The UK ME/CFS Biobank

Final Report – Executive Summary

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We would also like to thank all the members of the Steering Committee, who have diligently overseen the development and implementation of this project. Their altruistic contribution towards the project went well beyond the time they dedicated to attending our regular meetings. They added invaluable insights to our discussions, revised in detail the documents and protocols, and helped the research team establish important networks with support groups to recruit participants severely affected by ME/CFS.

The success of the UK ME/CFS Biobank would not have been possible without the hard work and dedication of the staff at the UCL/RFH BioBank, who oversee the meticulous processing and safety of the participants' samples, as well as that of our colleagues at the UK Primary Care Research Network, who were instrumental to the implementation and success of our recruitment strategy.

Most of all, we would like to express our sincerest appreciation to the many people – both those with and without ME/CFS – who have so generously contributed to the Biobank by donating their time, resources, and precious energy to participate in the project.

To all of you, our warmest thanks.

The UK ME/CFS Biobank

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Background

Myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS) is characterised by unexplained and persistent or recurrent incapacitating fatigue lasting over six months. It is accompanied by a variety of symptoms leading to substantial reductions in previous levels of occupational, educational, social, and personal activities (1, 2), and often to moderate or severe disability and with significant reductions in quality of life (3). With population prevalence rates estimated at 0.2% to 0.4%, ME/CFS has considerable social and economic impacts due to its chronic nature and it often affects the young in what should be the most productive periods of their lives, and also impacts those close to them (3, 4). Currently, there are no confirmatory diagnostic tests or effective evidence-based treatments to address the heterogeneity of symptoms and their fluctuating nature.

The lack of well-characterised, population-based, longitudinal studies and the need for biomedical research in ME/CFS were recognised in the Medical Research Council (MRC) research strategy in 2003 and highlighted in an 'MRC CFS/ME research workshop' in late 2009. The workshop and prioritisation meeting that followed in May 2010 stressed the need for high quality research to advance the understanding of the mechanisms of this disease (5).

In spite of some significant recent advances, the aetiology of ME/CFS remains elusive and the illness continues to be poorly understood. Research results have often not been reproducible. One of the reasons for this lies in an inconsistency in the type and quality of research methods used, including in the case definitions applied. This situation is unsatisfactory and perpetuates ME/CFS being considered a medically-unexplained condition. Moreover, it highlights the need for studies with robust methodologies, which, at a minimum, include the comprehensive phenotyping of cases and take into account variations in clinical presentation.

Results of our previous studies on the desirability and feasibility of a disease-specific biobank informed the project design. The need for biomedical research has been expressed by people with ME/CFS (PWME). In particular, PWME have called for studies in immunology and infection, which could lead to the identification of biomarkers and the development of diagnostic tests and treatments. This perspective was confirmed by our participatory research with PWME and a range of professional experts (6), which enabled us to document frustrations with the ongoing uncertainties about the causes and mechanisms of the disease. We observed that PWME are very supportive of research involving tissue sample collections, particularly blood samples. PWME gave clear indications that a repository of tissue samples for the study of ME/CFS to establish a key resource for high quality and ethically-approved biomedical research studies on ME/CFS would be both acceptable and desirable (6). A paper discussing this participatory research process has been submitted to an open access journal.

The UK ME/CFS Biobank project, envisioned as the UK's first biobank for the study of ME/CFS, was launched in August 2011 with the support of three main ME/CFS charities in the UK – Action for M.E., the Myalgic Encephalopathy Association (MEA), and the ME Research Group for Education and Support (ME Research UK) – and a private donor.

Project development

The project was undertaken in two phases lasting almost three years and included the recruitment of 210 people into the Biobank (130 with ME/CFS, 10 chronically-fatigued people without ME/CFS, and 70 healthy "controls").

The funders' generous support allowed the development of the project into a fully operational Biobank and provided the necessary time for securing funding from a mainstream health research agency.

Preparatory stages: Development of protocols and standard operating procedures (SOPs)

The first phase of the project was dedicated to preparatory stages, including:

- staff recruitment;
- development of study protocols for data collection, clinical assessment, blood sample collection, transportation, processing, and storage;
- preparation of the clinical assessment protocol and guidance;
- submissions to institutional and National Health Service (NHS) Ethics Committees and Research and Development (R&D) offices;
- preparation and execution of research agreements with collaborating NHS sites and subcontractors (e.g., for database development and a courier for transporting bloods);
- preparation of study site files;
- training health professionals at collaborating NHS sites on study protocols, including clinical assessment and phlebotomy protocols; and
- preparation and delivery of invitation packs to collaborating NHS sites for posting to the potential participants they had identified.

