

Research Strategy
2018 - 2022

Executive Summary

This Strategy builds on Coeliac UK's previous research strategy initiatives running from 2013-2016. We have worked with our members, healthcare professionals, our Health Advisory Council, researchers and research organisations, and policy makers with the aim of improving the lives of people living with coeliac disease and other gluten related immune conditions. Through collaboration with the James Lind Alliance Priority Setting Partnership and our Research Strategy Board we have set out our research goals and established the mechanisms required in order to achieve them.

We will fund research that underpins and integrates with the needs of patients and those who care for them, through our Research Fund we will develop a long term research agenda to improve the understanding, diagnosis, treatment and management of coeliac disease and other gluten related immune conditions.

We will proactively seek opportunities for match funding and develop partnerships both nationally and internationally in order to achieve our goals.

We recognise that the charity's membership is a valuable resource for the research community providing the largest register of patients with the condition in the UK. In addition, the employees and volunteers within the charity are an important source of expertise and as such they are increasingly involved as active members of research teams and can facilitate an outreach to the wider research community

Introduction

Coeliac UK was founded in 1968. It is the largest charity in the world supporting people living without gluten, representing more than 65,000 members with coeliac disease^a, dermatitis herpetiformis (DH), the skin manifestation of coeliac disease or other gluten related autoimmune conditions, such as gluten ataxianeuropathy and encephalopathy.

Screening studies in the UK show that the prevalence of coeliac disease is estimated to be 1 in 100 people.^[1,2] Over the years, there has been considerable progress in the way coeliac disease is identified but yet only 30% have a medical diagnosis.^[3]

To date there has been little progress towards understanding the nature of individual onset triggers, the consequences of late diagnosis, and there is still only one treatment, strict adherence to a lifelong gluten free diet.

We have committed significant funds into research in the last 15 years; research to understand the genetic basis^[4] and immune processes involved in the disease as well as identifying the major toxic fragments of gluten^[5], laying the foundations for a potential vaccine.

We now aim to increase and strengthen the research base in the UK and to support international collaborations to advance knowledge, understanding, diagnostics, therapeutic interventions and better management of the condition. Research of this kind is increasingly expensive, requiring innovative approaches to provide solutions to funding, such that a move to develop partnerships and collaborative working, both nationally and internationally is required.

We recognise our membership is a valuable resource for the research community providing the largest register of patients with the condition in the UK. In addition, the employees and volunteers within the charity are an important source of expertise and as such, they are increasingly involved as active members of research teams and can facilitate an outreach to the wider research community.

Our mission is to improve the lives of people living without gluten. By investing in research into the nature and effects of gluten, we hope one day to overcome coeliac disease. Our vision is for no life to be limited by gluten.

^a throughout this strategy, coeliac disease is to include, dermatitis herpetiformis and the other gluten related conditions such as gluten ataxia, peripheral neuropathy and encephalopathy.

Our goals and aims

Our Research Strategy aligns with the charity's overarching Strategy.

We have identified four key areas for research:

- **Understanding the cause** – identifying risk factors and triggers involved in the cause, risk or development of disease
- **Diagnosis** – discovering and developing diagnostic and predictive markers and technologies
- **Treatment** - discovering and developing treatments, in addition to the gluten free diet, in preclinical settings
- **Management** - research into the individual care needs and management of the disease and associated conditions, including provision and delivery of health and social care services

We will work to identify gaps in the evidence base and, where appropriate, commission work to fill those gaps.

Our aim is to support the small, but increasing number of researchers and research organisations who are developing greater interest in the study of coeliac disease. By promoting and funding this research, we hope to establish the field as a recognised academic research speciality.

