

**Design:** The methodology comprised a quasi-experimental historical cohort design as blinding was not feasible with a non-intervention group (500) recruited first. The intervention group was recruited following a washout period. Interviewer administered questionnaires were completed at each time point and reported quitting validated by urinary cotinine measurement once in pregnancy (visit 2) and once after (visit 4).

**Results:** The overall proportion of responder and non-responder women who reported being current smokers at the first ante-natal visit was similar, however differences emerged within the groups with a higher proportion of the intervention group who were current smokers (56.8%), being non-responders at visit 5, compared to the reference group (41.8%) ( $p < 0.05$ ). Spontaneous quitters at the booking visit were also less likely to stay with the programme (61.4% vs. 38.6%,  $p < 0.5$ ), with no difference in effect for intervention and reference groups ( $p = 0.8$ ). Fall off in response was an important element of the programme with 46.8% of the intervention group taking part at visit 5 compared to 53.2% in the reference group ( $p = 0.05$ ).

**Conclusion:** These findings indicate that smoking status and intervention arm each affected participation, which illustrates the importance of estimating such a preference effect in assessing an effective health promotion programme.

#### 043 THE (AB)USE OF SYMPTOM SCORES IN ASTHMA CLINICAL TRIALS: EVIDENCE FROM A SYSTEMATIC REVIEW

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**Background:** The utility of patients' self-reported asthma symptom scores in clinical trials has not been critically assessed. We investigated the types of symptom scores used in asthma clinical trials and how they are analysed and interpreted.

**Methods:** Systematic reviews conducted to inform asthma management guidance in England and Wales were used as an evidence base. These reviews identified 87 randomised controlled trials of the effectiveness and safety of inhaled corticosteroids and long-acting  $\beta$ -agonists, published during 1985 to 2006. From these trials we extracted and appraised information on the characteristics of the symptom scales employed, and the way the symptom scores were interpreted and analysed.

**Results:** Most (78) of the asthma randomised controlled trials (90%) reported the use of symptom scores, in all cases as secondary outcomes alongside measures of pulmonary function. Ten different numeric scales and 21 different classes of symptom combinations were identifiable among the 78 trials, which resulted in 44 unique symptom scoring scales. These scales could be further subdivided according to differences in the timing of symptom assessments and in the ways that the scores were coded. Only four (5%) of the trials used validated scales. Lung function and asthma severity typically worsen at night but in all of 11 trials that reported both day and night symptom scores, the scores were consistently lower at night, irrespective of the numerical scale, study design, and asthma interventions involved. Asthma symptom scores appeared to be ordinal measures and in most trials were analysed parametrically, without reference to any assumptions about the type of distribution or equality of the scale intervals. In the asthma trials, interpretation always focused on changes in scores and the statistical significance, rather than on actual symptoms and the significance to patients.

**Conclusions:** Symptom scores are widely used in asthma RCTs in conjunction with estimates of pulmonary function but they lack validation and are interpreted inconsistently and uncritically. The numerical interpretation of scores seems detached from considering the real importance of symptoms to patients. Due to the large number of unique scales in use, it is questionable whether symptom

scores can be meaningfully compared across studies, as is routinely attempted in meta-analyses. Adoption of a smaller set of validated symptom scales in asthma clinical trials could assist meta-analyses, improve understanding of how numeric scores reflect patient experiences, and enable a more thorough evaluation of the quantitative properties of the scales that are used.

#### 044 AN ANALYSIS OF THE STRUCTURE OF THE COMPONENTS OF METABOLIC SYNDROME USING MATROIDS

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**Background:** Metabolic syndrome (MetS) has been shown to be a risk factor for many chronic diseases, but the components of MetS are still controversial. In recent literature, exploratory and confirmatory factor analyses have been used to test the latent structure amongst MetS components and regression modelling is used to test the relation between chronic diseases and MetS components. The MetS components such as BMI, blood pressure and lipids are in general correlated and clustered, and this poses a challenge for statistical modelling. Collinearity amongst these components can have serious implications in regression analysis if not identified and treated with care. Whilst some exploratory analysis, such as principle component analysis (PCA), can provide an effective insight into the structure of the data, the results are often difficult to interpret to the non-statistician and lack the descriptive detail to explain effectively the clustering of the variables.

**Methods:** The approach we propose draws on a number of ideas in combinatorial mathematics and cluster analysis to generate a group of dependent subsets. The group is transformed into a matroid to ensure that the subsets adhere to the basic axioms of linear dependence. This allows the structure to be displayed in clear hierarchical form and provides an immediate interpretation of the clustering of the MetS components. We consider data from a paper by Shen (2003) in the *American Journal of Epidemiology*.

**Results:** The matroid technique identifies similar groups of dependent components to the factor analysis approach in the paper. These included: (1) glucose, PC glucose, insulin, PC insulin; (2) BMI, waist/hip ratio; (3) systolic BP, diastolic BP and (4) HDL and triglycerides. However, the matroid method additionally illustrates the dependencies at multiple collinearity thresholds. It shows the strengths of these dependencies and others, along with their location in the overall structure of the components of MetS. This reveals a concise depiction of the dependencies that the original factor analysis could not provide.

**Conclusions:** Presenting linear dependencies as subsets rather than latent variables gives the practitioner a greater choice of which variables to remove for regression analysis. This allows for an informed decision to be made about the inclusion of variables using clinical knowledge, as well as statistical reasoning, to limit the effects of collinearity in regression.

## Cancer II

#### 045 HELP-SEEKING BEHAVIOUR IN SMOKERS AND EX-SMOKERS WITH SYMPTOMS OF LUNG CANCER. THE APPLICATION OF AN INTEGRATED MODEL

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**Introduction:** Most patients with lung cancer in the UK are diagnosed when curative surgery is no longer an option and late

presentation of symptoms to a medical practitioner is recognised as part of the problem. This paper investigates response to symptoms of lung cancer in order to identify areas in which interventions have potential to increase early consultation.