The UK ME/CFS Biobank project was approved by the LSHTM Ethics Committee and NRES Research Ethics Committee (REC) London-Bloomsbury.

Once ethics approvals were granted, we began inviting potential participants through primary and secondary health services in East of England and London in March 2012.

The project was adopted by the UK Clinical Research Network (UKCRN) and assigned to the "Immunology & Inflammation" group in their Portfolio.[1] Inclusion in the UKCRN Portfolio facilitated a close collaboration with NHS sites. At the time of publication, the research team had approval to recruit participants through NHS East Coast Community Health Care, NHS Great Yarmouth & Waveney, NHS Suffolk, NHS Norfolk, and University College London Hospitals (UCLH).

Participant recruitment

Recruitment through NHS sites provided the opportunity to strengthen collaboration between academia and health services and optimised the limited funding available for the Biobank project by

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[1] In 2013, the Immunology & Inflammation group was dismantled and the Biobank project was reassigned to the "Primary Care" Clinical Research Group.

allowing the project direct access to the benefits of the NHS infrastructure, including staff expertise, clinics as recruitment centres, contacts and networks, and staff time and labour.

Following ethics and R&D approvals, the LSHTM team trained staff at collaborating NHS sites and provided recruitment SOPs to the study sites.

The collaborating NHS sites identified potential participants using GP surgeries' databases using the following criteria:

Inclusion criteria

ME/CFS cases: informed consent, 18 to 60 years old, and clinical diagnosis of ME/CFS according to Canadian (1) or CDC-1994 (2) criteria. Compliance with study criteria was confirmed by a clinical member of the research team (doctor) after reviewing the results of a range of laboratory tests used to exclude alternative diagnoses.

Healthy controls: informed consent, 18 to 60 years old, no past or present fatiguing illnesses and/or other major morbidity such as cancer or coronary heart disease.

Exclusion criteria

Cases: Recent use (in the preceding 3 months) of drugs known to alter immune function (e.g. azathioprine, cyclosporine, methotrexate, steroids); anti-viral medications and vaccinations; history of acute and chronic infectious diseases such as hepatitis B and C, tuberculosis, HIV (but not herpes virus or other retrovirus infection); other severe illnesses and severe mood disorders. Pregnant women and those within 12 months post-partum and/or currently lactating are excluded.

Healthy controls: all of the above, in addition to the presence of any fatiguing illnesses and other conditions that would exclude a diagnosis of ME/CFS (in those with fatigue), present or past.

Potential participants were invited to join the study by their doctor (affiliated with a collaborating NHS site) or by ME/CFS Disease Register staff if the patient was enrolled in the ME/CFS Disease Register. The LSHTM research team provided invitation packs to the participating NHS sites, which posted them to the potential participants identified in the database search. The invitation pack included an invitation letter from the health service, information about the study (with separate information sheets for cases and controls), a "Symptoms Assessment" form for determining case definition compliance, a consent form, a refusal form, and a stamped self-addressed envelope.

Because people severely affected by ME/CFS (that is, bed- or home-bound) often do not, or cannot, visit NHS services, and are particularly under-represented in ME/CFS research, information sheets and invitation packs were sent to support groups in the Greater London area for identification of and distribution to interested individuals in this segment of the ME/CFS population. Unfortunately, those very severely affected by the disease would be unable to participate because of the need to complete a half-hour clinical assessment and to provide a blood sample.

Potential participants with ME/CFS were also asked to invite a friend to participate as a healthy control and so invitation packs were provided to them for this purpose. Additionally, information packs were made available at NHS sites and at LSHTM to supplement healthy control recruitment.

