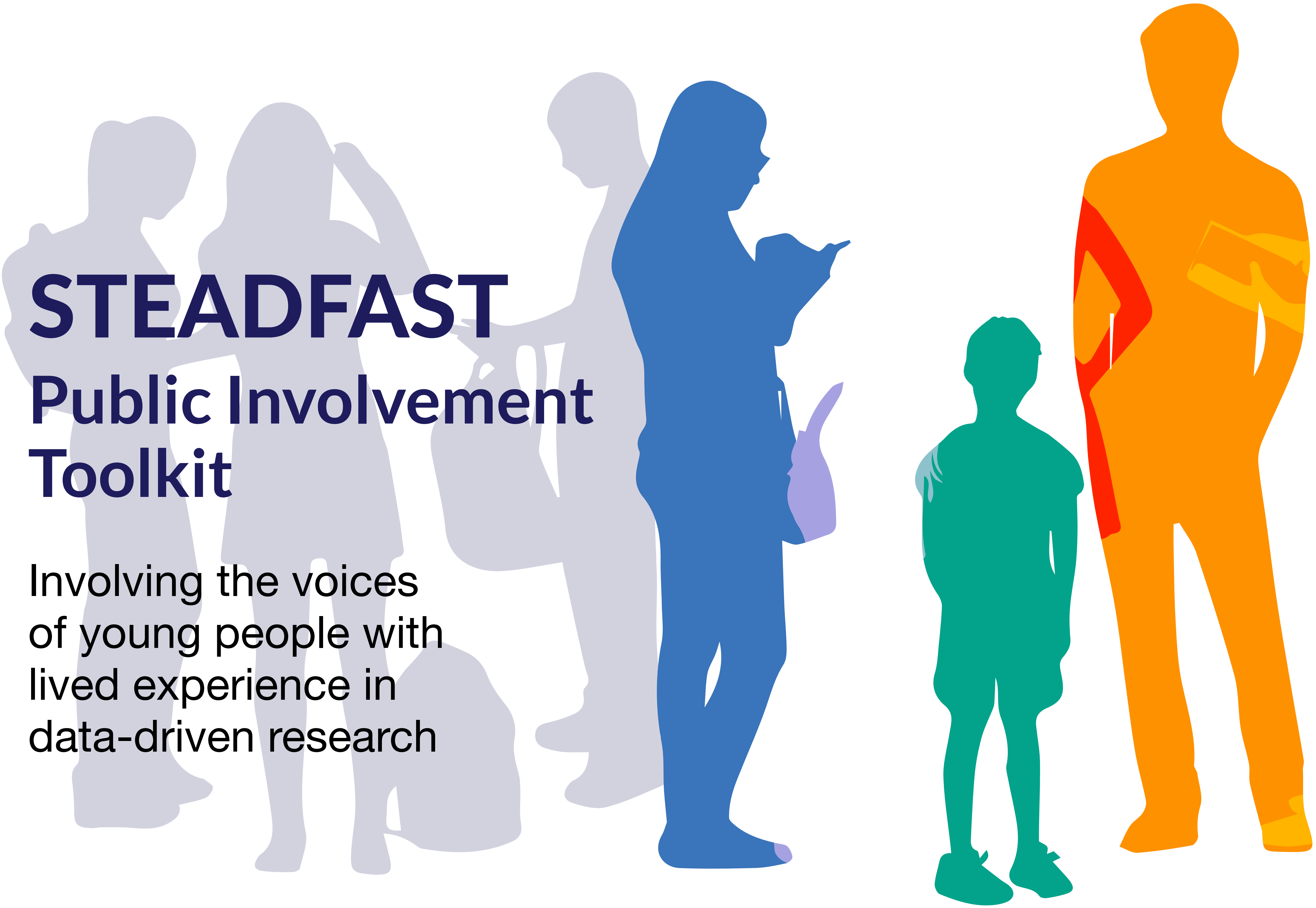

STEADFAST

Public Involvement Toolkit

Involving the voices of young people with lived experience in data-driven research

STEADFAST

The STEADFAST Project Team

Cardiff University, Diabetes UK, Egality Health, Helix Data Innovation,
& The Steadfast Young People's Advisory Group

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

egality
diversity in research
equality in health

Helix
Data
Innovation

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
School of Medicine
Ysgol Meddygaeth

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Centre for Trials Research
Canolfan Ymchwil Treialon

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Involving the voices of young people with lived experience in data-driven research

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Forward

STEADFAST explored the perspectives of young people around research which uses their sensitive data without consent at scale.