**Methods:** Qualitative interviews were conducted with 42 people with lung cancer who had taken part in a quantitative interview survey. Interviews focused on symptoms and response prior to initial presentation and diagnosis. An integrated model of help-seeking behaviour was developed with reference to sociological and psychological theories to inform data analysis. Respondents who consulted within 12 weeks of symptom on-set were distinguished from those who did not and evidence of difference in their accounts sought.

**Findings:** Sociological and psychological models of response to symptoms are remarkably similar. "Domains" of response included the nature of symptoms, explanations for them, descriptions of action taken over time and prompting to respond from a family member. Respondents reported drawing on existing knowledge of symptoms, their likely cause and perceptions of personal risk. The nature of symptoms (acute, severe, chronic) was reported as influential as were family members who noticed symptoms. Causal theorising was ubiquitous and included explanations for symptoms in relation to cause and label; likely consequences; perceptions of control; consequences and how long it was likely to last. Actions included self-medication and "wait and see" strategies which were reassessed over time. People who consulted within 12 weeks of onset described symptoms that were largely *acute* and noticed by others but otherwise no differences were apparent. Smokers in particular reported unrealistic optimism of personal risk of lung cancer.

**Conclusions:** Models of illness behaviour from different social science disciplines can be integrated and used to frame understanding of reports of response to symptoms of lung cancer. Knowledge of symptoms is not wide-spread and symptoms attributable to benign causes unless acute or severe. Family members and other play an important role in prompting response. Interventions can target knowledge and the role of others in the context of theories of behaviour change.

#### 046 THE COST OF HAVING CANCER: A SURVEY OF PATIENTS WITH CANCER IN IRELAND

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**Objectives:** Although awareness is growing that a cancer diagnosis may have an adverse financial impact on some patients, few studies have been carried out to date. Although costs are likely to be multi-dimensional, most studies have investigated single dimensions, such as employment or travel costs. We aimed to: (1) quantify the proportion of patients incurring cancer-related additional expenditure or financial difficulties; (2) identify patient sub-groups at greatest risk of cancer-related additional expenditure/financial difficulties; and (3) assess monetary and psychosocial consequences of cancer-related additional expenditure.

**Methods:** The study setting was Ireland, which has a mixed public-private healthcare system. A postal questionnaire was developed from literature review and qualitative interviews with hospital-based oncology social workers and cancer survivors. Questionnaire topics included: expenses incurred (e.g. hospital parking, prescriptions, GP visits, household utilities, etc.) and impact of cancer on income/benefits, meeting mortgage/loan payments, and household ability to make ends meet. The questionnaire also assessed levels of

concern about household financial situation since diagnosis with cancer, and depression, stress and anxiety (using the DASS). Individuals with a primary breast, prostate, or lung cancer diagnosed within the previous 18 months were identified from the National Cancer Registry, Ireland and invited to complete the questionnaire during June-September 2008.

**Results:** 740 completed questionnaires were received (response rate = 54%). Respondents had extra costs associated with travelling to hospital appointments (71%), parking (52%), GP visits (36%), consultant visits (45%), physiotherapy (9%) and counselling (6%). 59% reported increased household bills due to their cancer diagnosis. Meeting mortgage or loan payments was more difficult for 43% and 57% respectively. 30% of respondents reported decreased income. The consequences of additional expenses included: using savings (55% used some or all of their savings); borrowing money (11%); reduced spending on "extras" such as take-away meals (21%). One third was more concerned about their household's financial situation; this did not vary by socio-demographic factors. For 44% of patients the cancer diagnosis had made it more difficult for their household to make ends meet. This percentage was higher amongst patients who were younger, of working age, or had dependents. Those who reported more difficulty in making ends meet were significantly more likely to be depressed, stressed or anxious ( $p < 0.01$ ).

**Conclusions:** Most patients/families incur cancer-related additional costs. For some, these costs are substantial. The consequences of this additional expenditure are wide-ranging. These findings have important implications for patient support organisations, health and social services and policy makers.

#### 047 MORTALITY AND CANCER MORBIDITY IN A COHORT OF BRITISH MILITARY VETERANS INCLUDED IN CHEMICAL WARFARE AGENT EXPERIMENTS AT PORTON DOWN

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**Objective:** To study whether there may be long-term effects on the mortality and cancer morbidity of participants in experimental research related to chemical warfare agents conducted at the UK research facility at Porton Down.

**Design:** Historical cohort study.

**Setting and Participants:** 18 276 male members of the UK armed forces who spent one or more short periods at Porton Down between 1941 and 1989 and a comparison group of 17 600 non-Porton Down veterans followed to 31 December, 2004. All veterans were considered for the cancer analyses, excluding those known to have died or been lost to follow-up before 1 January 1971: 17 013 Porton Down and 16 520 non-Porton Down veterans.

**Main Outcome Measures:** Mortality and cancer rates in Porton Down veterans were compared to those of non-Porton Down veterans and the general population, adjusted for age and calendar period.

**Results:** Porton Down and non-Porton Down veterans were similar in military and demographic characteristics. Year of enlistment was the same (median = 1951) but the Porton Down veterans had longer military service (median = 6.2 vs 5.0 years). After a median follow-up of 43 years, 7306 and 6900 respectively had died. All-cause mortality was slightly greater in Porton Down veterans (RR 1.06, 95% CI 1.03 to 1.10,  $p < 0.001$ ), more so for deaths outside the UK (1.26, 1.09 to 1.46). Of 12 cause-specific groups examined, RRs were increased for deaths attributed to