When the signed consent and "Symptoms Assessment" forms were received by the research team, they were reviewed by the clinical researcher to confirm compliance with the inclusion and exclusion criteria for cases and controls. All potential cases would have received a diagnosis of ME/CFS at some time in the past. The clinical staff then assessed the diagnosis of ME/CFS according to the study's protocol, which requires compliance with the Canadian Consensus Criteria (1) and/or the CDC-1994 criteria (2). Cases meeting the former have been shown in most cases to also meet the latter criteria (4), and the former seems to characterise those who are most severely affected. Comprehensive phenotyping of patients at baseline also enabled categorisation of individuals according to other clinical criteria, such as the London (7) and International Consensus (8) criteria, although these definitions were not used to determine enrolment eligibility.

Once eligibility was established, the research team booked appointments for participants for clinical assessments and blood sample collection. Participants in the Greater London area with severe disease and/or mobility restrictions were seen at their homes. Consenting respondents ineligible according to the screening questionnaire were thanked by the research team and told that their ineligibility was based on the exclusionary criteria.

Clinical assessments & phlebotomy

Clinical assessments included the following clinical measurements:

- blood pressure and pulse taken at rest in seated and standing positions (both taken twice);
- hand grip strength test (three repeated 3-second measurements using the dominant hand);
- waist circumference;
- standing height;
- weight and bioimpedance (a measurement of body composition estimating body fat and lean body mass);
- spirometry; and
- pulse oximetry.

Recruitment took place in the East of England and within Greater London. Baseline blood tests were carried out at the James Paget University Hospital in Great Yarmouth, the Royal Free Hospital in London, and the Norfolk and Norwich University Hospital (NNUH). Samples were transported to the UCL/RFH BioBank immediately after collection to ensure receipt by the BioBank within six hours of collection for processing, aliquoting, and storage.

Baseline blood tests included a full blood count, blood chemistry, calcium, electrolytes, creatinine, serum creatine kinase, liver function tests, erythrocyte sedimentation rate, C-reactive protein, rheumatoid factor, thyroid function tests, tissue transglutaminase antibodies, serum vitamin B12, and serum folate. Additionally, participants were asked at the time of the clinical assessment to produce a sample of urine to be screened for glucose, blood, protein, and specific gravity.

The research team sent questionnaires to participants at the time of the blood collection covering demographic, socio-economic, and other exposure variables as well as clinical history, including information on illness onset and an extensive list of symptoms, family health history, and symptoms currently being experienced (at the time of the blood collection), which can all be linked to both the baseline laboratory tests and the de-identified blood samples. Questions were chosen taking into account the team's experience with ME/CFS research (4, 9) and variables captured by the UK Biobank project (10).

The following instruments were used to further characterise participants: Medical Outcomes Survey Short Form – SF-36v2 (11) for assessment of functional capacity; the pain analogue scale (12), for assessment of pain severity; a fatigue severity scale (13); the energy fatigue scale (14); a fatigue disability scale, based on the Karnofsky scale (15), the General Health Questionnaire – GHQ-28 (16-24), and the Epworth sleepiness score (25).

All participants meeting eligibility criteria were asked for blood samples (approximately 95ml), from which approximately 15ml was used for baseline laboratory tests to exclude other diagnoses. The remainder was processed and stored at the UCL/RFH BioBank for future ethically-approved studies, including those planned by the LSHTM research team, for which participants have given "a priori" consent.

The UCL/RFH BioBank, a state-of-the-science facility licensed by the Human Tissue Authority (Licence number 11016), which holds specific ethical approval for the processing and storage of biological samples. No personally-identifiable information is stored in the UCL/RFH BioBank database and so stored samples can be linked anonymously to a range of clinical and other non-identifiable data from participants.

Figure 1 summarises the UK ME/CFS Biobank recruitment procedures. Further details on the collection, transport, processing, and storage of blood samples follow:

- The LSHTM team prepared blood collection kits including the required number and type of Vacutainer tubes and a needle. SOPs for blood collection and transport were followed.
- Staff members at the UCL/RFH BioBank followed SOPs for receipt, logging, processing, and storage of samples. The Vacutainer blood tubes received at the BioBank yielded aliquots of serum, plasma (from both NaHep and EDTA tubes), peripheral mononuclear blood cells, a red blood cell/granulocyte pellet, and whole blood, in addition to the PAXgene tube for RNA. The separated cells, plasma and serum samples can be used for a range of investigations and techniques, including for RNA and DNA extraction.
- All samples can be stored at the UCL/RFH BioBank for up to five years in the first instance. Inventories of samples in the BioBank are sent regularly to the research team.