STEADFAST was a collaboration between charity Diabetes UK, the School of Medicine at Cardiff University, the STEADFAST Young People's Advisory Group, social enterprise Egality Health, science impact accelerator Helix Data Innovation and several community groups.

STEADFAST used the topic area of education outcomes in young people with type 1 diabetes as an exemplar of research in which large-scale sensitive data are linked without explicit consent and anonymised for use by researchers to answer important questions, supporting evidence-based policy.

Our STEADFAST Public Involvement Toolkit ('STEADFAST Toolkit') is a key output of STEADFAST. The Toolkit takes researchers through the steps that we found were the most productive in involving and engaging young people with type 1 diabetes in research, particularly issues that young people told us were important to them. Our STEADFAST Toolkit is primarily aimed to be used by researchers on projects using large-scale linked data, to help them with their public involvement efforts, but it could also be used by anyone interested in involving young people in research.

The STEADFAST Toolkit was developed following 19 online workshops with young people with type 1 diabetes from across the UK in the summer of 2022. The workshops were designed to inform and to elicit opinions from young people around the use of their linked health and education data in research. Alongside the discussion of use of their data, we also covered the context and benefits of using these data, to explore the support for young people available from schools, colleges and employers for type 1 diabetes management in educational and workplace settings. Further background on the project is available in our final project report available on the DARE UK website. This toolkit focuses on the processes we used for engagement. Our research findings are being developed into research articles for publication in peer-reviewed academic journals. In this toolkit we have included practical examples of activities to support public involvement with young people. While our project focused on type 1 diabetes and education, the strategies and activities should be transferable to young people with or without other health conditions.

Good public involvement is central to inclusive, ethical, impactful research. Our workshops were co-designed with the STEADFAST Young People's Advisory Group (YPAG), a panel of young people with type 1 diabetes aged 18 to 30, chaired by Dr Thomas Wylie, who lives with type 1 diabetes and is also a research manager at Imperial College London, and so able to interface between the views of other young people with type 1 diabetes and the research context. The STEADFAST Toolkit was developed in consultation with stakeholders, including representatives of Diabetes UK and its Diabetes Research Steering Groups; Health Data Research UK; Medical Research Council; use MY data; Association of British Pharmaceutical Industries (ABPI); The Association for Young People's Health; the Alan Turing Institute; the British Heart Foundation Data Science Centre; The Royal College of Paediatrics and Child Health; NHS Digital; Lilly; and the universities of Edinburgh, Warwick and Imperial College London. We are grateful for the support of community groups the Caribbean and African Health Network, South Asian Health Action, Chronically Brown, Research Black, and Dietician Ellouise.

In particular we would like to thank the 70 young people who participated in our workshops, and for their honesty and trust in sharing their views with us. We learned that public involvement requires skill, expertise and proper funding, and it's not simple to get it right. We hope you will find the STEADFAST Public Involvement Toolkit helpful in supporting your public involvement activities right through your research project.

Dr Rob French, Cardiff University and Lucie Burgess, Diabetes UK
STEADFAST Principal Investigators | On behalf of the STEADFAST team | January 2023

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PART ONE

STEADFAST Content, Aim & Objectives

Section 1: Overview and context of the STEADFAST project

Section 2: Involvement of young people in the context of data-driven research

Section 1:

Overview and context of the STEADFAST project

Background to STEADFAST

Type 1 diabetes is a common long-term health condition affecting around 40,000 young people in the UK. It requires daily management, including monitoring of blood glucose levels and taking insulin using injections or a pump. The four UK home nations have legal commitments to support young people with medical conditions in their education.

However, there are significant challenges in providing evidence to support interventions. Linking data about type 1 diabetes and education could help to provide this evidence base and to provide support for young people with type 1 diabetes, their families, health professionals, schools and universities.

