MINUTES OF THE CARNOUSTIE PATIENT PARTICIPATION GROUP HELD ON 15th JANUARY 2015

Present: Tracy Smith (Chair), Ronald Macdonald, Harry Chaplin, Wendy French, Malcolm Westwood

Attending: Lynn McGowan Group Business Manager

1. Welcome: The Chair thanked everyone for attending.

2. Apologies: Harry Taylor offered his apologies. Tracy advised the group that Harry has not been at all well. Tracy had been in touch with the family as Harry was possibly going into Hospital for some intensive care to get him back on his feet. The group all hoped to see Harry back to his usual self as soon as possible.

3. Minutes of meeting held on 15th December 2014:

(a) Approval: The minutes were approved by Malcolm Westwood and seconded by Ronald Macdonald without any changes.

(b) Matters Arising:

(1) Telephone System Renewal: This item was deferred until the February meeting.

(2) Spire: Malcolm and Ronald had received a response from the SPIRE steering group. Ronald was concerned that the paper had gone to several parties without Ronald's knowledge. However, the reply regarding stratified medical projects said that it could go ahead with SPIRE data, yet as SPIRE data is to be linked with genomic data, the boundaries appear to be very blurred. There were still questions not answered regarding a patient's right to opt out of SPIRE, yet they can still use your anonomised data. There are still many questions regarding SPIRE, data and Scottish law and these questions will rumble on for many months. One good thing that had come from all the questions raised was that the SPIRE Steering Group are to set up a helpline for patients with concerns. Malcolm suggested that the questions Ronald had drafted be put before the next SPIRE Steering Group meeting via Malcolm. Tracy agreed to forward the paper from Ronald to Malcolm through the PPG email account. Tracy felt the problems with putting all these questions to the SPIRE group would have little or no effect and by the time SPIRE had run a public campaign and opened up a helpline, the public will have sleepwalked into accepting SPIRE without a fight. Her belief is that the response from SPIRE would be that the project was too far down the track to be halted or changed.

Ronald had prepared a short paper for the group regarding all the terms used by SPIRE and he offered this to the group. The group were keen to get a better understanding of the whole SPIRE issue and Tracy agreed to forward the paper from Ronald.

(3) Boots: Tracy had been in touch with Mr Fenty, the Boots Manager after the letter had been received. He was very keen to meet with the group and suggested several dates. After consultation with the group, a date of 2nd February had been agreed upon. Tracy had scribbled a rough draft of suggested questions/topics for this meeting and the group discussed these at length. Tracy agreed to redraft the questions and send out to the group prior to the meeting with Mr Fenty. These included: suggesting a patient newsletter informing patients about text alerts for prescriptions being ready for pick-up, missing information regarding the public funded minor ailments service, satisfaction surveys, in-house performance targets, concerns regarding the overwhelming number of generic drugs put out to patients without any information or warnings/advice.

4. **Suggestion book:** There were no new entries in the Suggestion Book.

5. **AOCB:**

(a) Members Contact List: Tracy had over the last month updated the Patient Group Contact List for all members. However she strongly reminded members that the details on this list are to be treated as confidential and not to be released to any third party without first seeking approval from the person concerned. She had been aware of several instances where the members personal email details were divulged without consent. If any member does not want to give out their personal email details Tracy reminded the group they could use the carnoustieppg@hotmail.co.uk address to safeguard their details.

6. **Next Meeting:** The next meeting will be on 19th February 2015 at 10.30am.

INFORMATION DOCUMENT. **REFERENCE ONLY. NOT FOR PUBLICATION.**

What is meant by the terms Anonymisation and Pseudonymisation of data.

Information Source: Scottish Health Informatics Programme (SHIP) document.

Given that within the next few months the public in Scotland are to be informed of the Scottish Primary Care Information Resource (SPIRE) Project, and given that the Project information may include some or all of the following terminology:

- ***anonymisation; anonymised data; pseudonymisation and pseudonymised data***

it is considered important that this terminology is explained in order that it is readily understood by the members of the public who as registered patients of the General Practitioner (GP) Practices in Scotland will be invited to participate in the Project

What is anonymisation of data?

The process of anonymisation of data involves the removal of personal identifiers from a dataset to minimise the risk of disclosure (patient identification). Data which is *'truly anonymised'* contains no information that could reasonably be used, by anyone, to identify the individual who the data belongs. Data may be anonymised by, for example:

- Removing direct identifiers, for example, name or address;
- Aggregating or reducing the precision of information or a variable, for example, replacing the date of birth by age groups.
- Generalising the meaning of detailed text, for example, replacing a doctor's detailed area of medical expertise with an area of medical speciality;
- Using pseudonyms;
- Restricting the upper or lower ranges of variables to conceal or hide outliners, for example, top-coding salaries.

What is pseudonymisation of data?

The process of pseudonymisation of data is the replacement of normal personal identifiers, such as name, address, National Health Service (NHS) number, etc. with artificially created identifiers so as to conceal the identity of the individual.