Figure 1 – Recruitment procedures
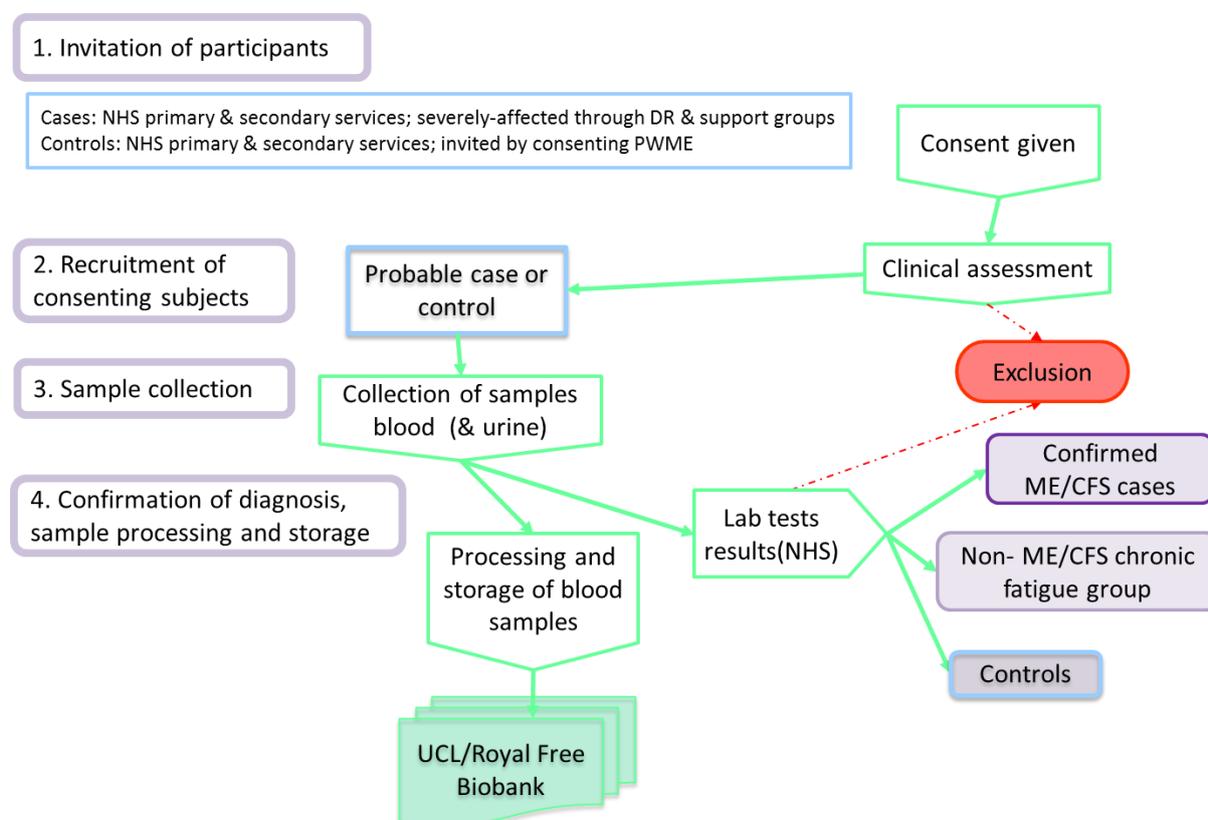
Results and available resources

The team successfully met the target number of recruited participants agreed with the funders; 210 cases and controls were recruited and assessed during the grant period. A total of 240 participants were recruited to account for a number of exclusions and withdrawals after recruitment (in accordance with the original Funding Agreement and subsequent Deeds of Amendment) to reach the target number of 210 cases and controls. Of the 210 remaining after exclusions and withdrawals, 130 were ME/CFS cases, 10 were characterised as chronically fatigued non-ME/CFS according to study criteria (recruited for control purposes), and 70 were healthy controls, all of whom were clinically assessed, provided blood samples, and submitted a full set of data via the questionnaires.

From the invited participants, two were excluded for presenting exclusionary criteria and 18 participants that repeatedly missed appointments or did not send completed questionnaires after consent were excluded from the cohort. Additionally, we received ten withdrawal requests, six from people with ME/CFS and four from healthy controls.

