strength I only have to make use of when it is necessary; it is not necessarily the default state of working, as I had previously thought. Due to my experiences on the course, I can now truly appreciate the value of support from others, and how this can enrich professional development and learning experiences.

Attribute affected:	Transformed to:
Remote / independent working (S)*	Remote / independent working when necessary (S)
	Preference for independent working (W)
	Appreciation of support from others (S)
Reluctance to involve / depend on others (W)*	

*S = strength; W = weakness

● *Additional: new weaknesses identified from current reflection*

Reflection on all the above factors and the general progression through the doctorate course has led me to become aware of further weaknesses, which could be addressed through future experiential learning.

Drive and ambition was identified as a strength in the first SWAIN analysis. I have long considered this to be a positive attribute which has fuelled my determination to complete every task I set out to achieve. For example, at the beginning of the research planning process (quarter 1, 2011), I planned out in detail each step of the process, culminating in the submission of this thesis and the subsequent presentation and *viva voce*. I remain on course with the time-bound steps of this timeline (appendix entry 21). This is in line with my long-held belief that a decision to undertake a task must inevitably lead to the completion of that task. On reflection, however, this suggests an unwillingness to even consider the *possibility* of failure, and this unwillingness leads to a lack of contingency planning in case of unforeseen obstacles and events. I believe the root of this to be a general fear of failure, which I have only now become aware of due to my reflection on the whole doctorate process and the development that has occurred as a result. In terms of addressing this in the future, I will be sure to consider the effects of unforeseen events on projects and tasks, and to clearly outline contingency plans, even when this does not feel necessary. I believe it is also necessary for me to come to terms with the idea that failure can itself be a learning process, and can provide valuable material for

personal reflection and further development. For example, the first presentation to the study group did not go well, but this provided the opportunity to develop and improve my skills in this area for future presentations.

Attribute:	Led to:
Drive and ambition (S)*	Fear of failure (W)*
	Lack of contingency planning (W)

*S = strength; W = weakness

Table 7.2 summarises how weaknesses identified in the first SWAIN analysis were acted upon in order to eliminate them or minimise their effects on further personal development. This leads to a second SWAIN analysis, with new strengths and weaknesses relevant to my current situation, and new needs and aspirations to take forward.

Table 7.2: Elimination or minimisation of weaknesses identified from SWAIN analysis				
From SWAIN analysis 1				*From SWAIN analysis 2*
Remote / independent working (S*) Reluctance to involve / depend on others (W*)	→	Support from first supervisor (N*) Support from tutors (N) Support from peer group (N)	→	Remote / independent working when necessary (S) Preference for independent working (W) Appreciation of support from others (S)
Lack of experience writing at doctoral level (W)	→	Experience writing / reviewing at doctoral level (N) Write and publish research article(s) (N)	→	Writing at an appropriate level (S)
Lack of experience presenting (W)	→	Experience delivering presentations (N)	→	Presentation skills (S)
Lack of statistical analysis knowledge (W)	→	Experience of statistical analysis methods (N)	→	Competence with statistical analysis methods (S)
Lack of specialised knowledge (W)	→	Development of specialised knowledge base (A*) Broad knowledge base (S) Spirometry training and experience (N) Plan and undertake research project (N)	→	Specialised knowledge base and competency in spirometric testing (S)
Drive and ambition (S)		→		Fear of failure (W) Lack of contingency planning (W)
		Plan and undertake research project (N)	→	Planning long-term projects (S)

*S = strength; W = weakness; A = aspiration; N = need

SWAIN analysis 2

Table 7.3 presents a SWAIN analysis, conducted as I approach the end of the professional doctorate process.

Table 7.3: SWAIN analysis, following completion of the professional doctorate	
STRENGTHS	**WEAKNESSES**
● adaptability	● preference for independent working
● prioritising / organising workloads	● fear of failure / unwillingness to contemplate failure
● remote / independent working when necessary	● determination and drive can blind to potential failures, and over-ride the need for contingency planning
● appreciation of the value of support from others	
● broad knowledge base	
● specialised knowledge in occupational respiratory issues and competency in conducting and interpreting spirometric tests	
● writing at a level suitable for doctoral work and for publication	
● presentation skills	
● ability to use appropriate statistical analysis methods for data manipulation	
● drive and ambition for progression	
● work ethic, professionalism	
● planning large / long-term projects	
ASPIRATIONS	**INTERESTS**
● professional development	● chemical industry
● maintain specialised knowledge base	● employee health and well-being
● conduct further research	● respiratory exposure, lung function / spirometry
● publish further research	● further investigation / follow-up of occupational health / exposure issues
● increased professional recognition through dissemination	
NEEDS	
● to conceive, plan and undertake further research projects, with appropriate contingency planning	
● to have support from employer: time allowed for planning and conducting research	
● to successfully write, submit and publish research article(s) in an appropriate journal	
● to keep up-to-date with developments in spirometric equipment, testing and/or interpretation via relevant literature, network of contacts, and refresher courses where appropriate.	

Conclusion

Reflection on the professional doctorate process and its developmental effects has demonstrated how powerful learning can be as an instrument for personal change. I have undergone true experiential learning throughout this course, and can now understand the value of an integrative approach, linking academic learning, work-based learning and personal development in such a way that one could not occur without the others. Strengths and weaknesses have been identified and addressed, with future needs clearly defined in order to meet aspirations and interests. The most important weaknesses in terms of personal development were not those weaknesses arising from a lack of experience, but deep-rooted personality attributes that, if left unaddressed, could limit further development and progress. One of those weaknesses (reluctance to involve others) was minimised, and the other, yet to be addressed (fear of failure), was discovered directly as a result of this reflective account.

This course has been a challenging experience, in terms of academic and integrative learning and practical issues such as time constraints, and yet with challenge comes reward. This process has enabled me to undergo significant developments both professionally and personally. I have achieved significant goals up to this point – publication of my work, conducting original research – and what I have learnt as a professional doctorate student will stay with me as I continue to progress further and achieve future goals.

Summary

This chapter has revisited the objectives defined in chapter 1 and assessed the work undertaken against those objectives, outlining any future work necessary to achieve them or to follow up the research carried out.

This chapter has also given a reflective account of personal and professional development throughout the course, and identified weaknesses remaining to be addressed and future needs to be fulfilled.

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Appendix

Entry 1: Critical Appraisal Skills Programme (CASP) – Case Control
Entry 2: Critical Appraisal Skills Programme (CASP) – Cohort
Entry 3: Spirometry training certificate (Royal Brompton, London, UK)
Entry 4: CPL Aromas' Health Surveillance programme
Entry 5: Data collection sheet
Entry 6: CPL Aromas' spirometry protocol
Entry 7: Email from Dr. Reuben Ogollah (28/07/2011), re: sample size
Entry 8: Ethical approval, SHSSW Research Ethics Committee
Entry 9: Information sheet for employees
Entry 10: Informed consent form
Entry 11: Confidentiality agreement
Entry 12: Invitation letter to companies
Entry 13: Acceptance form for the employer
Entry 14: Spirometry results form
Entry 15: Health and safety procedure, Cresylic acid
Entry 16: Pre-placement questionnaire
Entry 17: Pre-placement questionnaire, scoring guide
Entry 18: Poster presentation, European Respiratory Society, September 2012
Entry 19: Presentation feedback, January 2010
Entry 20: Presentation feedback, February 2011
Entry 21: Professional Doctorate study timeline

APPENDIX ENTRY 1

Critical Appraisal Skills Programme (CASP) – Case Control

CRITICAL APPRAISAL SKILLS PROGRAMME
making sense of evidence

11 questions to help you make sense of a Case Control Study

General comments

- Three broad issues need to be considered when appraising a case control study.

  Are the results of the study valid?

  What are the results?

  Will the results help locally?

  The 11 questions on the following pages are designed to help you think about these issues systematically.

- The first two questions are screening questions and can be answered quickly. If the answer to those two is "yes", it is worth proceeding with the remaining questions.

- There is a fair degree of overlap between several of the questions.

- You are asked to record a "yes", "no" or "can't tell" to most of the questions.

- A number of italicised hints are given after each question. These are designed to remind you why the question is important. There will not be time in the small groups to answer them all in detail!

A/   Are the results of the study valid?

Screening Questions

1 Did the study address a clearly focused issue?
 	
HINT: A question can be focused in terms of:
 	
   - *the population studied*
   - *the risk factors studied*
   - *whether the study tried to detect a beneficial or harmful effect?*
	Yes
	❏
		Can't tell
		❏
			No
			❏

2 Did the authors use an appropriate method to answer their question?
 	
HINT: Consider
 	
   - *Is a case control study an appropriate way of answering the question under the circumstances? (Is the outcome rare or harmful?)*
 	
   - *Did it address the study question?*
	Yes
	❏
		Can't tell
		❏
			No
			❏

Is it worth continuing?

Detailed Questions

| 3 Were the cases recruited in an acceptable way?

HINT: We are looking for selection bias which might compromise the validity of the findings:

   - *Are the cases defined precisely?*
   - *Were the cases representative of a defined population (geographically and/or temporally)?*
   - *Was there an established reliable <u>system</u> for selecting all the cases?*
   - *Are they incident or prevalent?*
   - *Is there something special about the cases?*
   - *Is the time frame of the study relevant to the disease/exposure?*
   - *Was there a sufficient number of cases selected?*
   - *Was there a power calculation?* | **Yes**
❏ | **Can't tell**
❏ | **No**
❏ |

4. Were the controls selected in an acceptable way?	Yes	Can't tell	No
	❏	❏	❏

HINT: We are looking for selection bias which might compromise the generalisability of the findings:

- *Were the controls representative of a defined population (geographically and/or temporally)?*
- *Was there something special about the controls?*
- *Was the non-response high? Could non-respondents be different in any way?*
- *Are they matched, population based or randomly selected?*
- *Was there a sufficient number of controls selected?*

5. Was the exposure accurately measured to minimise bias?	Yes	Can't tell	No
	❏	❏	❏

HINT: We are looking for measurement, recall or classification bias:
- *Was the exposure clearly defined and accurately measured?*
- *Did the authors use subjective or objective measurements?*
- *Do the measures truly reflect what they are supposed to measure? (have they been validated)*
- *Were the measurement methods similar in cases and controls?*
- *Did the study incorporate blinding where feasible?*
- *Is the temporal relation correct (does the exposure of interest precede the outcome?)*

6.

A. What confounding factors have the authors accounted for?

List the other ones you think might be important, that the authors missed *(genetic, environmental and socio-economic)*

B. Have the authors taken account of the potential confounding factors in the design and/or in their analysis?

HINT:
- *Look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors.*

List:

Yes	Can't tell	No
❏	❏	❏

B/ What are the results?