Data which is pseudonymised is anonymous to the people who receive and hold it, for example, an approved researcher or research team, but it contains information or codes which allows others, for example, the data controller to identify an individual from it.

The links between the artificial (pseudonymised) and the normal identifiers are securely stored separately to the anonymised data.

Therefore, although an approved researcher or research team to whom the data is anonymous may not have to act in accordance with the Data Protection Act 1998, those who know the code to identify the data will still need to comply with the legislation pertaining to data protection.

The use of pseudonymised data is common in research.

The benefits of anonymisation and pseudonymisation of data.

There are many examples of the benefits derived from the analysis of anonymised and pseudonymised healthcare data in Scotland. Research using such data has increased the knowledge base, helped to improve health outcomes, informed the effectiveness, efficiency and safety of the health services being provided and offered within the NHS in Scotland and has influenced international medical best practice.

Scottish Primary Care Information Resource (SPIRE) Information Notes.

What is SPIRE Project.

The Scottish Primary Care Information Resource (SPIRE) project is a new project in Scotland to develop a secure service to simplify and standardise the process for extracting **Anonymised data** from General Practitioner (GP) Practice systems for a number of purposes, for example:

- audit
- disease surveillance,
- benchmarking
- planning
- research
- Quality and Outcomes Framework (QOF) payments to General Practitioners.

What will SPIRE do.

The Scottish Primary Care Information Resource (SPIRE) project will incorporate robust Information Governance (IG) and

1. Extract Primary Care Information data for example for QOF payments, 'Flu surveillance etc.
2. Extract Primary Care Information data to populate a National Dataset.
3. Extract Primary Care Information data for bespoke requests, for example, approved
4. Provide a National Analysis and Intelligence Service

- **All** data extracted will be anonymised before being securely transferred to a ***'safe haven'*** in the NHS National Services Scotland (NHSNSS).
- Access to any extracted data will be carefully controlled and monitored.
- Patients will be able to **opt-out** of the SPIRE Project
- GP Practices will be able to choose whether to participate in options de-identified (anonymised), stored and used and the types of security controls in place will be described and available to GP Practices and patients using a range of communication tools.
- The will be a public information campaign to inform the public about the Project.

What is Stratified Medicine.

Stratified medicine is an innovative treatment concept based on the use of genetic or other molecular information to select the best therapeutic strategy in order to improve health outcomes. Such as effectiveness and safety, for a targeted group of patients sharing similar biological characteristics. The latest advances in science have resulted in major developments in molecular biology leading to the emergence of a new approach to healthcare. Stratified medicine employs these advances to create better diagnostic tools and targeted therapeutics. To put it simply. The one-size-fits-all standardised or empirical approach is replaced by a group specific disease management strategy based on the recognition that specific molecular aberrations responsible for the disease process, for example, carcinogenesis can be managed by specific drugs or approaches. **The future of healthcare is about getting the right medicine to the right patient at the right time through stratified medicine.**

Stratified Medicine in Scotland.

The Stratified Medicine Scotland Information Centre (SMS-IC) will be housed within the Learning and Teaching Facility at the New South Glasgow Hospital Campus which is scheduled to open in 2015.

According to Stratified Medicine Scotland *the Stratified Medicine Scotland Information Centre (SMS-IC) aspires to be a world-class centre of research, innovation and* ***commercialisation*** *in stratified medicine.* Their information document provides the following information – Stratified medicine involves examining the genetic make-up of patients and their differing responses to drugs designed to treat specific diseases. By building up an understanding of the ***'strata'*** of responses and the genetics of the disease, medical researchers hope to create more personalised and effective forms of treatment for groups of patients likely to benefit. Significant in electronic health records (EHRs) and translational medicine research, coupled with a vibrant healthcare technology industry, positions Scotland as the location to drive forward the stratified medicine agenda globally.

SMS-IC is a unique partnership comprising the **Universities of Glasgow**, **Edinburgh**, **Dundee** and **Aberdeen**; **NHS Greater Glasgow and Clyde**, **NHS Grampian**, **NHS Lothian** and **NHS Tayside**; and the key business partners, global biotechnology company **Thermofisher Scientific**, and biomedical infomatics company, **Aridhia Informatics**. The SME [small and medium enterprise] partners involved in the SMS-IC are **Arrayjet, Biopta, DestiNA, Genomics, Fios Genomics** and **Sistemic.**

The Scottish Funding Council is providing £8million over five years to back the creation of the £20million SMS-IC at the new South Glasgow Hospitals Campus.

What is Genomic data – What is DNA.

Refers to data or information derived from genetic mapping and DNA (Deoxyribonucleic acid) sequencing of sets of genes or the complete genomes of selected organisms. **Genomics** is defined as a branch of biotechnology concerned with applying the technique of genetics and molecular biology to the genetic mapping and DNA sequencing of sets of genes or genomes of selected organisms using high-speed methods, with organizing the results in databases, and with the application of the data as in medicine or biology.

DNA is a **chemical compound** that contains the instructions needed to develop and direct the activities of nearly all living organisms. DNA molecules are made of two twisting, paired stands, often referred to as a double helix.