Table 1 shows that there are three times more women than men with ME/CFS in the cohort, and the median age for both groups (of cases and controls) was in the mid-forties, and the differences were not statistically significant. All recruited cases complied with the CDC-1994 study criteria, of whom 87.7% (114 participants) also complied with the Canadian Consensus Criteria.

Table 1 – Distribution of participants in the UK ME/CFS Biobank, by category of recruitment, gender and median age

Gender	ME/CFS cases			Healthy controls		
	n	%	Median age	n	%	Median age
Male	33	25.4	44.5	23	32.9	42.5
Female	97	74.6	43.3	47	67.1	44.6
Total	130	100.0		70	100.0	

A detailed descriptive analysis of the current cohort of participants recruited to the Biobank will be submitted to an open access scientific paper, and for this reason we are limiting the data presented in this report.

Severely-affected participants reported feeling privileged to take part in the study despite the enormous demands on their energy that participation involved.

The research team developed access and approval procedures to allow external researchers the opportunity to utilise the UK ME/CFS Biobank's de-identified data and samples.

Additionally, the research team developed an extensive customised database to securely store the data collected from our participants, including information from the questionnaires, clinical assessments, and blood tests. This database is a powerful tool for data organisation and analysis both in-house and for export to external researchers for ethically-approved studies.

The successful implementation of the Biobank was instrumental in the LSHTM team's securing funding from the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health (NIH). The NIH grant is enabling the team to expand recruitment by 300 participants, who will be followed up at six months in addition to baseline assessment and blood collection. This new cohort of participants includes a control group of people with Multiple Sclerosis (MS).

Sample quality control

In December 2013, groups led by Professor Riley and Professor Dockrell assessed the quality of the samples stored at the UCL/RFH BioBank by testing the general recovery and viability of the peripheral blood mononuclear cells (PBMCs) and the function of the Natural Killer (NK) cells. Additionally, tests were carried out to assess the RNA and microRNA preserved in the tubes. These types of blood derivatives will be used by studies on immunology and gene expression, respectively.

Aliquots of blood derivatives from ten participants were selected for the quality tests and included males and females recruited at different time points from different health services.

Recovery of cells was very good in the majority of cases and viability of the recovered cells was excellent. The populations of cells recovered were for the most part within reference ranges for frequencies of cell types in human peripheral blood. RNA was extracted from 10 aliquots of stored PAXgene blood samples using the PAXgene Blood miRNA kit so both messenger RNA and microRNA

could be kept. All ten samples were good quality as assessed by Agilent Bioanalyser. To check that the samples were appropriate for downstream analysis, quantitative reverse-transcriptase PCR (qRT-PCR) was conducted for both mRNA and μRNA, which worked well for all samples. With these results we considered the PAXgene tubes stored in the Biobank to contain good quality RNA, which can be used in downstream applications.

Steering Committee

Throughout the course of the project, the Steering Committee, comprising the CURE-ME team at LSHTM, an affiliated physician, two to three patient representatives, a research colleague from LSHTM and a representative from each of the three main charity funders, met quarterly. As well as overseeing project progress, the Committee ensured that the needs and opinions of people with ME/CFS were respected, that resources were used wisely, and that there was ongoing strategic planning.

Collaborations

Integral to the success of the UK ME/CFS Biobank was its inclusion in the UKCRN Portfolio and its adoption by the Primary Care Research Network (PCRN) for East of England.

Inclusion in the Portfolio augmented available resources, expanding access to and strengthening our ability to quickly recruit study participants. Responses from local CRN staff and GP clinics were very positive and the "hub-and-spoke" model used to recruit participants was so successful that the project was profiled in an internal NHS publication. Membership in the CRN Portfolio allowed direct access to research nurses and support staff, who were integral to the identification and invitation of potential participants, the clinical assessment process, and coordination with research partners for blood collection and testing, all in a cost-effective manner.

We also strengthened partnerships with hospitals and physicians in central and the Greater London area, including the Royal Free Hospital in London, which has been a recruitment site for the project through its Clinical Immunology Department.

This project also facilitated the development of an international consortium of ME/CFS researchers, many of whom are supportive of the creation of a pan-European network of ME/CFS biobanks with harmonized protocols for clinical assessments, sample, and data collection, research questionnaires, and laboratory processing procedures. This network will optimise sample sharing between biobanks for future research studies at our respective institutions and also allow outside researchers access to larger sample sizes and the comparison of cohorts from different geographic regions.