Wide public understanding and strong support are critical for the use of sensitive data in research, such as health and education data. It is particularly challenging to engage in such conversations with younger individuals, both from a methodological and practical perspective. Prior to STEADFAST, researchers at Cardiff University, charity Diabetes UK and partners previously developed a data access framework and set up a Young People with Type 1 diabetes Panel to support research into education outcomes for young people with type 1 diabetes.

STEADFAST builds on this prior work. Through STEADFAST, we explored the best ways to inform, engage and involve young people ages 13-24, their families and the wider public in important issues around the use of their sensitive data for research. We set ourselves a target of participation in the project of at least 50% from under-represented groups, which we defined in this context as young people from the lowest five deciles of deprivation, and ethnic minorities.

Our focus was on public involvement in research projects using large-scale personally-identifiable and sensitive data without consent. Personal data can be split into two main categories: personal data that can be used to identify an individual such as name, postal address, contact details, date of birth and NHS number; and sensitive data relating to characteristics such as health, religion, ethnicity, political opinions, sexual orientation, financial data, employment data, biometric and genetic data. Definitions of what is, and is not, sensitive data could also be informed by the voices of young people themselves. Young people told us that it should not be automatically assumed that data relating to their education, such as exam results or absenteeism from school, is not sensitive. Therefore, we consider it is important in data-driven research projects to ascertain the types of data that young people themselves would define as sensitive.

Funding acknowledgement

STEADFAST was funded by UK Research & Innovation (Grant Number MC_PC_21031) as part of Phase 1 of the DARE UK (Data and Analytics Research Environments UK) programme, delivered in partnership with Health Data Research UK (HDRUK) and Administrative Data Research UK (ADRUK). DARE UK aims to develop next-generation trusted research and analytics environments for public good. The full title of our project is STEADFAST - Education Outcomes in Young People with type 1 diabetes: Innovative Public Involvement and Governance to Support Public Trust.

Ethical approval

Ethical approval was granted by the Cardiff University School of Medicine Ethics Committee. It is important to note that we sought ethical approval and conducted aspects of our project as research, in order to publish our findings in a peer-reviewed journal. While ethical approval is not necessary for public involvement, we found the research ethics framework useful for ensuring we maintained the same high standards of governance expected of research, for example in information governance of participants' data and safeguarding practices for younger participants.

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Section 2:
Involvement of young people in the context of data-driven research

What is public involvement in research?

The National Institute for Health Research (NIHR) defines public involvement in research, 'as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. It is an active partnership between patients, carers and members of the public with researchers that influences and shapes research.'

We adopt the term 'public involvement' for what has previously been called 'Public and Patient Involvement and Engagement' (sometimes using the acronyms PIE or PPIE), because it includes 'patients, potential patients, carers and people who use health and social care services as well as people from specific communities and from organisations that represent people who use services. Also included are people with lived experience of one or more health conditions, whether they're current patients or not.'[1]

Why is it important to involve young people in data-driven research?

Young people may have different opinions to adults about what matters to them[2]. It is good practice to involve people in research that affects them, whether or not this research requires their consent, because research which is informed by experiences of the public or patients is more relevant[3]. It is also crucial to include the voices of young people from under-represented communities, because research which does not involve diverse groups may be biassed or less impactful (Pii et al. 2019, Yeoh et al. 2021). In our view, public involvement is especially important when using population-scale datasets in which the research is highly data-driven or analytical, and in which there is a risk that the 'human factor' and impact on the individual could be lost; this perspective was reinforced by the young people who participated in STEADFAST.