Each DNA strand is made up of four chemical units, called nucleotide basis, which comprise the genetic 'alphabet'. The bases are: Adenine (A); Thymine (T); Guanine (G) and Cytosine (C). Bases on opposite strands pair specifically: an (A) always pairs with a (T); a (C)always pairs with a (G). The order of the (As), (Ts), (Cs) and (Gs) determines the meaning of the information encoded in that part of the DNA molecule just as the order of letters determines the meaning of a word.

An organism's complete set of DNA is called a genome. Virtually every single cell in the body contains a complete copy of the approximately 3 billion DNA base pairs, or letters, that make up the human genome.

NOTE: Rapid progress is being made in the emerging field of **pharmacogenomics**, which involves using information about a patient's genetic make-up to better tailor drug therapy to their individual need.

Comment re 'Stratified Medicine Project'

It is considered that the reply regarding Stratified Medicine Project (SMP) is slightly disingenuous. While it is true that Stratified Medicine Projects can go ahead without SPIRE data. This is happening . It is, however, easy to see that in the future GP Practice data will be combined with genomic data. This concept is mentioned in many of the healthcare research websites.

Initial Stratified Medicine Scotland Information Centre (SMS-IC) Projects.

- **Ovarian Cancer:** High Grade Serious Ovarian Cancer (HGSOC) is the 5th most common cancer. The study led by Professor Charlie Goulay at Edinburgh will focus on understanding if the use of a novel class of PARP (*poly ADP ribose polymerase*) inhibitor drug can be extended for use into a wider group of HGSOC patients. Currently these drugs are only prescribed in patients having genetic mutations in their germline DNA. I If the mutation is not present, the drug is ineffective) This represents about 15% of all HGSOC patients.

- **Oesophageal Cancer:** is a highly aggressive common form of cancer with a rising incidence worldwide and poor prognosis. The study led by Professor Zofia Miedzybrodzka and Dr Russell Petty at Aberdeen University and NHS Grampian will focus on the identification of a genetic signature for Gefitinib response in tumour samples from patients in the COG (Clinical Oncology Group) study. Gefitinib known by brand name IRESSA is a type of biological therapy called a tyrosine kinase inhibitor (TKI). Tyrosine kinase is a protein that plays a part in triggering the growth of cancer cells. Gefitinib blocks tyrosine kinase from sending growth signals. If successful, the project will lead to development of a test that will allow clinicians to predict if their oesophageal cancer patient will respond to this drug, and thus potentially to worldwide use of this medicine to combat this devastating disease. Currently clinicians can not predict which patients will or will not respond to this expensive biological drug.

- **Rheumatoid Arthritis:** is the most common of the chronic inflammatory arthritic conditions. Within Europe the direct cost of managing rheumatoid arthritis is in the region of £11.6 billion per annum whilst the indirect costs of managing long-term social security cost are an additional £14.1 billion per annum. Current rheumatoid arthritic drug therapy is dominated by methotrexate (MTX) which works well in patients who respond to it. 60% of rheumatoid arthritis patients on MTX either do not respond or show toxic side effects. Non MTX responding patients are escalated through a series of disease modifying ant-rheumatic drugs leading to the more recent and expensive biological therapies. Currently if the patients does not respond to MTX it may take years of iterative drug escalation until their rheumatoid arthritis is effectively managed with concomitant worsening of the patient's condition. The study led by Professor Iain McInnes at Glasgow University will focus on trying to identify a genetic signature in rheumatoid arthritic patients that can predict those who will and those who will not respond to MTX treatment at the onset of their disease. If successful it will allow rheumatologists to more accurately assign patients to drugs that will work well for them, possibly creating a more compelling argument to rapidly advance patients to biological therapy.

- **The Irritable Bowel Disease (IBD)/Chronic Obstructive Pulmonary Disease (COPD)** : **is led** by Dr David Bunton a Biopta. Based in Glasgow Biopta has been providing contract research services to the pharmaceutical industry since 2002 and has established itself as a world leader in the use of fresh functional human tissues to better predict drug activity prior to clinical trials. The project aims to help Biopta undertake early identification of patient variability through a phamacogenomics strategy. Biopta has observed that in-vitro responses to known drugs using human tissue samples collected from patients with IBS or COPD can vary quite significantly between patients. The project aims to better understand this behaviour by comparing the responses obtained ex-vivo human assay systems with the genotype of the tissue donors. It will engage NHS Scotland's bio-repository network and will demonstrate a close coupling of tissue access and functional bioassays in disease relevant tissues. The object is to create a preclinical model to understand the genetic basis for variability to known drugs and to relate genomics to the variation in drug efficacy between patients; this will, for the first time, provide a means to understand patient stratification at an early stage of drug development.

NOTE:

- **In-vitro:** refers to a biological process made to occur in a laboratory vessel or other controlled experimental environment rather than with a living organism or natural setting.

- **Ex-vivo:** Latin *"out of living"* means that which takes place outside an organism. In science *ex vivo* refers to experimentation or measures done in or on tissue from an organism with the minimum alteration of natural conditions.