How we will achieve our goals

- Ensuring people affected by coeliac disease and other gluten related immune conditions have the opportunity to have their say
- Increase capacity for research within the UK
- Encourage collaborations, nationally and internationally and across disciplines and diseases.
- Communicate and disseminate evidence

Research priorities

In 2017, we completed a James Lind Alliance Priority Setting Partnership. We have identified a top ten list of research priorities from consulting individuals affected by coeliac disease and/or other gluten related immune conditions and healthcare professionals:

- 1 **What are the risk factors or triggers** (eg environmental, lifestyle, dietary, additional genetics) involved in the development of coeliac disease in people who are genetically predisposed to the condition ie HLA-DQ positive? Do they determine when someone will develop coeliac disease and/or predict how severe disease-associated symptoms and complications will be
- 2 How can **healthcare professionals be best supported** to accurately diagnose and manage coeliac disease and other gluten related autoimmune conditions to achieve **earlier diagnosis and improve patient care?**

- 3 What is the **spectrum of neurological forms** of coeliac disease and how does neurological dysfunction develop? How are they best diagnosed and managed?
- 4 Are there **less invasive tests** (apart from gastroscopy and duodenal biopsy) for recognising coeliac disease and is it possible to accurately test for coeliac disease once gluten has been excluded from the diet?
- 5 What are the **associations between coeliac disease and other conditions** eg Type 1 diabetes, autoimmune thyroid disease, and what factors influence the risk of developing such conditions?
- 6 What is the **best means of follow up management** of people with coeliac disease and/or other gluten related autoimmune diseases, including help with sticking to the gluten free diet and prevention of long term health complications? *(taking into consideration things like other conditions, age, education, socioeconomic status, mental health, no symptoms)*
- 7 What are the **best ways to educate people working in the catering/hospitality industry** about the gluten free diet to improve safety for people with coeliac disease when eating out?
- 8 How can coeliac disease be **cured** so that consideration for a gluten free diet is no longer necessary?
- 9 How can **coeliac disease and associated complications be prevented** in genetically vulnerable individuals (eg using drugs, vaccinations or modification of diet)?
- 10 How can a greater understanding of the causes of refractory coeliac disease Types I and II be used to develop and improve diagnosis and treatment of the conditions?

We do not intend to exclusively restrict our funding to these priorities, and will continue to support all aspects of research into coeliac disease and the impacts of gluten. However, applications that specifically address any of these priorities will be considered more favourably.

Key principles

- A robust framework will be established in order to call for research proposals, undertake scientific peer review, award funding, manage grants and ensure maximum impact of research findings through dissemination and publication.
- We will fund research and make significant contributions to the long term research agenda in understanding, diagnosing, managing and treating coeliac disease.
- All funded research will be assessed for intellectual property to ensure appropriate recognition and remuneration from investments.
- We will promote the clinical translation of new methodologies, technologies and findings for the benefit of patients.
- Research proposals will be peer reviewed and assessed for relevance to the charity's research priorities, patients' needs and scientific excellence.

- All research funded by Coeliac UK must aim to benefit people with coeliac disease. Researchers must understand and appreciate the importance of translating their research into practice for the benefit of people with coeliac disease.
- Only appropriately, qualified individuals, as determined during the peer review process, may receive research funding.
- Applicants must be contracted to work in an appropriate institution which has the necessary networks to support education, training, ethical standards and professional development.
- All grant applications must include either a lead applicant or collaborator based at a UK university or NHS institution.
- All research proposals must have a statement of originality. Replication of work carried out elsewhere will not generally be accepted, although there may be exceptions where the same research question may have a different outcome depending on the cultural environment.
- The Charity will consider exceptional proposals of novel research, not included within the scope of this Strategy. Such proposals must demonstrate how the research will further the understanding of coeliac disease and the potential to improve the lives of people affected by the condition.

Types of grants

Calls for research, themes and priorities, are ultimately approved by the Board of Governors. The research call and application process will be clearly advertised on the Coeliac UK website and networks, with relevant professional bodies and via national research call networks.

Research Programmes

The charity will award programme grants designed to answer a single question or a small group of related questions, which must be directed at the charity's research priorities. It is expected that programmes will establish a network of researchers, of which at least one must be based in the UK. The programme should aim to create a virtual network of excellence in research into coeliac disease, with the foundation for longevity and for further research into the condition, beyond the original research programme grant. Collaborations across disciplines and conditions, where appropriate, are encouraged. As is securing additional funding outside of Coeliac UK.

Innovative grants

The charity will award grants to provide support for innovative short term, small scale pilot or proof of concept projects.

Research Fellowships

The objective of the fellowship (clinical or non-clinical) is to build capacity in research into coeliac disease and the impacts of gluten, where there is currently a deficit, by encouraging the best graduates to embark on an early career in this field.