Related to this, the EUROpean M.E. NEtwork (EUROMENE) has been strengthened and collaborative applications are underway. Partners include researchers from a range of disciplines located across Europe and collaborations in the U.S. and the Southern Hemisphere are also being developed.

We will continue to nurture collaborations with colleagues both in the UK and abroad to identify synergies and further develop the Biobank network, thereby expanding our collective resource.

Dissemination

The team has employed various channels to raise the profile of the UK ME/CFS Biobank.

In March 2012, the team arranged a public screening at LSHTM of the film "Voices from the Shadows", including an introductory talk and panel discussion. Attendees included both patients and researchers and directly led to the addition of a recruitment site.

In April 2013, the team organized a Biobank Procedures Workshop at LSHTM to discuss the UK ME/CFS Biobank's mission, strategy, management, and procedures for making the resource available to outside researchers. The workshop included members of the Steering Committee, UCL/RFH BioBank staff, and three speakers, including the Legal Counsel for the UK Biobank, the Chief Investigator of the UK Primary Sjögren's Syndrome Registry, and the Biobank Facilitator at the UCL/RFH BioBank. Decision-making was based on a collaborative model and the discussion covered how we would make our samples available, to whom, and for what purposes, among other things.

In December 2013, the team arranged and hosted a talk at LSHTM by a prominent American ME/CFS researcher on ME/CFS case definitions.

Additionally, the team was very active in spreading the word about the project and its objectives to both researchers and the broader public, presenting at:

- the SMi's 3rd Annual Biobanking conference (6/14);

- the Biomedical Research for ME Colloquium Meeting (BRMEC4) preceding the 8th Invest in ME International ME/CFS Conference, London (5/14);

- the IACFS/ME 11th Biennial International Conference: Translating Science into Clinical Care, San Francisco, USA (3/14);

- an "Exercise and ME/CFS – the evidence" event, Bristol (2/14);

- the "CFS/ME 2013: Update on Aetiology, Diagnosis and Management" conference, Newcastle (12/13);

- Annual General Meetings (AGMs) and research conferences for Action for M.E., London (10/11; 11/13);

- an "Open Access Biobanks @ UCL" workshop, Institute of Child Health, London (4/13);

- the first annual Norwegian ME/CFS Meeting, ME/CFS Center, Oslo University Hospital, Norway (12/12); and

- patient support group meetings in Derbyshire, Cambridge, Central London, and Richmond ('12-'14).

Finally, the Biobank project has been covered in publications produced by the funding charities as well as patient-created newsletters distributed on the internet, and interest from other media, such as from documentary filmmakers, has been strong as well.

The CURE-ME team's website (www.lshtm.ac.uk/mecfs) was developed during the course of the project, providing an overview of work to date and presenting a public face of the team to individuals and research groups across the world.

Going forward, the team will maintain and develop the CURE-ME team's website, including creating webpages containing procedural information and materials for applying to use the Biobank's samples and data, so that researchers have easy access to current information and documents.

The team will continue to publicise the availability of the resource to external researchers in the UK and around the world by attending meetings with researchers, potential donors, and other interested parties.

Lessons learned

Any start-up involves learning from experience and this project has been no exception. In retrospect, there was an underestimation of the breadth and intensity of the scope of the work. The benefit of partnering with local research networks in primary care was invaluable, but the effort associated with obtaining additional local ethical reviews and site contracts was not fully appreciated at the outset.

A pilot application used to trial the UK ME/CFS Biobank application procedures (for using the stored samples) rendered a clear picture of the potential challenges the team will need to overcome to avoid delays related to peer review and execution of legal agreements.

There is an evident hunger for biomedical research in this field borne out by the eagerness of PWME to participate and of fellow researchers seeking research partnerships. The overwhelming willingness of people to participate (as their health allowed) in a study from which they may not benefit directly was gratifying and confirmed an altruistic spirit in this group. On the other hand, the recruitment of healthy controls was more challenging than expected, however the team was able to achieve the targeted number for this group after making changes to the recruitment strategy.