7. What are the results of this study? *HINT:* - *What are the bottom line results?* - *Is the analysis appropriate to the design?* - *How strong is the association between exposure and outcome (look at the odds ratio)?* - *Are the results adjusted for confounding and might confounding still explain the association?* - *Has adjustment made a big difference to the OR ??*	
8. How precise are the results? **How precise is the estimate of risk?** *HINT:* - *Size of the P-value* - *Size of the confidence intervals* - *Have the authors considered all the important variables?* - *How was the effect of subjects refusing to participate evaluated?*	
9. Do you believe the results? *HINT:* - *Big effect is hard to ignore!* - *Can it be due to chance, bias or confounding?* - *Are the design and methods of this study sufficiently flawed to make the results unreliable?* - *Consider Bradford Hills criteria (e.g. time sequence, dose-response gradient, strength, biological plausibility)*	**Yes** ❑ **No** ❑

Is it worth continuing?

C/ Will the results help me locally?

10. Can the results be applied to the local population? *HINT: Consider whether* - *The subjects covered in the study could be sufficiently different from your population to cause concern.* - *Your local setting is likely to differ much from that of the study.* - *Can you estimate the local benefits and harms?*	**Yes** ❏	**Can't tell** ❏	**No** ❏
11. Do the results of this study fit with other available evidence? *HINT:* - *Consider all the available evidence from RCTs, systematic reviews, cohort studies and case-control studies as well for consistency.*	**Yes** ❏	**Can't tell** ❏	**No** ❏

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making.
However, for certain questions observational studies provide the only evidence.
Recommendations from observational studies are always stronger when supported by other evidence.

APPENDIX ENTRY 2

Critical Appraisal Skills Programme (CASP) – Cohort

CRITICAL APPRAISAL SKILLS PROGRAMME
making sense of evidence

12 questions to help you make sense of a cohort study

General comments

- Three broad issues need to be considered when appraising a cohort study.

    Are the results of the study valid?

    What are the results?

    Will the results help locally?

    The 12 questions on the following pages are designed to help you think about these issues systematically.

- The first two questions are screening questions and can be answered quickly. If the answer to those two is "yes", it is worth proceeding with the remaining questions.

- There is a fair degree of overlap between several of the questions.

- You are asked to record a "yes", "no" or "can't tell" to most of the questions.

- A number of italicised hints are given after each question. These are designed to remind you why the question is important. There will not be time in the small groups to answer them all in detail!

A/ Are the results of the study valid?

Screening Questions

	Yes	Can't tell	No

1 Did the study address a clearly focused issue?
 	
HINT: A question can be focused in terms of:
 	
    - the population studied
    - the risk factors studied
    - the outcomes considered
    - is it clear whether the study tried to
      detect a beneficial or harmful effect?
	❑	❑	❑

2 Did the authors use an appropriate method to answer their question?
 	
HINT: Consider
 	
    - Is a cohort study a good way of
      answering the question under the
      circumstances?
    -Did it address the study question?
	❑	❑	❑

Is it worth continuing?

Detailed Questions

	Yes	Can't tell	No

3 Was the cohort recruited in an acceptable way?
 	
HINT: We are looking for selection bias which
        might compromise the generalisability of
        the findings:
 	
    - Was the cohort representative of
      a defined population?
    - Was there something special about the
      cohort?
    - Was everybody included who should
      have been included?
	❑	❑	❑

4. Was the exposure accurately measured to minimize bias? *HINT: We are looking for measurement or classification bias:* *- Did they use subjective or objective measurements?* *- Do the measures truly reflect what you want them to (have they been validated)?* *- Were all the subjects classified into exposure groups using the same procedure?*	**Yes** ❑	**Can't tell** ❑	**No** ❑
5. Was the outcome accurately measured to minimize bias? *HINT: We are looking for measurement or classification bias:* *- Did they use subjective or objective measurements?* *- Do the measures truly reflect what you want them to (have they been validated)?* *- Has a reliable <u>system</u> been established for detecting all the cases (for measuring disease occurrence)?* *- Were the measurement methods similar in the different groups?* *- Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?*	**Yes** ❑	**Can't tell** ❑	**No** ❑
6. **A. Have the authors identified all important confounding factors? List the ones you think might be important, that the authors missed.** **B. Have they taken account of the confounding factors in the design and/or analysis?** *HINT:* *- Look for restriction in design, and techniques eg modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors*	**Yes** ❑ **Yes** ❑ **List:**	**Can't tell** ❑ **Can't tell** ❑	**No** ❑ **No** ❑

7. A. Was the follow up of subjects complete enough?	Yes ❏	Can't tell ❏	No ❏

B. Was the follow up of subjects long enough?
 	
HINT:
  - The good or bad effects should have had long enough to reveal themselves
  -The persons that are lost to follow-up may have different outcomes than those available for assessment
  - In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?
	Yes ❏	Can't tell ❏	No ❏

B/ What are the results?

8. What are the results of this study? HINT: - What are the bottom line results? - Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference? - How strong is the association between exposure and outcome (RR,)? - What is the absolute risk reduction (ARR)?	9. How precise are the results? How precise is the estimate of the risk? HINT: - Size of the confidence intervals
10. Do you believe the results? HINT: - Big effect is hard to ignore! - Can it be due to bias, chance or confounding? - Are the design and methods of this study sufficiently flawed to make the results unreliable? - Consider Bradford Hills criteria (eg time sequence, dose-response gradient, biological plausibility, consistency).	Yes ❏ Can't tell ❏ No ❏

C/ Will the results help me locally?

11. Can the results be applied to the local population?
 	
HINT: Consider whether
 	
  - The subjects covered in the study could be sufficiently different from your population to cause concern.
  - Your local setting is likely to differ much from that of the study
  - Can you quantify the local benefits and harms?
	Yes ❏	**Can't tell** ❏	**No** ❏

12. Do the results of this study fit with other available evidence?	**Yes** ❏	**Can't tell** ❏	**No** ❏

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making.
However, for certain questions observational studies provide the only evidence.
Recommendations from observational studies are always stronger when supported by other evidence.

APPENDIX ENTRY 3

Spirometry training certificate (Royal Brompton, London, UK)

TO WHOM IT MAY CONCERN

I can confirm that:

Garry Dix

Attended the two day accredited Spirometric
Training Course at The Royal Brompton Hospital, Lung Function Unit,
on the 1st and 2nd March 2010.

The course covered all aspects of Spirometry including:

Quality control techniques
Performance of tests
Interpretation of test results
Cross Contamination.

Mr. D. Cramer

Mr. S. Ward

Mrs. S. Thomas

Course Tutors

02/03/10

APPENDIX ENTRY 4

CPL Aromas' Health Surveillance programme

CPL Aromas
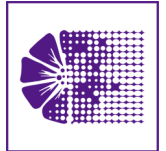
Health & Safety
BRIEFING

To all Brixworth Personnel:

Health Surveillance

According to the Control of Substances Hazardous to Health (COSHH) Regulations 2002, we have a legal requirement to carry out health surveillance for our employees where:

- There is a disease associated with the substance in use (e.g dermatitis)
- It is possible to detect the disease or adverse change

Starting in March 2010, it is our intention to introduce a program of health surveillance for CPL employees at Brixworth. The aims of the program are to:

- Protect the health of employees by early detection of adverse changes or disease;
- Collect data for detecting or evaluating health hazards;
- Evaluate our control measures.

The initial checks are designed to establish a baseline, then if there is any deterioration over time, we can identify any potential issues at an early stage before they become a major problem.

The surveillance activity will centre around lung function tests and checks on skin condition. The extent of the checks made will very much depend on the type of work the employee is involved in. Garry Dix will be the person who will represent CPL in carrying out this work, and this will involve him working on a one-to one basis with employees. Any information that Garry collects will be held in strictest confidence, and only he will have access to these records.

If anyone requires any further information or clarification, please speak to either Garry or myself.

Brian White
No: B110- 22.2.10
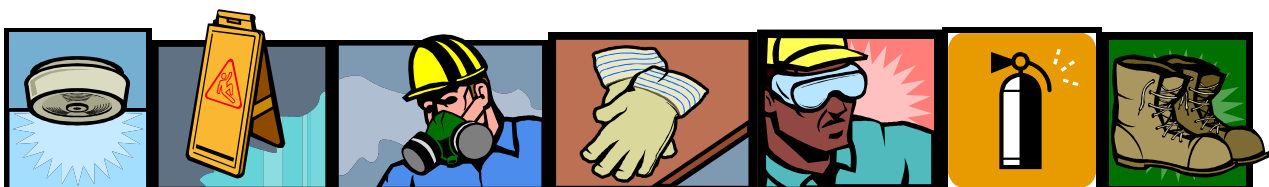
Employee Induction Program – Health Surveillance

Name:	Start Date:
Location:	Job Function:

● **Health Surveillance is a LEGAL REQUIREMENT, as defined under specific legislation:**

Control of Substances Hazardous to Health (COSHH) Regulations
Health Surveillance
11. — (1) Where it is appropriate for the protection of the health of his employees who are, or are liable to be, exposed to a substance hazardous to health, the employer shall ensure that such employees are under suitable health surveillance.

(2) Health surveillance shall be treated as being appropriate where—
(b) the exposure of the employee to a substance hazardous to health is such that —
(i) an identifiable adverse health effect may be related to the exposure,
(ii) there is a reasonable likelihood that the adverse effect may occur under the particular conditions of his work, and
(iii) there are valid techniques for detecting indications of the adverse effect, and the technique of investigation is of low risk to the employee.

(3) The employer shall ensure that a health record is made and maintained and that that record or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.

● **Health Surveillance is also an ETHICAL REQUIREMENT:**

As part of due diligence and our duty of care to you the employee, it is important that we monitor your health (in relation to your work-place activities), so that work-related health issues can be foreseen and avoided where possible.

Please remember that as well as fulfilling a legal requirement, this system is for YOUR benefit as an employee.

● **Qualified Person:**

The Health Surveillance system is overseen by Garry Dix in the Regulatory Department at Brixworth. Garry has a post-graduate Medical qualification (PGDip Medical Toxicology), has taken the Hippocratic Oath, and is currently studying for a Professional Doctorate. Garry therefore fulfils the criteria of a 'Qualified Person' to manage a Health Surveillance system, as defined by the Health & Safety Executive (HSE).

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● Advice given:

You may be given advice by the Qualified Person following an assessment – it is your choice and your responsibility to follow such advice. Please remember that any such advice will be given in the best interests of your work-related health.

● Storage of records:

All Health Surveillance records will be kept in a secure location by the Qualified Person, who will have sole access to these records. In the event that the Qualified Person leaves CPL Aromas, and no suitably qualified replacement is appointed, you will be given the option of taking your individual records home and storing them personally.