Under the United Nations Convention on the Rights of the Child, which came into force in the UK in 1992, children have the right to say what they think should happen when adults are making decisions that affect them and to have their opinions taken into account. The Convention clearly applies to research contexts[4]. According to the UK data protection regulator, the Information Commissioner's Office (ICO), children have the same rights as adults over their personal data, but they need 'particular protection' when their personal data is processed, as they may be less aware of the risks than adults[5]. However the ICO does not provide specific guidelines about what this particular protection may involve. It is important to note that STEADFAST focused on young people over the age of 13, who are not, strictly speaking, children in terms of data protection law (the General Data Protection Regulation in Europe states that the age at which a young person is able to give their own consent to data processing is 16 years, with member states able to set their own age of consent to a minimum age of 13). The Nuffield Council on Bioethics provides three helpful scenarios in which a child's or a young person's potential for input into a research decision raises ethical considerations; within the STEADFAST project, we considered young people within 'Case Three: children and young people who potentially have the capacity and maturity to make their own decisions about taking part in a particular research study, but who are still considered minors in their domestic legal system'[2].

A key aspect of the DARE programme, through which STEADFAST was funded, is the importance of building public trust in research that uses large linked datasets across research domains (e.g. health and education) with or without consent. Evidence of public trust, particularly for unconsented data-driven research, is required by ethics committees, funders, data providers and regulators. Aside from the expectations of regulators, public involvement enables researchers and research funders to seek views from the public which can influence research for the better; to explain the public benefits of data-driven research; to improve its quality; to reduce bias and enhance its diversity, and to ensure its impact is focused on public benefit.

Public involvement in data-driven research is particularly critical for research projects which use population-scale data without consent. The advantage of using data without consent is that such data give a fuller picture of the health of the population compared to consented datasets, as they are more inclusive of diverse individual characteristics, geographies and sectors of society. Gaining consent for very large datasets may not be practical or economically feasible. At the time of writing, to access health data without consent for research in England and Wales, researchers can make an application to the Confidentiality Advisory Group of the Health Research Authority[7]. They must demonstrate that the research is in the public interest, that the research would not be feasible or economically-viable with consent and that appropriate public engagement has taken place. A full explanation of the legal basis for accessing health data for research is beyond the scope of this Toolkit, but STEADFAST was specifically focused on aiming to develop the public involvement best practices that the Health Research Authority and other regulators would expect in large-scale data-driven research.[6]

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Involving young people in health research - existing resources and frameworks

There are many existing frameworks and resources available to guide researchers through public involvement, of which the best known in health research are probably the UK Standards for Public Involvement[8] and the National Institute for Health Research (NIHR)[9] Guidance for Researchers in NHS[10], Health and Social Care Research. Diabetes UK published guidance on public involvement in research it funds in 2017.

The UK Standards for Public Involvement are based on six key strategies: (i) Inclusive Opportunities, accessible and inclusive according to research need; (ii) Working Together, building and sustaining successful respectful co-productive relationships; (iii) Support and Learning, developing skills for public involvement members; (iv) Governance, involving members in management, regulation and decision making; (v) Communication, adequately informing public involvement members using plain accessible language; (vi) Impact, clearly communicating evidence of public involvement impact[11].

Existing resources and frameworks focused specifically on the involvement of young people in research include:

Nuffield Council on Bioethics - Involving Children and Young People in Health Research - Getting it Right[12]

This helpful guide points out that young people have the ability to make their own decisions, but are not treated as adults by the laws of their country. It also explains the rules on assent and consent, and offers advice on making decisions in research in collaboration with families.