Sustainability and next steps

The research team at LSHTM is continuing participant recruitment and will be initiating virological, immunological, and gene expression analyses on the collected samples with a grant from the U.S. NIH (1R01AI103629). For this grant, we added a group of participants with Multiple Sclerosis, who will be fatigued controls, adding considerable strength to our chances of identifying a biomarker and/or developing a diagnostic test for ME/CFS and thus contributing significant value to the Biobank's collections.

Building on the experience of the first phase of the project, recruitment and assessment procedures were reviewed and refined, necessitating ethics amendments.

A primary purpose of the UK ME/CFS Biobank is to make samples of well-characterised patients and controls available to external researchers. Therefore, a priority is to ensure the continuity and sustainability of the Biobank to enable further studies in this field, particularly those related to biomarker discovery for diagnosis and treatment.

The next step is to further elucidate the requirements of the Biobank "opening its doors", including publishing the application procedures and adapting them as needed according to our experience with their implementation and use.

As funding allows, the research team will identify and hire a primary point of contact for fielding inquiries from researchers; processing applications; arranging the Steering Committee's scientific subcommittee's review and external peer review, including identification of reviewers if needed; liaising with applicants on any outstanding ethics concerns or paperwork; coordinating with the UCL/RFH Biobank Ethical Review Committee (B-ERC) on applications as needed; and communicating decisions to applicants.

As part of the Biobank service, the team will manage and maintain sample and data records; liaise with the UCL/RFH BioBank regarding holdings and release of samples; create customized datasets for researchers as required taking into account case definition, available data, and derivatives; and ensure that a sufficient supply of samples remains available.

Before any samples or data are released, the team will agree administrative costs with the applicants. Materials Transfer Agreement (MTA) and Data Transfer Agreement (DTA) templates will be kept current in collaboration with the relevant legal bodies at LSHTM and UCL/RFH, and in all cases the MTA and/or DTA, as applicable, will be signed by all relevant parties prior to the sharing of any data or samples.

To ensure that samples and data are appropriately used, the team will maintain a database of approved projects, which will allow follow-up on a regular basis on project status and assurance that users are appropriately acknowledging the contribution of the UK ME/CFS Biobank to their research in their publications. The team will develop a portfolio of publications made possible by the Biobank.

To ensure sustainability of the resource, the team will review the cost recovery scheme to ensure that the fees recovered recuperate expenditures as anticipated. If needed, the team will revise the scheme in accordance with the identified needs and common practice at other biobanks.

A project-specific account at LSHTM will allow the management of incoming and outgoing funds specific to running the Biobank as an open resource and the reinvestment of received funds back into the resource (i.e., using administrative fees from supplying samples to researchers to fund sample and data replacement through continued recruitment and follow-ups).

A separate scheme for corporate use of samples and data will be considered by the team as a means of contributing to the sustainability of the resource.

An important consideration to take into account in the efforts to continue to develop this resource is the retention of the longitudinal aspect of sample and data collection. This feature sets it apart from similar resources and must continue to be developed in "real-time" by following up participants at regular intervals as funding allows.

The team will continue to seek sources of mainstream funding to achieve these objectives and to keep the resource viable in both the short- and long-term.

Conclusion

This project saw the genesis and launch of the UK ME/CFS Biobank, and support from Action for M.E., the ME Association, ME Research UK, and a private donor ensured its full realisation. Pilot funding from the charities and the private donor directly led to the successful application for mainstream research funding from the U.S. NIH, which will fund the project through mid-2016.

Feedback from patients, enrolled participants, and fellow researchers has been universally positive throughout the course of the project.

The Biobank is a resource developed not only for those directly involved in its creation, but also for the international community of researchers interested in conducting ethical and progressive research on ME/CFS. The Biobank should be ready to consider applications from researchers worldwide seeking to utilise its samples and data in 2015, subject to funding being available for this.

The UK ME/CFS Biobank is a valuable resource requiring continuous funding to achieve its full potential, including the expansion of participant recruitment and long-term follow-up as well as the processing and analysis of samples and data to test a range of study hypotheses. Long-term sustainability will be dependent on securing financial support for this vital infrastructure, which will allow the ongoing sharing of samples and data with the research community.

As of June 2014, the Biobank held approximately 12,000 samples from about 300 participants (funded by all sources). Our hope is these samples hold the key to improved diagnosis, treatment, and perhaps even a cure for the millions of people around the world with ME/CFS.

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