● If your work activities at CPL Aromas will involve the regular use of chemicals:

You will be given a pre-placement or initial Health Surveillance questionnaire, and you will be required to complete this and return it to the Qualified Person; you may be asked to update these questionnaires periodically.
You will also be required to attend a session with the Qualified Person, who will take an initial set of measurements. These will be taken using a machine called a spirometer, which measures lung function and simply requires you to blow into the machine as directed, and a dermal hydration analyser, which uses a probe to measure the hydration levels of the skin on your hands and forearms. These are very simple tests and can be carried out quickly. You will be required to attend these sessions periodically to provide updated measurements.

● If your work activities at CPL Aromas will not involve the regular use of chemicals:

You will be offered the opportunity to take part in the program and undergo lung function and dermal assessments as described above.

Signed: _____   Date: _____
                    Manager

Signed: _____   Date: _____
                    Employee

Health Surveillance
UPDATE

● Two rounds of Health Surveillance assessments have been carried out so far at Brixworth (March and May). The next round will take place at the beginning of July.

● 50 individuals have now been assessed.

● Lung function (spirometry) tests have shown no respiratory issues that need to be addressed. Even the smokers among you have performed well!

● Skin hydration tests have shown some skin dryness with some individuals – advice given:
     - use the moisturising cream provided in the workplace;
     - if possible, also use hand moisturising cream at home;
     - when using washing-up liquid (whether at home or in the workplace), it is very important to wear gloves – washing-up liquid is a product designed to remove fats and oils, and this is exactly what it will do to your skin.

● So-called "Barrier / Protective cream" has been removed from the site by Brian at my request, for these reasons:
     - "Barrier / Protective cream" is a marketing term, and does not accurately describe what the product does. This cream does not provide any protective function whatsoever.
     - using this cream may provide a false sense of protection for the individual; i.e. someone might use the cream and believe it provides the same protection as gloves.
     - applying "Barrier cream" immediately before putting on gloves may actually increase your skin's permeability. If you wish to use cream before putting gloves on, you can use the regular moisturising cream, but you MUST give it a few minutes to soak in (e.g. while you are changing).

Health Surveillance
UPDATE

CPL Aromas
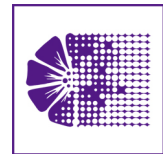
● Hand-washing (QC) – Brian is organising a hand-washing and hand-cream dispenser for the QC lab. If hand-washing product is required in the meantime, please ask Brian. Please do NOT wash your hands using washing-up liquid.
If Product Performance or the Sampling area also require this, please let Brian know.

● Cotton inserts – a number of individuals are now using cotton inserts underneath gloves, and have found these helpful. If anyone else feels these would be useful, please talk to Brian or myself. (You do NOT have to pay for these yourself.)

● Finger-cots have been trialled for me by some of the QC staff. These are basically the finger part of a glove, and provide protection for the thumb and forefinger without having to wear a full glove. I am about the order the first quantity of these, in XL size. If you feel these might be useful to you, please ask myself or Brian.

● Next stages – I have initially concentrated on BX staff for whom chemical use is a direct element of their work – Production, Sampling, QC, PPD etc.
The assessments will also be offered to BX office staff on a voluntary basis, should anyone wish to take advantage of this. (TBA)
I will also set up the same service for staff at Barrington Hall, again initially concentrating on those who use chemicals as part of their normal work. (TBA)

● All staff taking part have been co-operative and supportive of what is a completely new service at CPL. I would like to thank all of you for your assistance and support.

Garry Dix
Regulatory Dept.

APPENDIX ENTRY 5

Data collection sheet

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

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The purpose of this data collection sheet is to collect information which will be used, together with lung function data, for a study on the effects of respiratory exposure to chemicals. This study will form part of the Researcher's Doctoral thesis.

All information provided is strictly confidential, and will be stored securely by the Researcher. Only the researcher will have access to this information. No individual identifiers will be used at any stage of the research or in presentation or publication of the results.

Please try to answer all questions.

SECTION 1: PERSONAL INFORMATION

NAME:	
Date of Birth: (DD/MM/YYYY)	
MALE / FEMALE:	
COMPANY:	
DEPARTMENT:	

BIRTH WEIGHT
If you know your approximate birth weight, please enter it here. You may use imperial (e.g. "8lbs 3oz") or metric measurements (e.g. "3.63kg"):

EXERCISE HABITS
Please choose a number between 1 and 5 to represent the time you spend on exercise or equivalent physical activity: *(1 = Never, 5 = Every day)*

1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

PreAssess Issue v1 Aug 2011

SECTION 2: SOCIO-ECONOMIC INFORMATION

MARITAL STATUS			
Please tick ONE of the following:			
Single	Married or with long-term partner	Divorced	Widowed
☐	☐	☐	☐

EDUCATIONAL LEVEL			
Please tick ONE of the following:			
GCSE or equivalent	A-level / AS-level or equivalent	Undergraduate degree / Honours degree / Diploma or equivalent	Postgraduate qualification
☐	☐	☐	☐

HOUSEHOLD INCOME				
Please choose a number between 1 and 5 to represent your overall household income: (1 = low income, 3 = average income, 5 = high income)				
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

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DISTANCE OF FAMILY HOME FROM MAJOR ROAD				
Please estimate the distance between your family home and the nearest regularly-used main road or 'A' road. Tick ONE of the following:				
House is on a major road	House is less than 150 metres from major road	House is between 150 and 500 metres from major road	House is between 500 metres and 1 kilometre from major road	House is greater than 1 kilometre from major road
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

SECTION 3: SMOKING HISTORY

SMOKING STATUS		
Please tick ONE of the following, and answer any following questions:		
Non-smoker	**Ex-smoker**	**Current smoker**
☐	☐ ⇩	☐ ⇩
	How many years ago did you quit?	*How many do you smoke per day on average?*
		For how many years have you been smoking?

SECTION 4: ASTHMA & OTHER CHEST CONDITIONS

ASTHMA & ALLERGIES		
Do you have asthma?	Yes ☐	No ☐
Did you suffer with asthma as a child?	Yes ☐	No ☐
Does anyone in your family have asthma?	Yes ☐	No ☐
Do you suffer seasonally with hay-fever?	Yes ☐	No ☐
Does anyone in your family suffer seasonally with hay-fever?	Yes ☐	No ☐
Do you have any allergies? (If 'Yes', please give details)	Yes ☐ ⇓	No ☐
	Please give details:	

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OTHER CHEST PROBLEMS		
Do you have any chest problem, condition or illness that is NOT asthma? (for example, chronic obstructive pulmonary disease, bronchitis)	Yes ☐ ⇓	No ☐
	Please give details:	
	How long have you been aware of this?	
Does anyone in your family have any chest problem, condition or illness that is NOT asthma?	Yes ☐ ⇓	No ☐
	Please give details:	

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CHILDHOOD CHEST ILLNESSES		
As a child, did you suffer with any chest illness or disease such as pneumonia or whooping cough?	Yes ☐ ⇓	No ☐
	Please give details:	

SYMPTOMS				
Please rate the following symptoms in terms of their effects on your day-to-day life. **Symptoms are rated from 1 to 5, where 5 = no effects.** **Please choose a number between 1 and 5 for each symptom.**				
BREATHLESSNESS: (please choose one)				
1: Breathless after getting dressed	**2: Breathless after a short walk**	**3: Breathless after walking uphill or flights of stairs**	**4: Breathless after brief or mild exercise**	**5: Breathless only after prolonged exercise / Never feel breathless**
☐	☐	☐	☐	☐

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WHEEZING: (please choose one)

1: Wheezing after getting dressed	2: Wheezing after a short walk	3: Wheezing after walking uphill or flights of stairs	4: Wheezing after brief or mild exercise	5: Wheezing only after prolonged exercise / Never wheeze
☐	☐	☐	☐	☐

COUGHING: (please choose one)

1: Coughing when at rest	2: Coughing after a short walk	3: Coughing after walking uphill or flights of stairs	4: Coughing after brief or mild exercise	5: Never have coughing episodes
☐	☐	☐	☐	☐

LIMITATION OF REGULAR ACTIVITIES: (please choose one)

1: My chest or breathing problem severely restricts my daily activities	2: My chest or breathing problem restricts at least one daily activity	3: My chest or breathing problem does not restrict daily activities, but does prevent me from exercising	4: My chest or breathing problem does not restrict daily activities, but does prevent me from prolonged exercise	5: I do not have a chest or breathing problem, so my daily activities are not restricted
☐	☐	☐	☐	☐

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INTERRUPTION OF SLEEP: (please choose one)				
1: Every night, my chest or breathing problem causes me to wake in the night, or earlier than I otherwise would have	**2: My chest or breathing problem regularly causes me to wake in the night, or earlier than I otherwise would have**	**3: My chest or breathing problem sometimes causes me to wake in the night, or earlier than I otherwise would have**	**4: My chest or breathing problem rarely causes me to wake in the night, or earlier than I otherwise would have**	**5: I do not have a chest or breathing problem that causes me to wake in the night, or earlier than I otherwise would have**
☐	☐	☐	☐	☐

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SECTION 5: PREVIOUS OCCUPATIONAL EXPOSURE

In ANY previous jobs, have you been exposed to any of the following substances?

Please ONLY consider exposure during paid or voluntary employment.

Wood-dust (e.g. wood-working)	Mushroom compost (from mushroom growing sheds)	Poultry-house dust	Hay	Coal-dust
☐	☐	☐	☐	☐
Flours or grains (e.g. bakery, food processing)	**Smelting fumes or dust**	**Quartz dust**	**Construction or building dust**	**Pesticides**
☐	☐	☐	☐	☐
Aluminium	**Nickel (e.g. from welding)**	**Cadmium**	**Platinum salts (platinum refining)**	**Hair bleaching powder**
☐	☐	☐	☐	☐

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Have you EVER been employed in the following jobs:			
Printing, painting/decorating, OR spray-painting	Plastics manufacturing	Pharmaceutical manufacturing	Road laying / working with asphalt or tar
☐	☐	☐	☐
Medical technician	Industrial cleaner OR hospital cleaner	Domestic / household cleaner	Production of flavourings / flavours
☐	☐	☐	☐
Metalworker OR foundry worker	Textiles worker	Farm worker OR working with animals	Hairdresser
☐	☐	☐	☐

SECTION 6: PREVIOUS NON-OCCUPATIONAL EXPOSURE

Have you EVER taken part in the following hobbies:			
Wood-working	Metal-working or soldering (includes jewellery-making)	Painting	Activities using glues or adhesives, such as model kits
☐	☐	☐	☐

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Signature:	
Print name:	
Date:	

After the research has been completed, I wish this information to be:	
Destroyed by the Researcher	**Returned to me by post**
☐	☐
	Please provide address:

Researcher Contact Details:
Garry Dix
Doctoral student, University of Portsmouth
Email: garry.dix@cplaromas.com
Direct dial: 01604 799918

APPENDIX ENTRY 6

CPL Aromas' spirometry protocol

CPL Aromas

Protocol for taking Lung Function Measurements using MicroPlus Spirometer

- Ensure the room is at an acceptable ambient temperature.