Research studies of public involvement

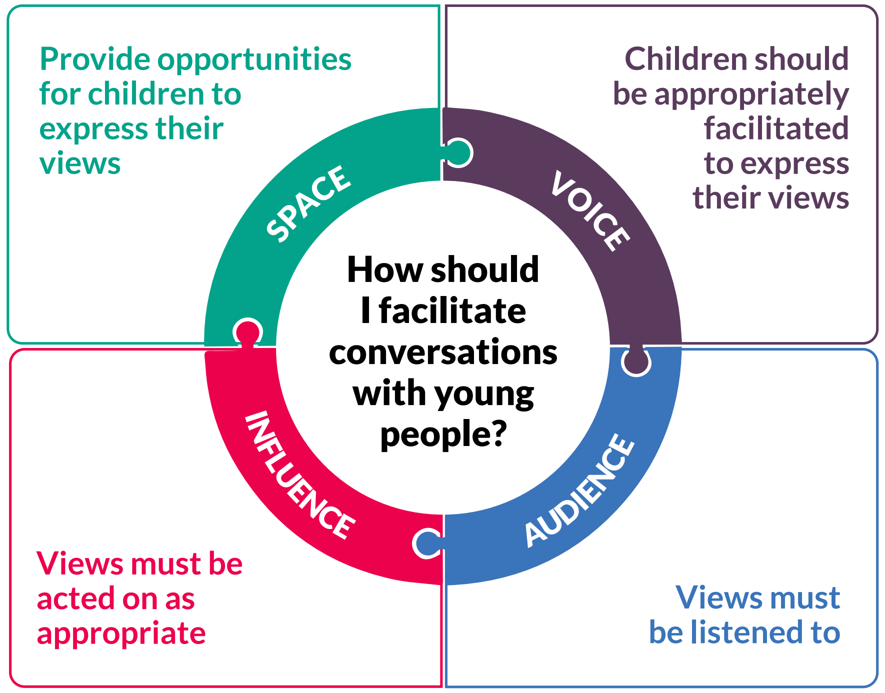
The methods and impact of public involvement are an emerging research topic in their own right, however there is very little research specifically focused on the involvement of young people in health research, or on public involvement for data-driven research. We conducted an initial light-touch literature review at the beginning of STEADFAST to understand the methods and tools that researchers had used previously.

Bird et al. (2013) identified the risks and benefits of collaboration with the public and patients in research. UKRI summarised the challenges of involvement of young people in research using routinely collected data across healthcare and education without consent[13]. Yeoh et al. (2021) published an article on patient involvement in rheumatology research, describing the patient involvement work of the NIHR Biomedical Research Centres. They stated that three essential ingredients were needed to ensure that research met the properties of patients: patient involvement, patient engagement and patient participation. Kaisler and Missbach (2020) developed a Public and Patient Involvement and Engagement Toolkit in Austria through multi-disciplinary co-production workshops involving researchers and patients, including young people. van Schelven et al. (2020) conducted a scoping review of public involvement with young people with chronic conditions in health and social care, and found that there was dearth of literature in the area and very little current evidence of impact from public involvement activities. They identified only 23 studies which addressed public involvement of young people with chronic conditions in health or social care research published since 1990, the year that the UN Convention on the Rights of the Child was ratified. Desborough et al. (2022) recently explored a research team's experiences of co-production in research with young people with type 1 diabetes.

The lack of existing methods and pathways to impact for the involvement of young people in data-driven health research, was a gap that STEADFAST aimed to address.

Lundy Model of Participation

Professor Laura Lundy published her model of child participation in education policy in 2007, based on Article 12 of the United Nations Convention of the Rights of the Child (Lundy 2007). Lundy argued that the concept of 'pupil voice' was not enough, and that other concepts of space, audience and influence were needed to fully conceptualise the rights of children enshrined in Article 12. The Lundy Model of Participation recommends that child participation should use four guiding principles: **space**, **voice**, **audience** and **Influence**.