PhD Fellowships

PhD fellowships are designed to encourage the best graduates to embark on a research career in coeliac disease and impacts of gluten.

Fellowships must be hosted within the UK and linked to an institution that has the appropriate infrastructure, support and expertise to encourage and nurture a future career working in this field.

Sponsored dissertations

The charity may provide a small grant (max. £1000 per student) to encourage undergraduates or postgraduates (including but not limited to dietitians, immunologists, food technologists, clinicians, epidemiologists, social scientists, psychologists, medical students) studying at UK institutions, to focus on coeliac disease and the impact of gluten in their project work.

The primary objective is to place coeliac disease, a culturally specific condition, on the research agenda of UK academic institutions, whilst commissioning research that supports the charity's research priorities.

Research governance

We will ensure we meet the Association of Medical Research Charities standards of best practice in research governance.

Good governance is important in ensuring that we fund high quality and relevant research that has an impact on people living with coeliac disease.

Our Research Awards Panel comprises expert researchers working in relevant/associated fields. Grant applications will be screened and subject to peer review by our Research Awards Panel. Applications will be reviewed by both external peers and our lay Member Review Panel. All applications will be scored and judged on the quality of science and relevance to coeliac disease. The Research Awards Panel will make recommendations for funding to our Board of Governors based on the results of the review process.

Progress, annual and final reports from funded research will also be reviewed by the Research Awards Panel.

Professional and public engagement

We will strive to ensure the evidence we generate and that of others is used to its full capacity. We will communicate and disseminate the outcomes of research, both positive and negative to both the research community and people affected by coeliac disease.

The results of our research can underpin our policy positions and campaigning, as well as influence the research agenda of others.

We will aim to hold an annual research symposium for healthcare professional members of the charity and researchers. This will provide the opportunity for researchers, including those funded by Coeliac UK, to share their research findings and best practice with others whilst also contributing to their continuing professional development.

This is to ensure the achievements and the implications of the research Coeliac UK has funded are recorded and communicated. This information allows us to determine if the research has been carried out in accordance with the grant conditions and objectives of the charity. It also helps with the reporting to our members and for our future planning and strategy development.

We will continue to engage the gluten free community and others in understanding the aims of our research and supporting our need for further funding through our communication channels, including social media, our website and printed publications.

Involving people affected by gluten

Our members and their carers/families play a vital role in research, their participation in the past has advanced the understanding of coeliac disease and the impact of gluten.

We will use our available communication channels to connect our members with researchers; via our website, electronic newsletter, Crossed Grain magazine and social media networks.

In 2014, we introduced the Member Review Panel to give our members the opportunity to have their say. Members of the panel review lay summaries of research grant applications and score them. The feedback from the panel influences what research we fund.

Our staff

Our staff has a wealth of experience, expertise and knowledge of coeliac disease and the impact of gluten. Where appropriate we will support researchers in the preparation of their research proposals and/or applications for funding. Where resource allows and the expertise is available, we contribute to steering committees, collaborate on projects and facilitate an outreach to the wider research network.

Your views

If you have any comments or questions about our Research Strategy 2018-2022 please contact our Research Manager at heidi.urwin@coeliac.org.uk

References

- [1] West J, Fleming KM, Tata L J et al. Incidence and prevalence of celiac disease and dermatitis herpetiformis in the UK over two decades: population-based study. *Am J Gastroenterol*. 2014 May;109(5):757-68. doi: 10.1038/ajg.2014.55. Epub 2014 Mar 25
- [2] Bingley PJ, Williams AJ, Norcross AJ et al. Undiagnosed coeliac disease at age seven: population based prospective birth cohort study. *BMJ*. 2004 Feb 7;328(7435):322-3
- [3] West J, Otete H, Sultan AA et al. Changes in the testing for and incidence of coeliac disease in the UK 2005-2015: a population based cohort study. Poster presentation Coeliac UK Research Conference, 15 March 2018.
- [4] Coeliac UK website; To determine heritable germline genetic variants pre-disposing to coeliac disease. www.coeliac.org.uk/vanheel
- [5] Coeliac UK website; Comprehensive gluten T-cell epitope mapping in coeliac disease. www.coeliac.org.uk/anderson