- Allow 10 minutes for the spirometer to acclimatise.

- Ensure you are wearing gloves (change gloves between patients).

- Invite patient in; ask patient to sit down, ensure they are comfortable.

- Explain what the spirometer is and that it measures lung function.

- Ask about contraindications – do not perform the spirometry if any contraindications exist.

Contraindications:

Glaucoma

Recent eye surgery

Pregnancy

Recent pneumothorax (collapsed lung)

Coughing up blood

Recent abdominal surgery

Heart problems / chest pains

Recent heart attack or stroke

- Explain procedure (reminder if patient has been seen before), and the correct technique. Remind the patient that you will also talk them through it.

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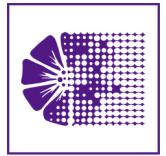
• Take a disposable one-way mouthpiece and attach to the spirometer's central section. Allow the patient to see you do this; remind them that it is disposable and one-way for hygiene reasons.

• Technique:

- Switch on the spirometer.

- Hand the spirometer to the patient.

- The patient should take a number of deep, relaxing breaths, followed by one large breath in to completely fill the lungs. They should be encouraged to do this.

- With that full breath, the patient should place their lips around the disposable mouthpiece, ensuring that their lips form a tight seal. Observe that the seal is sufficient.

- The patient should then begin the manoeuvre. They should be encouraged to blow out as hard and as fast as they can initially, and then for as long as they can in one single breath. They will often need encouragement to continue the manoeuvre for as long as necessary.

- Observe the rotating vane within the spirometer's central part – this is crucial to the measurement mechanism. When the vane ceases spinning, there is no air passing through the mechanism, and you can tell the patient to stop and withdraw from the mouthpiece. You may find it necessary to explain the mechanism to the patient, as they will tend to feel as if they are 'empty' far sooner than they actually are.

- Ask the patient if they are feeling any dizziness or light-headedness; if so, you may need to allow time to recover before proceeding. Do not proceed further if you are in any doubt about this – re-arrange the appointment and try again.

• Annotate the results from the spirometer's display onto the spirometry record sheet – allow the patient to see you do this.

• Have the patient perform 3 of these manoeuvres. Annotate all the results, and make a note of the highest measurement for each measure.

CPL Aromas

• The best measurements can be used later for comparison against predicted values and calculation of percentage-of-predicted (%PRED) figures.

• Sign and date the record sheet, and ask the patient to do the same.

• The sheet should be stored with the patient's Occupational Health record, in a secure lockable cabinet.

• Between patients, dispose of the mouthpiece, and wipe the central section and the area held by the patient with an alcohol wipe. Once daily during every round of appointments, the central section should be removed and disinfected with PeraSafe cleaning fluid. The spirometer should be returned to the manufacturer annually for calibration.

• Note: these results are strictly confidential. The patient's results should not be discussed with anyone else, unless you have the express permission of the patient to do so and you have discussed and agreed on a set course of action that is necessary for the well-being of the patient.

• Note: you must remain friendly and approachable during the assessments. At any point during the assessment a patient may show interest and ask you what the measurements mean, what the point of spirometry is, and so on. You must answer such questions with openness, honesty and clarity.

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March 2010

APPENDIX ENTRY 7

Email from Dr. Reuben Ogollah (28/07/2011), re: sample size

From:	Reuben Ogollah <Reuben.Ogollah@port.ac.uk>
Sent:	28 July 2011 15:55
To:	Garry Dix
Subject:	Re: FW: Statistical info following meeting 25/03

Hi Gary,

Find below the modification of the sample size based on the reduction of power and an increase of effect size:

The sample size calculation is based on the primary outcome, that is, the FEV_1 measure expressed as percentage of predicted values. Analysis of covariance (ANCOVA) will be used to compare the FEV_1 measures between the two groups at the end of the shift adjusting for the baseline FEV_1 measures and other four possible confounders, namely, smoking, family history of respiratory problems, personal history of respiratory problems, and Body Mass Index.

Option 1

A total sample of 108 patients will be required to provide an 80% chance of detecting a statistically significance differences in the mean FEV_1 measures between the exposed and the non-exposed groups (assuming a 7% percentage of variance explained, implying an effect size of 0.27) at a 5% two-sided significance level.

Option 2.....you could probably go for this

A total sample of 126 patients will be required to provide an 80% chance of detecting a statistically significance differences in the mean FEV_1 measures between the exposed and the non-exposed groups (assuming a 6% percentage of variance explained, implying an effect size of 0.25) at a 5% two-sided significance level.

Option 3

A total sample of 168 patients will be required to provide a 90% chance of detecting a statistically significance differences in the mean FEV_1 measures between the exposed and the non-exposed groups (assuming a 6% percentage of variance explained, implying an effect size of 0.25) at a 5% two-sided significance level.

BW,

Reuben

>>>

From:	Garry Dix <garry.dix@cplaromas.com>
To:	"Reuben Ogollah (Reuben.Ogollah@port.ac.uk)" <Reuben.Ogollah@port.ac.uk>, "isobel.ryder@port.ac.uk" <isobel.ryder@port.ac.uk>
Date:	27/07/2011 15:31
Subject:	FW: Statistical info following meeting 25/03

Hi Both,

Further to the below,

I will meet Reuben at 3pm tomorrow, then Isobel immediately afterwards.

Reuben, can you let me know where to meet you?

Thanks

G

Garry Dix BSc (Hons) PGDip AMRSC
Chemicals & Health Effects Advisor
Brixworth, UK

Main: +44 (0) 1604 882 100
Direct: +44 (0) 1604 799 918
Ext: 2918
www.cplaromas.com

CPL Aromas

From: Garry Dix
Sent: 27 July 2011 15:12
To: 'Reuben Ogollah'; isobel.ryder@port.ac.uk
Subject: RE: Statistical info following meeting 25/03

Hi Reuben,

Many thanks for setting aside time to see me tomorrow. (Previous emails below)

Isobel – Reuben is available between 3pm-5pm. Can you let me know when you are available around this time so I can set definite times.

Thanks both

G

Garry Dix BSc (Hons) PGDip AMRSC
Chemicals & Health Effects Advisor
Brixworth, UK

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Direct: +44 (0) 1604 799 918
Ext: 2918
www.cplaromas.com

From: Reuben Ogollah [mailto:Reuben.Ogollah@port.ac.uk]
Sent: 12 May 2011 16:19
To: Garry Dix
Subject: RE: Statistical info following meeting 25/03

Hi Gary,

I've just done a rough calculation of the sample size. It can never be precise as a lot of parameters which we don't have are required.

The sample size calculation is based on the primary outcome, that is, the FEV_1 measure expressed as percentage of predicted values. Analysis of covariance (ANCOVA) will be used to compare the FEV_1 measures between the two groups at the end of the shift adjusting for the baseline FEV_1 measures and other four possible confounders, namely, smoking, family history of respiratory problems, personal history of respiratory problems, and Body Mass Index. Assuming a 5% partial percentage of variance explained by these factors, a total sample of 244 patients will be required to achieve a 90% power to detect differences in the mean FEV_1 measures between the exposed and the non-exposed groups versus the alternative of equal means using an F test with a 5% two-sided significance level.

The above calculation is based on the final analysis being done using ANCOVA, if you plan to analyse using any other method then the sample size will be different.

Regards,

Reuben

>>>

> **From:** Garry Dix <garry.dix@cplaromas.com>
> **To:** Reuben Ogollah <Reuben.Ogollah@port.ac.uk>
> **Date:** 11/05/2011 11:25
> **Subject:** RE: Statistical info following meeting 25/03
>
> Hi Reuben,
>
> How is it going with the below info?
>
> Thanks
> Garry
>
>
> ***Garry Dix BSc (Hons) PGDip AMRSC***
> ***Chemicals & Health Effects Advisor***
> ***Regulatory Dept.***
> ***CPL Aromas***

From: Reuben Ogollah [Reuben.Ogollah@port.ac.uk]
Sent: 30 March 2011 16:04
To: Garry Dix
Subject: Re: Statistical info following meeting 25/03

Thanks Gary, I'll have a look early next week and get back to you.

Regards,

Reuben.

>>>

From:	Garry Dix <garry.dix@cplaromas.com>
To:	"reuben.ogollah@port.ac.uk" <reuben.ogollah@port.ac.uk>
CC:	Garry Dix <garry.dix@cplaromas.com>
Date:	30/03/2011 15:24
Subject:	Statistical info following meeting 25/03

Hi Reuben,

Information below as requested.

I will be away from the 5th to the 9th of April, so if you need further clarification of anything before you do the sample size calculation, please email before the 5th. Otherwise, I look forward to hearing back from you before you are on holiday from the 11th April.

Stats info for Sample Size calculation:

• Summary:
Multi-site cross-sectional analysis with controls.
Investigating the effects of respiratory exposure to chemicals and chemical compounds on lung function of employees within the fragrance industry.
Lung function will be measured for each participant at the beginning and end of shift – this gives a cross-shift decline. Exposed group will be employees working directly with chemicals; non-exposed group will be employees with no direct contact with chemicals. Outcome will be continuous rather than binary, with a comparison of means between the exposed and non-exposed groups.

• Outcome measures:
Lung function measured using spirometric measurements.

• Primary outcome measure:
FEV_1 (forced expiratory volume in one second)
Converted to percentage of predicted values, so written as "88%pred" (for example)

• Secondary outcome measures:
FVC (forced vital capacity)
PEF (peak expiratory flow)
Both also converted to percentage of predicted values.

• Clinically important difference in cross-shift decline:
Greater than 5% difference in cross-shift decline is clinically significant.

• Expected difference in cross-shift decline between exposed and non-exposed:
Cross-shift decline in previous similar studies varies between 1.5% - 12%.
If a range of expected difference is sufficient for you, then take 2% - 10%.
If you need a specific figure, take 6%.

• Number of confounders (4):
1) Smoking
2) family history of respiratory problems
3) personal history of respiratory problems
4) BMI

• Power: 90%
• Significance: 5%

• One overall analysis combining multi-site data: adjust for any factors within companies (e.g. better ventilation)

• Appropriate statistical analysis = multivariate analysis

Thanks
Garry

Garry Dix BSc (Hons) PGDip AMRSC
Chemicals & Health Effects Advisor
Regulatory Dept.
CPL Aromas
Direct Dial: 01604 799918
Tel: 01604 799900 ext 2918
Fax: 01604 882707

APPENDIX ENTRY 8

Ethical approval, SHSSW Research Ethics Committee

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

School of Health Sciences and Social Work

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and Social Work
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James Watson Hall (West)
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Mr G. Dix
School of Health Sciences and Social Work
University of Portsmouth

28 June 2011

Dear Garry,

Application to SHSSW Research Ethics Committee:

Thank you for submitting the above application to the SHSSW Research Ethics Committee.

Ethics committee members have raised one or two concerns they would like you to address before going ahead with your research project. Formally this is known as a '**favourable opinion with provision**'. In particular we would like you to:

1. Consider the possibility that employees could become anxious about possible ill effects of their work. If so, you may need to provide a contact or source where people can go for more information if they have concerns.

2. Related to the above, consider what you might need to do if there is an issue found following the spirometric tests which falls outside the remit of the study. What might the referral route need to be? What support mechanisms?

3. Discuss with the employers what their responsibilities might be should the spirometric tests positively identify issues arising from exposure to these chemicals. How would this be addressed?

4. Reflect on whether there a potential conflict of interests between your position within the organisation CPL Aromas and the companies you are approaching? Would they understand themselves as CPL's competitors and do any issues arise from this?

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5. Make it clearer to potential participants that you are doing this project for the award of a Professional Doctorate, including saying this at an earlier point in your information sheet etc.

6. Related to the above, use University headed paper on all documents.

7. You also refer to a questionnaire for participants to complete – it would be helpful for us to see this too.

We recommend that you discuss these concerns with your supervisor in the first instance.

The Committee would appreciate a response regarding these points before a favourable opinion can be given.

Yours sincerely

John Crossland
Chair of SHSSW Research Ethics and Peer Review Committee

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Garry Dix

From: garrydix@aol.com
Sent: 05 July 2011 11:03
To: Garry Dix
Subject: Fwd: Amended version (and apology)

-----Original Message-----
From: John Crossland <John.Crossland@port.ac.uk>
To: garrydix <garrydix@aol.com>
Sent: Tue, 5 Jul 2011 10:41
Subject: Re: Amended version (and apology)

Thanks Garry, that's really helpful and meets all our requirements. Can I suggest just one more small amendment that has occurred to me in reading your responses? When you give your contact details you list yourself in your professional role. I wonder whether it might be helpful to foreground your role as a doctoral researcher by using your Portsmouth email address and contact details, especially as this was discussed with the industry executives?

Clearly you also need to acknowledge your employment and professional status, maybe you could offer that as an alternative contact or perhaps merge the two by describing your status on the information sheet as 'Doctoral Researcher', not your professional role, and putting the address as 'c/o CPL Aromas etc', and giving your Portsmouth email address?

Best regards (and good luck with it all!),

John

John Crossland
Senior Lecturer (Social Work with Older People) School of Health Sciences and Social Work University of Portsmouth
James Watson West
2 King Richard 1st Road
Portsmouth
PO1 2FR

D/L: +44 (0)23 9284 2837
T: +44 (0)23 9284 4440
F:+44(0)23 9284 4402
>>> <garrydix@aol.com> 04/07/2011 14:30 >>>
Dear John,

Please find attached my comments in response to the Ethics Committee's feedback. I have also attached the documents amended in line with the feedback. (Please note that I have highlighted additions to the Information Sheets.)

Best regards,
Garry

From: John Crossland <John.Crossland@port.ac.uk>
To: garrydix <garrydix@aol.com>
CC: Isobel Ryder <Isobel.Ryder@port.ac.uk>; Rebecca Stores <Rebecca.Stores@port.ac.uk>
Sent: Fri, 1 Jul 2011 14:35
Subject: Amended version (and apology)

Dear Garry,

Please find attached an amended version of the feedback letter from the SHSSW ethics committee. Unfortunately, I included some feedback (item 8 in the previous version) that was intended for another postgrad student. I would appreciate it if you would delete that version.
Please accept my apologies for this mistake.

Best regards,

John

John Crossland
Senior Lecturer (Social Work with Older People) School of Health Sciences and Social Work University of Portsmouth
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APPENDIX ENTRY 9

Information sheet for employees

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

Information Sheet for Employees – Research Proposal *(v3-0611)*

The purpose of this Information Sheet is to invite you to take part in a research study, and to explain the aims and basic outline of the study.

What is the purpose of the research?

The purpose of the research is to investigate the effects of chemicals use on lung function. This will either confirm that existing protective measures are adequate, or suggest where improvement is needed.

This study will form part of the researcher's Professional Doctorate studies, which are undertaken via Portsmouth University. Successful completion of the study and presentation of the results will lead to the award of a Doctorate.

Why have I been invited to participate?

You have been invited to take part in the study because you are an employee within the fragrance production industry, and either:

- you use chemicals as a routine part of your daily work, or:
- you do NOT use chemicals as a routine part of your daily work, and you will act as a reference population for comparison.

Do I have to participate?

Your participation in the study is entirely voluntary. If you do choose to take part, you may withdraw at any time without giving a reason.

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

School of
Health Sciences
and Social Work

University of
PORTSMOUTH

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What will I be required to do?

You will be required to attend an appointment with the researcher, arranged in your workplace at the beginning of your working shift, for an assessment of your lung function. This will be carried out using a device called a spirometer, which measures lung function and simply requires you to blow into the machine as directed by the researcher. You will then be required to attend an identical appointment at the end of your working shift. These appointments take a maximum of 15 minutes.

Prior to this, you will be given a questionnaire to complete and hand to the researcher.

How will my data be used?

Lung function results will be used for statistical calculations. Information taken from the questionnaire – such as smoking habits – will also be used.

Will my name be visible alongside the results of my lung function tests?

The study is designed so that your data will be completely anonymous – no individual identifiers will be used in calculations or seen in the presentation of results, at any stage.

All lung function data and questionnaires are strictly confidential, and will be stored for the duration of the study in a lockable cabinet to which only the researcher has a key. Following the completion of the study, all personal data will either be returned to you or destroyed by the researcher, at your preference.

How is the study funded?

The researcher's annual university fees and all costs associated with the study, chiefly travel costs and equipment consumables, are funded by CPL Aromas.

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and Social Work
University of Portsmouth
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Review and approval

Formal ethical approval for this study will be sought from the School of Health
Sciences and Social Work (SHSSW) Research Ethics and Peer Review (RE&PR)
Committee at Portsmouth University.

Researcher contact information

Garry Dix

Doctoral Researcher

c/o CPL Aromas

Quarry Road, Scaldwell Industrial Estate, Brixworth, Northants NN6 9UB

hsc90520@myport.ac.uk; garry.dix@cplaromas.com

Direct Dial: 01604 799918

APPENDIX ENTRY 10

Informed consent form

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

School of Health Sciences and Social Work

University of Portsmouth

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Informed Consent Form *(v2-0611)*

Name:	Date of Birth:
Company:	Location:
Job Function:	

Research project: Study to investigate effects of chemicals use on lung function.

Name of Researcher(s): Garry Dix, Professional Doctorate student at the University of Portsmouth. Direct Dial: 01604 799918. Email address: garry.dix@cplaromas.com

1. I confirm that I have read and understand the Information Sheet for Employees for the above research project, and have had the opportunity to ask questions which have been answered fully.   ***PLEASE TICK BOX:***

2. I understand that my participation is voluntary and I am free to withdraw at any time without giving reason. If I decide to withdraw from the study I will notify the researcher as soon as possible.   ***PLEASE TICK BOX:***

3. I understand that data from lung function assessments and questionnaires will be used for statistical analysis for the purposes of this study; this data will be used anonymously, and no individual identifiers will be used in the calculation or presentation of results. I hereby give permission for such data to be used as described.   ***PLEASE TICK BOX:***

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and Social Work

University of
Portsmouth

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T: +44 (0)23 9284 4440
F: +44 (0)23 9284 4402

4. I agree to take part in this research project.   *PLEASE TICK BOX:*

Signed: _____   Date: _____
                Participant

Signed: _____   Date: _____
                Researcher

APPENDIX ENTRY 11

Confidentiality agreement

CPL AROMAS LTD

CONFIDENTIALITY AGREEMENT

THIS AGREEMENT relates to and is solely concerned with the collection, storage and subsequent disposal of research data for the purposes of a research study undertaken solely by Garry Dix, Chemicals & Health Effects Advisor at CPL Aromas, hereinafter referred to as the Researcher.

THIS AGREEMENT is made this …………..day of ………………….. between the Researcher, whose contact details are given at the end of this document, and ……………………………………………………………………………… , whose registered office is at ……...…………………………………………………….. ……………………………………………………………………………………….. and any division or subsidiary thereof.

THE SPONSOR of the research study is CPL Aromas Ltd whose registered office is Barrington Hall, Hatfield Broad Oak, Bishop's Stortford, Hertfordshire CM22 7LE, and any division or subsidiary thereof, hereinafter referred to as CPL Aromas.

THE CONFIDENTIAL INFORMATION consists of: a) lung function (spirometry) test results conducted on staff during a single pre-shift assessment and a subsequent single post-shift assessment; and b) information given by staff on confidential pre-assessment questionnaires. a) and b) are hereinafter referred to collectively as the Confidential Information.

IT IS AGREED as follows:-

(1)   ……………………………….. agrees to allow staff to participate in the research study on a voluntary basis.

(2)   ………………………………… agrees to provide a suitable private area on their premises for the Researcher to conduct spirometric assessments.

(3)   CPL Aromas agrees to provide suitable facilities for the Researcher to plan and organise the research study, and to release the Researcher for site visits to participating companies for the purposes of data collection and such organisational meetings that are required.

(4)   The Researcher agrees to treat individual identifiers and company identifiers supplied as part of the Confidential Information as strictly confidential and not to divulge such identifiers to any third party for any purpose whatsoever.

(5)   The Researcher agrees to use the Confidential Information only for the purpose provided and hold the Confidential Information securely. The Confidential Information shall be stored by the Researcher in a secure, lockable cabinet to which only the Researcher shall have access, and/or electronically on a password-protected personal computer.

(6)   CPL Aromas agrees to take part in the research as a participating company, and agrees to allow staff to participate in the research study on a voluntary basis.

(7)   The Researcher agrees that no part of the Confidential Information will be made available to other parties at CPL Aromas. The Researcher further agrees that for the purposes of this research, CPL Aromas are considered to be a participatory company, and no information, reports or articles will be made available to CPL Aromas except that which will be made simultaneously available to other participatory companies.

(8)   The Researcher agrees that upon completion of the study, the Confidential Information shall be either destroyed by the Researcher or returned to each individual participant without unreasonable delay, and that this shall be the choice of the individual participant. Electronic information shall be permanently erased.

(9)   The Researcher agrees that in the presentation and defence of the research and findings, no individual identifiers or company identifiers will be included in any material pertaining to such presentation and defence.

(10)   The Researcher agrees that no individual identifiers or company identifiers will be included in articles arising from this research that are submitted for publication in a relevant peer-reviewed journal, or any material pertaining to such submissions. The Researcher further agrees to make available to all participating companies any articles intended for submission for publication, and/or any preliminary reports, in advance of submission.

(11)   The validity, interpretation and effect of this Agreement shall be governed by the laws of England and Wales.

(12)   This Agreement represents the entire Confidentiality Agreement between the parties and may be amended only by an instrument in writing signed by the parties hereto.

Signed by:

The Researcher
Garry Dix BSc (Hons) PGDip AMRSC
garry.dix@cplaromas.com
(01604) 799918
c/o CPL Aromas, Quarry Road, Scaldwell Industrial Estate, Brixworth, Northants
NN6 9UB.

Signed by:

for and on behalf of ………………………………………….

APPENDIX ENTRY 12

Invitation letter to companies

Garry Dix
Chemicals & Health Effects Advisor, Regulatory Dept.
CPL Aromas
Quarry Road, Scaldwell Industrial Estate
Brixworth, Northants NN6 9UB
garry.dix@cplaromas.com

February 2011

Welcome to the Information Pack for Employers, outlining my proposed research study and inviting you as a company to participate.

The purpose of the study is to investigate the effects of respiratory exposure to chemicals on lung function, and to develop a predictive pre-employment screening (PES) occupational health questionnaire.

This Information Pack comprises the following, which should explain the aims, justification, design and methodology of the proposed study:

● Information Sheet for Employers v1

● Information Sheet for Employees v2

● Proposal Presentation (print version)

● Consent Form v2

● Spirometry Protocol

You will shortly be formally invited to participate in the study. I would greatly appreciate it if you would read the enclosed information carefully, and discuss this with the appropriate person(s) in your workplace.

Should you have any questions or require further clarification, please contact me at the above email address.

Please also advise me of the relevant contact person within your workplace – I will require regular contact with this person for organisational purposes.

Thank you for taking the time to read this Information Pack and consider this proposal.

Best regards,

Garry Dix BSc (Hons) PGDip AMRSC

Researcher contact information:

Garry Dix
Chemicals & Health Effects Advisor, Regulatory Dept.
CPL Aromas
Quarry Road, Scaldwell Industrial Estate
Brixworth, Northants NN6 9UB
garry.dix@cplaromas.com
Direct Dial: 01604 799918

APPENDIX ENTRY 13

Acceptance form for the employer

Acceptance Form (for the Employer)

Research project: Study to investigate effects of chemicals use on lung function.

Name of Researcher(s): Garry Dix, Professional Doctorate student at the University of Portsmouth. Direct Dial: 01604 799918. Email address: garry.dix@cplaromas.com

I confirm that I have read and understand the Information Sheet for Employers for the above research study.

I hereby declare that ………………………………………………………………………
are willing to participate in the research study as described. This declaration is given in line with stipulations detailed in the Confidentiality Agreement drawn up for this study. I understand that the Confidentiality Agreement must be signed by both parties before data collection commences.

Signed:

on behalf of ……………………………………………………………………………………

Print name: …………………………………………………………………………………

Job title / Department: ……………………………………………………………………....

Date: …………………………………………………………………………………………...

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

I nominate the following colleague to act as a contact liaison for the Researcher, for the purposes of receiving and distributing pre-assessment questionnaires, and to aid in organising the timing of the Researcher's site visits.

Name: …………………………………………………………………………………

Job title / Department: ……………………………………………………………….

Email address: ………………………………………………………………………..

Telephone: …………………………………………………………………………….

APPENDIX ENTRY 14

Spirometry results form

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Portsmouth

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NAME:	
AGE:	
MALE / FEMALE:	
COMPANY:	
POSITION:	

CODE No:	
COMPANY CODE No:	

Weight (kg)	Height (m)	Body mass index (kg / m^2)
Sitting height, SiH (m)	Stool height (m)	Upper body segment, UBS (m) (SiH minus stool height)

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Spirometry (lung function) readings PRE-SHIFT:						
	Reading 1	**Reading 2**	**Reading 3**	**Predicted**	**Best of 3**	**%PRED**
FEV$_1$ (litres)						
FVC (litres)						
PEF (litres/min)						

Spirometry (lung function) readings POST-SHIFT:						
	Reading 1	**Reading 2**	**Reading 3**	**Predicted**	**Best of 3**	**%PRED**
FEV$_1$ (litres)						
FVC (litres)						
PEF (litres/min)						

SPIR Issue v1 July 2011

School of
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and Social Work

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Portsmouth

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Cross-shift decline:			
	Absolute decline from baseline	**%pred decline from baseline**	**> 7% difference %pred Y/N**
FEV$_1$ (litres)			
FVC (litres)			
PEF (litres/min)			

Employee:					
Signature:		**Print name:**		**Date:**	
Researcher:					
Signature:		**Print name:**		**Date:**	

APPENDIX ENTRY 15

Health and safety procedure, Cresylic acid

Garry Dix

From:	Brian White
Sent:	25 July 2012 10:54
To:	Garry Dix
Subject:	FW: Safety Procedure for Handling Cresylic Acid
Attachments:	SOP 041 Handling of Cresylic Acid.pdf

For your information

From: Brian White
Sent: 12 June 2012 14:58
To: Wong Chi Wah; Mandy Cheung; Frank Ballen; Donato Natalizio
Cc: Alan Osbiston; George Ewen; Elaine Brown; Mary Flowerdew
Subject: Safety Procedure for Handling Cresylic Acid

Dear All

We have recently carried out a risk assessment to look at our handling methods for cresylic acid (00641) in our Brixworth factory. This was prompted by some recent incidents where production employees sustained minor chemical burns to the skin following exposure.

Cresyilic acid is a particularly nasty chemical, presenting a dual hazard - it is toxic as well as corrosive. We thought we had adequate protection in place for our employees, but this was not the case.

After consulting our supplier, examining the Safety data sheet for 00641 and risk assessing our methods, we have published a procedure for safe handling – please see attached. If creylic acid is being handled at your site, please ensure that this procedure is introduced. Any suggested improvements are welcome.

This procedure has been written specifically for a production situation. We also need to consider how to handle safely in other areas such as goods-in sampling, QC testing, perfumery, etc. Another similar material under consideration is para cresol (00484), although the quantities used are smaller.

We will pass on further procedures when completed.
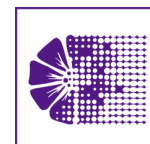
Regards

Brian White
QSHE Manager
CPL Aromas Ltd
EU Manufacturing, UK

Main: +44 (0) 1604 882100
Direct: +44 (0) 1604 799907
Fax: +44 (0) 1604 882707
Email: brian.white@cplaromas.com
Web: www.cplaromas.com

Please consider the environment before printing this e-mail

1

Safe System of Work **Handling Cresylic Acid in Production**	Author	BW
	Date	17.5.12
	Issue No	1
SOP-041	Page	1 of 2

CPL Aromas

1   **PURPOSE**

To define a safe method for the handling of **cresylic acid (00641)** and formulae containing the **cresylic acid.** This procedure has been written for the handling of quantities of 1kg or more, and so applies to operations in the factory and warehouse.

2   **SAFETY CONSIDERATIONS**

- Cresylic acid is both **toxic** and **corrosive**, and therefore needs to be handled in the correct way to prevent skin exposure.
- The personal protective equipment (PPE) required, should provide a suitable barrier to protect the skin, and should be such that it give full body cover:
    - o   Full chemical body suit and bootees with high levels of protection against organic acids (e.g. made from Microchem® 4000)
    - o   Acid resistant gauntlets (e.g. PVC type)
    - o   Full face visor
- The PPE is to be worn as per the photograph below:

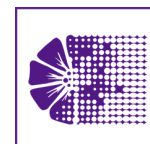Ensure that the:
- o   Hood is pulled *over* the mask
- o   Sleeves are pulled down *over* the gauntlets
- o   Trouser legs are *over* the bootees

This will prevent any splashing from finding its way onto the skin

3   **GENERAL RULES**

- Full PPE **MUST** be worn at all times when handling 00641 or 00641 containing products.
- If the correct PPE is not available, then the job **MUST NOT** go ahead.

Safe System of Work	Author	BW
Handling Cresylic Acid in Production	Date	17.5.12
	Issue No	1
SOP-041	Page	2 of 2

CPL Aromas

4   COMPOUNDING

- Before decanting anything from the IBC, ensure that the top bung is loosened. This will prevent the contents from surging.
- If using a pipe to decant, ensure that the pipe is securely fastened, and not showing any obvious signs of wear.
- One person only should be in the vicinity when decanting.
- Spills and drips must be cleaned up as soon as they occur.

5   MIXING & PACKING

- The pumping operation must be supervised at all times by the operator, so that if there are any problems, they can be addressed quickly.
- Before commencing pumping, ensure that the pump pipework is inspected for any signs of wear. Check that the pipe is well secured to the pump handle. Worn parts should be replaced/tightened.
- To prevent unnecessary exposure, only one person should be in the vicinity of the pumping operation.
- The pump is dedicated and is housed in a dedicated cupboard.
- Put a bucket under the tank outlet to collect drips. Care needs to be taken when uncoupling the pipework and emptying out the pipes to ensure none of the drips lands on the floor.
- Spills and drips must be cleaned up as soon as they occur.

6   SPLASHES

- For severe splashing over the suit, then take care when removing the suit so as not to expose the skin.
- Any skin exposure, and the acid should be washed off **immediately** with plenty of soap and water.
- For severe splashing over the skin, then the drench shower should be used **immediately**.
- Seek first aid attention for any chemical burn sustained. If there are any doubts or concerns over the injury, then a hospital visit is required.

7   WASTE DISPOSAL

Waste **MUST NOT** be put in with general waste, but should be processed by a licensed waste disposal company.
- Used absorbent materials must be placed in thick gauge polyethylene bags and the top secured.
- Likewise soiled suits, gauntlets, etc should be sealed for disposal.

COSHH Manager
CPL Aromas Intranet

View Item: [_____]

[Supplier Documents]   [Item Consumption]
[View Hazard]   [Print]   [Update]

[View]

Item Code:	00641
Item Description:	CRESYLIC ACID 50 MC
Alternative Name:	Cresylic acid
Status:	Production

Document Control

Assessed By:	Anne Connet
Assessed Date:	26/07/2011
Next Assessment:	26/07/2016

Usage Information

Primary Use:	Fragrance Ingredient
Appearance:	Liquid
Frequency of Use:	Medium (Up to 5 times a week)
Usage Volume:	High (More than 2000 kilogram per year)
Locations:	Laboratories, Production, Warehouse

Risks

Flammability:	Low (Flashpoint > 61°C)
Exposure Limits:	WEL-TWA: 22 mg/m³ WEL-STEL:
Physical Effects:	High (Corrosive, C) Eyes: Yes Lungs: Yes Skin: Yes
Health Effects:	High (Toxic, T) Inhalation: Yes Ingestion: Yes Skin: Yes

Monitoring

Health Surveillance:	No
Workplace Exposure:	Yes

Controls

Remove:	(none)
Substitute:	(none)
Dilute:	(none)
Use PPE:	Yes Gloves: Must be worn Glasses: Must be worn Dust Mask: Not required Body Protection: Must be worn Face Shield: Must be worn Respirator: Not required
PPE Comments:	Gauntlets must be worn

Recently Viewed Items More »

CRESYLIC ACID 50 MC 00641	
TERPINEOL 900 00544	
BENZYL SALICYLATE 00066	
HEXYL CINNAMIC ALDEHYDE 00267	
ACETYL PYRIDINE 2- 04538	

Due Assessment More »

AMYL SALICYLATE 00305	23/02/2012
ORANGE OIL (NAT MIX) GUINEA SWEET DECOL 01259	02/04/2012
KOUMALACTONE 10% TEC 05308	22/06/2012
HYPO- LEM/DIHYDROCITRONE LLYLNITRILE 03261	09/07/2012
CEDAR LEAF OIL/THUJA OIL (NAT) 00317	09/07/2012
CREMOPHOR CO60 00126	13/07/2012
STYRAX RESINOID (NAT) HONDURAS 03285	13/07/2012
TERPINENE-4-OL 00741	19/07/2012
ETHYL BENZOATE 00936	19/07/2012
SULFOX 00907	19/07/2012

APPENDIX ENTRY 16

Pre-placement questionnaire

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

School of Health Sciences and Social Work

University of **Portsmouth**

PRE-PLACEMENT RESPIRATORY QUESTIONNAIRE (Fragrance industry)

Please complete the following questions. A score will be calculated from the answers and used to evaluate your respiratory function. This is independent of any lung function testing which may be required as part of your working role.

All information provided is strictly confidential, and will be stored securely as part of your personal file.

Physical information (such as height) will be measured during an appointment.

Please try to answer ALL other questions.

SECTION 1: PERSONAL INFORMATION

NAME:	
Date of Birth: (DD/MM/YYYY)	
MALE / FEMALE:	
COMPANY:	
DEPARTMENT:	

BIRTH WEIGHT
If you know your approximate birth weight, please enter it here. You may use imperial (e.g. "8lbs 3oz") or metric measurements (e.g. "3.63kg"):

Predictive Q Issue v1 Aug 2012

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_____

Please leave blank, to be measured during appointment:

Weight (kg)	Height (m)	Body mass index (kg / m^2)
Sitting height, SiH (m)	Stool height (m)	Upper body segment, UBS (m) (SiH minus stool height)

_____

SMOKING STATUS		
Please tick ONE of the following:		
Non-smoker	Ex-smoker	Current smoker
☐	☐	☐

EXERCISE HABITS				
Please tick ONE of the following, to represent the time you spend on exercise or equivalent physical activity: *(1 = Never, 5 = Every day)*				
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

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SECTION 2: SOCIO-ECONOMIC INFORMATION

MARITAL STATUS			
Please tick ONE of the following:			
Single	Married or with long-term partner	Divorced	Widowed
☐	☐	☐	☐

EDUCATIONAL LEVEL			
Please tick ONE of the following:			
GCSE or equivalent	A-level / AS-level or equivalent	Undergraduate degree / Honours degree / Diploma or equivalent	Postgraduate qualification
☐	☐	☐	☐

HOUSEHOLD INCOME				
Please tick ONE of the following, to represent your overall household income: (1 = low income, 3 = average income, 5 = high income)				
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Predictive Q Issue v1 Aug 2012

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

DISTANCE OF FAMILY HOME FROM MAJOR ROAD				
Please estimate the distance between your family home and the nearest regularly-used main road or 'A' road. Please tick ONE of the following:				
House is on a major road	House is less than 150 metres from major road	House is between 150 and 500 metres from major road	House is between 500 metres and 1 kilometre from major road	House is greater than 1 kilometre from major road
☐	☐	☐	☐	☐

SECTION 3: SYMPTOMS & HISTORY

SYMPTOMS				
COUGHING - Please tick ONE of the following:				
1: Coughing when at rest	2: Coughing after a short walk	3: Coughing after walking uphill or flights of stairs	4: Coughing after brief or mild exercise	5: Never have coughing episodes
☐	☐	☐	☐	☐

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ASTHMA & HAY-FEVER		
Do you have asthma?	Yes ☐	No ☐
Does anyone in your family have asthma?	Yes ☐	No ☐
Do you suffer seasonally with hay-fever?	Yes ☐	No ☐

CHILDHOOD CHEST ILLNESSES		
As a child, did you suffer with any chest illness or disease such as pneumonia or whooping cough?	Yes ☐ ⇓	No ☐
	Please give details:	

PREVIOUS OCCUPATION(S)			
Have you EVER been employed in the following jobs:			
Printing, painting/decorating, OR spray-painting ☐	**Plastics manufacturing** ☐	**Pharmaceutical manufacturing** ☐	**Road laying / working with asphalt or tar** ☐
Medical technician ☐	**Industrial cleaner OR hospital cleaner** ☐	**Domestic / household cleaner** ☐	**Production of flavourings / flavours** ☐
Metalworker OR foundry worker ☐	**Textiles worker** ☐	**Farm worker OR working with animals** ☐	**Hairdresser** ☐

Signature:	
Print name:	
Date:	

Predictive Q Issue v1 Aug 2012

APPENDIX ENTRY 17

Pre-placement questionnaire, scoring guide

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

**School of
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University of Portsmouth

PRE-PLACEMENT RESPIRATORY QUESTIONNAIRE (Fragrance industry)

ATTACHMENT: SCORING GUIDE

Select the appropriate score from each question response. Add the scores to give a total score, and convert this to a percentage of the maximum possible score.

SECTION 1: PERSONAL INFORMATION

NAME:	
Date of Birth: (DD/MM/YYYY)	
MALE / FEMALE:	
COMPANY:	
DEPARTMENT:	

BIRTH WEIGHT		
If you know your approximate birth weight, please enter it here. You may use imperial (e.g. "8lbs 3oz") or metric measurements (e.g. "3.63kg"):		
Score: for each kg below 5.06kg, score 1.10 *Note: if given in imperial measurements, convert to kg.*	Score:	

Weight (kg)	Height (m)	Body mass index (kg / m^2)	
Sitting height, SiH (m)	Stool height (m)	Upper body segment, UBS (m) (SiH minus stool height)	
Score (BMI): *BMI = <25.0: score 2.86* *BMI = 25.0 – 29.9: score 1.43* *BMI = ≥30: score 0*		Score:	
Score (UBS): *for each metre below 0.96m, score 23.53*		Score:	

SMOKING STATUS		
Please tick ONE of the following:		
Non-smoker	**Ex-smoker**	**Current smoker**
☐	☐	☐
Score: *Non-smoker: score 0* *Former smoker: score 2.18* *Smoker: score 4.36*		Score:

Dr Jeannette Bartholomew BSc PhD PGCE ILTM
Head of School

EXERCISE HABITS				
Please tick ONE of the following, to represent the time you spend on exercise or equivalent physical activity: **(1 = Never, 5 = Every day)**				
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Score: 0	*Score: 1.80*	*Score: 3.60*	*Score: 5.40*	*Score: 7.20*
			Score:	

SECTION 2: SOCIO-ECONOMIC INFORMATION

MARITAL STATUS			
Please tick ONE of the following:			
Single	**Married or with long-term partner**	**Divorced**	**Widowed**
☐	☐	☐	☐
Score: 7.46	*Score: 3.73*	*Score: 0*	*Score: 0*
		Score:	

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EDUCATIONAL LEVEL			
Please tick ONE of the following:			
GCSE or equivalent	**A-level / AS-level or equivalent**	**Undergraduate degree / Honours degree / Diploma or equivalent**	**Postgraduate qualification**
☐	☐	☐	☐
Score: 0	Score: 1.18	Score: 2.36	Score: 3.54
			Score:

HOUSEHOLD INCOME				
Please tick ONE of the following, to represent your overall household income: (1 = low income, 3 = average income, 5 = high income)				
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Score: 0	Score: 2.17	Score: 4.34	Score: 6.51	Score: 8.68
				Score:

DISTANCE OF FAMILY HOME FROM MAJOR ROAD				
Please estimate the distance between your family home and the nearest regularly-used main road or 'A' road. Please tick ONE of the following:				
House is on a major road	House is less than 150 metres from major road	House is between 150 and 500 metres from major road	House is between 500 metres and 1 kilometre from major road	House is greater than 1 kilometre from major road
☐	☐	☐	☐	☐
Score: 3.52	*Score: 2.64*	*Score: 1.76*	*Score: 0.88*	*Score: 0*
				Score:

SECTION 3: SYMPTOMS & HISTORY

SYMPTOMS				
COUGHING - Please tick ONE of the following:				
1: Coughing when at rest	2: Coughing after a short walk	3: Coughing after walking uphill or flights of stairs	4: Coughing after brief or mild exercise	5: Never have coughing episodes
☐	☐	☐	☐	☐
Score: 5.84	*Score: 4.38*	*Score: 2.92*	*Score: 1.46*	*Score: 0*
				Score:

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ASTHMA & HAY-FEVER		
Do you have asthma?	Yes ☐	No ☐
	Score: 4.28	*Score: 0*
		Score:
Does anyone in your family have asthma?	Yes ☐	No ☐
	Score: 0.88	*Score: 0*
		Score:
Do you suffer seasonally with hay-fever?	Yes ☐	No ☐
	Score: 0.47	*Score: 0*
		Score:

CHILDHOOD CHEST ILLNESSES		
As a child, did you suffer with any chest illness or disease such as pneumonia or whooping cough?	Yes ☐	No ☐
	Score: 1.05	*Score: 0*
		Score:

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PREVIOUS OCCUPATION(S)			
Have you EVER been employed in the following jobs:			
Printing, painting/decorating, OR spray-painting ☐	Plastics manufacturing ☐	Pharmaceutical manufacturing ☐	Road laying / working with asphalt or tar ☐
Medical technician ☐	Industrial cleaner OR hospital cleaner ☐	Domestic / household cleaner ☐	Production of flavourings / flavours ☐
Metalworker OR foundry worker ☐	Textiles worker ☐	Farm worker OR working with animals ☐	Hairdresser ☐
Score: *if ONE OR MORE of the listed occupations is ticked, score 0.58.* *Note: score ONLY 0.58, regardless of number of occupations ticked.*		Score:	

Total score:		**Maximum possible score:**	59.85
		Percentage of total score:	**%**

APPENDIX ENTRY 18

Poster presentation, European Respiratory Society, September 2012

Chemical exposure and lung function in the fragrance industry: a multi-site cross-sectional study

Garry R. Dix BSc (Hons) PGDip AMRSC

School of Health Sciences and Social Work, University of Portsmouth, UK; CPL Aromas, Brixworth, Northants, UK

Introduction

Respiratory studies within the fragrance industry have historically been carried out on single raw materials or on the final product as used by the consumer. Fragrance production employees, however, are exposed to large quantities of mixtures over working shifts, at exposure levels orders of magnitude higher than the final consumer.

There is a lack of published literature studying the effects of exposure to chemicals on fragrance production employees.

This study aims to answer the research question (below) by conducting a multi-site cross-sectional study using employees from the fragrance industry.

In fragrance industry employees, is occupational respiratory exposure to chemicals linked to a reduction in lung function?

Methods

A cross-sectional study was designed, using an exposed group (fragrance production and associated functions, n=60) and a control group (non-exposed fragrance industry employees, e.g. office staff, n=52). 5 UK companies took part, giving a total of 112 participants. This was calculated as sufficient to achieve 80% power and 5% significance. Spirometric measurements (FEV$_1$, FVC and PEF*) were taken pre-shift and post-shift, and cross-shift change was calculated. Questionnaires were completed by participants for information on potential confounding factors (smoking, personal or family history of respiratory problems, body mass index).

Analysis of covariance (ANCOVA) was performed using the statistical package SPSS (version 18).

* FEV$_1$ = forced expiratory volume in 1 second; FVC = forced vital capacity; PEF = peak expiratory flow

Results

Adjusted mean difference in cross-shift change between groups (exposed vs. control) for each outcome measure was **NOT** observed to be statistically significant.

Outcome measure	Mean post-shift measurement (SD)	F value (df)[+]	P-value[+]
FEV$_1$, %predicted			
Control (reference), n=52	99.0 (12.9)	0.127 (1,105)	0.722
Exposed, n=60	98.0 (14.5)		
FVC, %predicted			
Control (reference), n=52	107.8 (14.3)	0.022 (1,105)	0.883
Exposed, n=60	105.9 (14.2)		
PEF, %predicted			
Control (reference), n=52	103.4 (15.6)	0.176 (1,105)	0.676
Exposed, n=60	98.6 (16.8)		

[+]Adjusted for the baseline (pre-shift) measures as well as BMI, smoking status, personal history of respiratory problems and family history of respiratory problems

Conclusions

Occupational respiratory exposure to chemicals used in fragrance production was **NOT** observed to have a significant effect on lung function.

The results of this study are limited to UK sites, and the industry would benefit from extension of the study to non-UK sites.

Bibliography

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APPENDIX ENTRY 19

Presentation feedback, January 2010

Course Participant: GARRY DIX

Oral assessment for Doctoral level Unit: PdD01

Fields:	Clarity and explanation. To include:	Remarks
Content and Explanation - there is no set order for this presentation; students are free to present as they choose. *Consider:* • *Is this vague or confusing?* • *Are there definitions that the audience need to know* • *Are the ideas easy to follow?* • *Is the material presented relevant/sufficient to illustrate main points?*	Rationale for topic/problem chosen Description/explanation of topic (which *might* include use of theory/definitions as appropriate) Relevance and need of research question in relation to: a) The Workplace/Practice Relevance and need of research question in relation to b) Current literature Presentation of a clearly defined and focused research question	. Nice introductory overview with terms clearly explained. Good contextual information to give both the local and national situation. Breakdown of PECO appears realistic.
Organisation of argument	**Logical sequence and structure of talk. Consider:** • Overall structure of talk • Flow from one section to the next • Relevant time allocation to sections	Good logical flow to slides with interesting content ,clip art. Etc. Appropriate use of time allocation to each section. Well done.
Presentation-	**Ability to engage audience. Consider:** • Eye contact • Use of language • Pitch & pace correct for specified audience • Clarity of power point presentations • Response to questions √ • Suitable quantity of information for time allocation/requirement of assessment	Good response to questions. However, when talking in future, turn your body so that you can see the slides as well as remain engaged with the audience.
Additional comments from Markers		

Agreed Mark (subject to changes at the Board of Examiners) – PASS

Professional Doctorate Programme
Unit 1: Professional Review & Development

Name: Garry Dix.   Health Surveillance.

Date: 22/01/2010.

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

- at times, too much wording on slides - can lose interest.

- good use of clip-art to break up monotony of slides

Coherence of approach

a good logical running order.

brought together with good research question.

Engagement with the group

Answered questions with ease & confidence.

Comments for progress:

would encourage ↑ eye-contact with group → always looking at screen; during the talk. - came across as nervous.

Professional Doctorate Programme
Unit 1: Professional Review & Development

Name: Gary Dix   — Health Surveillance

Date:

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Clear -and included explanation of areas that may be new to group membes.

Coherence of approach

followed a logical patten

Engagement with the group

Answered questions with clarity.

Comments for progress:

I wonder how you will be able to manage the mixed needs as these seem to change quite rapidly eg give up smoking/change home cleaning materials -quite a challenge I think.

Professional Doctorate Programme
Unit 1: Professional Review & Development

Name: GARRY DIX

Date: 22|1|2010

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Good

Coherence of approach

Good

Engagement with the group

Good

Comments for progress:

Define measurement criteria more specially

APPENDIX ENTRY 20

Presentation feedback, February 2011

Assessment Criteria - Presentations

Student name   Garry DIX   Course   PDs in Healthcare
or number:

Unit   Publication & Dissemination

Unit   Dr I Ryder
co-ordinator:

Marker: Prof G Mills   Agreed   Pass
                            Dr A Dewey, Dr S Kilburn   Mark:

Presentations will be assessed in relation to the following criteria
✓

In the work there is.-	Little or no evidence	satisfactory level of evidence	good standard achieved	high standard achieved
Competent use of appropriate media			✓	
Relevance of material to address topic set			✓	
Clear and effective presentation of material			✓	
Ability to engage in academic debate			✓	
Use of relevant and current literature to view the topic in perspective			✓	
Logical and coherent structure and style			✓	
Lucid and accurate use of language			✓	

Comments:

Marker 1:
- Good engagement with the audience. Kept to time.
- Shown knowledge gap in fragrance industry. Exposure of employees to respiratory hazards.
- Researched literature. PECO given. Question defined.
- Exposed vs non-exposed (non-clinical).
- Sample size issue 70-75, power calculation discussed. Widen to fragrance industry.
- Second question – answered well.
- Gaps identified in methodology that need addressing.

Marker 2:
- Explore diseases more – asthma – will you need to tie in lung function with exposure, as it is reversible? Yes, you do ie pre/post test.
- Emphysema is outdated term, replaced by COPD. This is irreversible so FEV may be nil.
- PECO should be design-free. C – not exposed.

Marker 3:
- Range for low + illness related.
- Answered questions well.
- More use of graphs, pictures illustrations please.
- Perhaps type a little larger for those at the back.
- Measurement of FEV over time.

FIRST MARKER Sig …………………………………………   **Date:**

SECOND MARKER Sig ……………………………………..   **Date:**

School of Health Sciences & Social Work

Name: Gary Dix

Pathway:

Date: 11. 02 . 11.

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Professional powerpoint.

Kept to time

Handouts Provided.

Coherence of approach

Logical approach.
Background.
Literature
Research approach.

Engagement with the group

Clear Verbal presentation
Maintained eye Contact.
responded to questions

Comments for progress:

More consideration of inclusion /
exclusion. and measures.
taking note of who are smokers etc
time of year,

well done.

Jan

Name: GARY DIX

Date: 11 – 2 – 11

Pathway:

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Good use of Power point slides, easy to read.
Explained abbreviations.

Coherence of approach

Easy to understand
loud enough to hear

Engagement with the group

Looks + engages c̄ group.

Comments for progress:
Good use of PECO
Research Question
methodology. — problems c̄ sample size – thought of ways
round it.
Included Bias + Confounders.
? Ethics·   No costings for funding grant

Professional Doctorates in Healthcare
Unit 3: Publication & Dissemination

Name: ~~Graham~~ Dix Gary.

Date: 11.02.2011

Pathway:

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Very clear & presentation.

Style was excellent.

Coherence of approach

√ The main reasons for research was were well articulated.

Logical.

Engagement with the group

— Good eye contact.

— Answered the questions appropriately & which raised some next steps which ~~Graham~~ Gary has will consider as his project develops.

Comments for progress:

Gary's research has is proving very well & is making a great progress

Professional Doctorates in Healthcare
Unit 3: Publication & Dissemination

Name: Gary Dix

Date: 11/2/11

Pathway:

Peer Feedback for Progress: *please comment in relation to the following:*

Clear and effective presentation of material

Clear presentation & slides. Dropped
voice a little occasionally
Kept to time

Coherence of approach

Logical linear approach to the subject
led us through

Engagement with the group

Mild humour helped with the engagement
Which was generally good.

Comments for progress:

APPENDIX ENTRY 21

Professional Doctorate study timeline

28/04/2011: Portsmouth Session; submit PDd03 Portfolio

May 2011: PDd01 Portfolio Part2

August 2012: Finalise predictive questionnaire

September 2012: Send draft thesis for comments

April/May 2011: Ethics

June/July 2012: Write up Part2, Draft

July 2012: Health Surveillance, BX

October 2012: Critical reflection

April 2011: PDd03 Portfolio

25/05/2011: Portsmouth – submit PDd01 Portfolio Part2

17-19/05/2011: ECHA, Helsinki

April/May 2012: Develop predictive questionnaire

March 2012: Health Surveillance, BX

November 2012: Finish off thesis

25/03/2011: Tutorial & Statistics Meeting, Portsmouth

May/June 2011: Formal invites to companies

February / March 2012: Write up Part1, Draft

January 2012: Health Surveillance, BX

December 2012: Submit final thesis

January 2013: Health Surveillance, BX

21/03/2011: Presentation, BX Managers' Meeting

June 2011: Literature Review for Research Part1

December 2011 / January 2012: Statistical analysis

11-18/03/2011: Health Surveillance, BX

July 2011: Literature Review for Research Part2

16/06/2011: IFRA-UK, London

October/November 2011: Visit sites, collect data

January/February 2013: Final presentation & viva voce

03/03/2011: Presentation, IFRA-UK Exec Committee

July/August 2011: Develop questionnaires

04-15/07/2011: Health Surveillance, BX

August/September 2011: Collate company responses, send questionnaires

01/09/2011: Holiday, TBC

15/09/2011: IFRA-UK, London

19-30/09/2011: Health Surveillance, BX

29/09/2011: IFRA-UK AGM, TBC

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