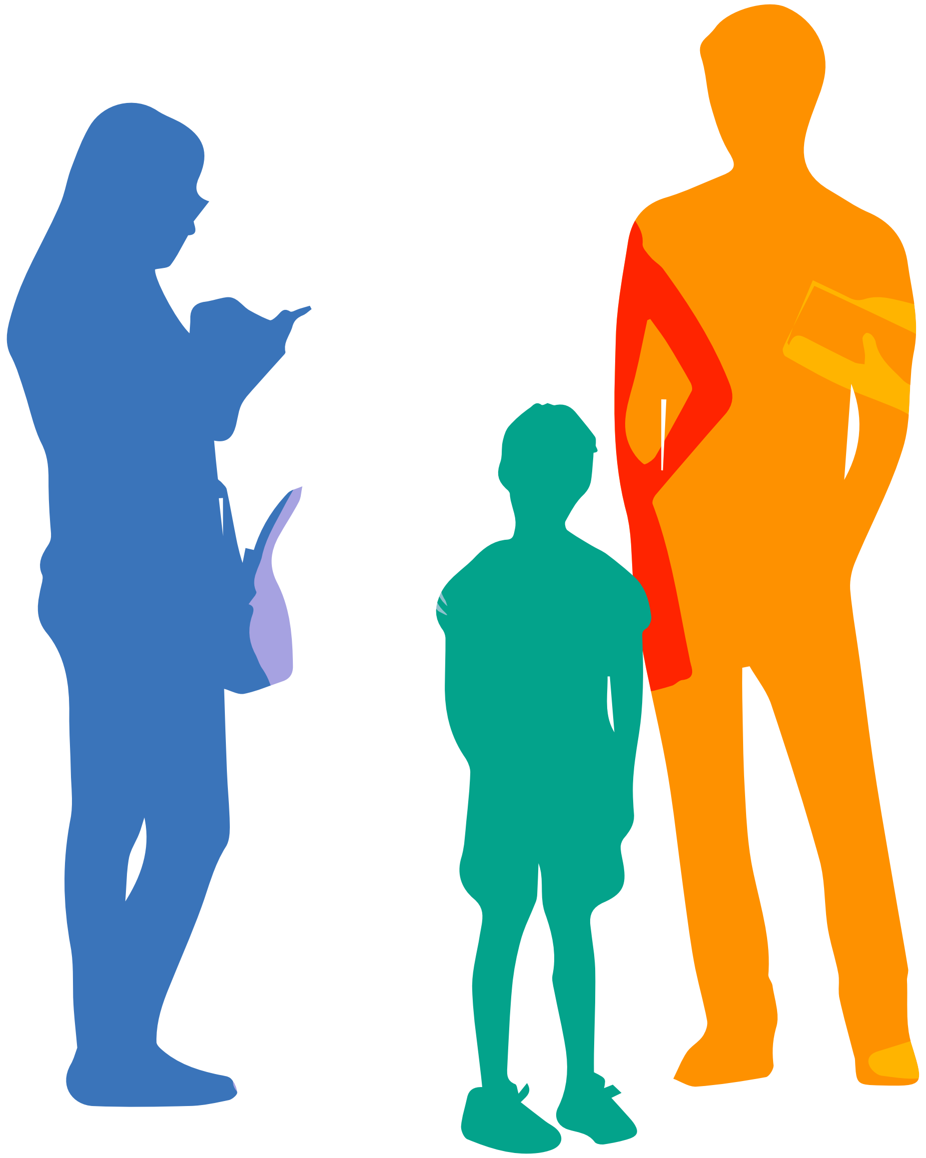


Provide opportunities for children to express their views

Children should be appropriately facilitated to express their views

Views must be acted on as appropriate

Views must be listened to



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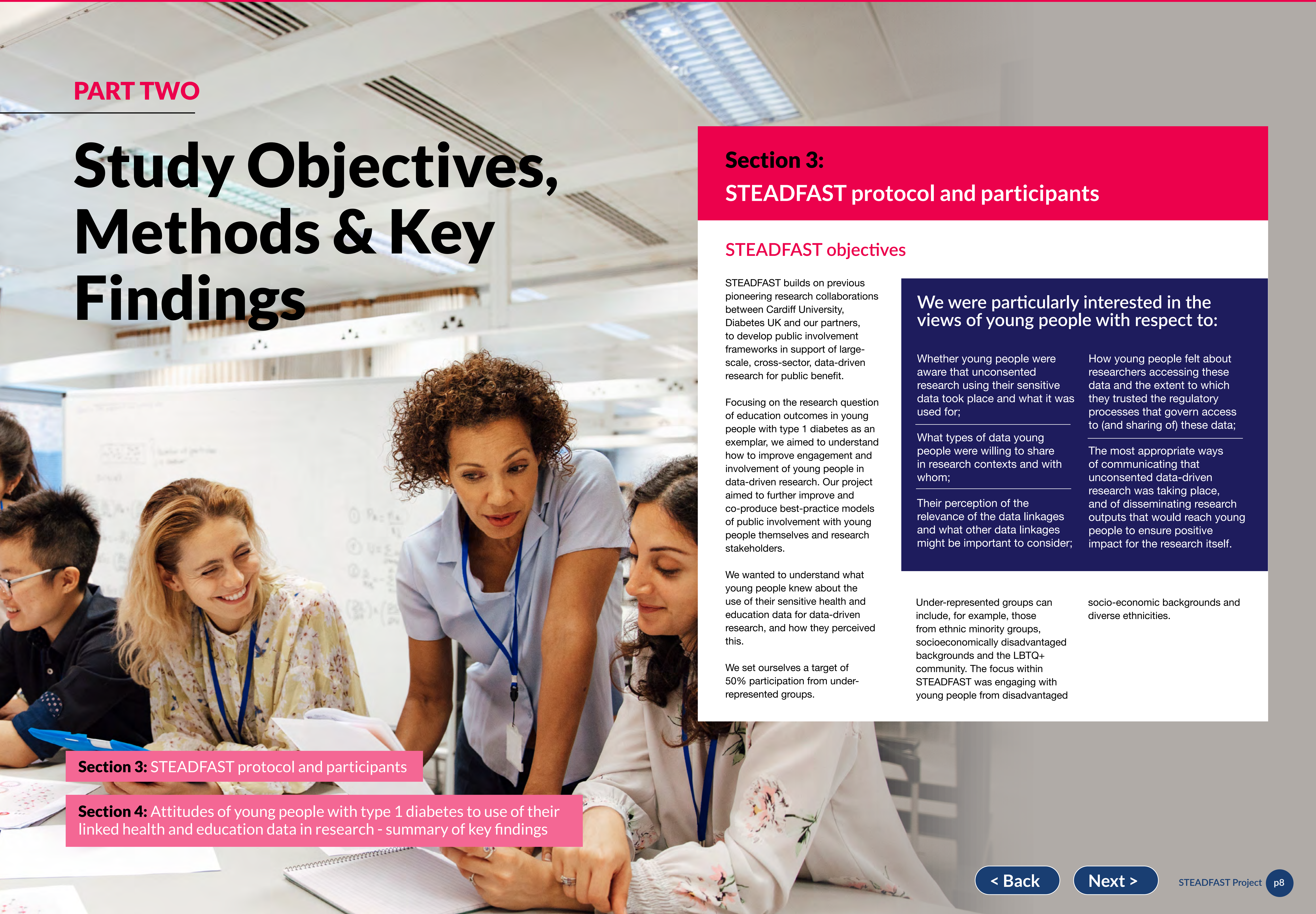

PART TWO

Study Objectives, Methods & Key Findings

Section 3:
STEADFAST protocol and participants

STEADFAST objectives

STEADFAST builds on previous pioneering research collaborations between Cardiff University, Diabetes UK and our partners, to develop public involvement frameworks in support of large-scale, cross-sector, data-driven research for public benefit.

Focusing on the research question of education outcomes in young people with type 1 diabetes as an exemplar, we aimed to understand how to improve engagement and involvement of young people in data-driven research. Our project aimed to further improve and co-produce best-practice models of public involvement with young people themselves and research stakeholders.

We wanted to understand what young people knew about the use of their sensitive health and education data for data-driven research, and how they perceived this.

We set ourselves a target of 50% participation from under-represented groups.

We were particularly interested in the views of young people with respect to:

Whether young people were aware that unconsented research using their sensitive data took place and what it was used for;

What types of data young people were willing to share in research contexts and with whom;

Their perception of the relevance of the data linkages and what other data linkages might be important to consider;

How young people felt about researchers accessing these data and the extent to which they trusted the regulatory processes that govern access to (and sharing of) these data;

The most appropriate ways of communicating that unconsented data-driven research was taking place, and of disseminating research outputs that would reach young people to ensure positive impact for the research itself.

Under-represented groups can include, for example, those from ethnic minority groups, socioeconomically disadvantaged backgrounds and the LBTQ+ community. The focus within STEADFAST was engaging with young people from disadvantaged socio-economic backgrounds and diverse ethnicities.

Section 3: STEADFAST protocol and participants

Section 4: Attitudes of young people with type 1 diabetes to use of their linked health and education data in research - summary of key findings

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Project timeline, methodology and outputs

The STEADFAST project was delivered over 8 months from January - August 2022. The STEADFAST Toolkit was finalised between September and December 2023. Figure 1 below provides a summary of the project timeline, key phases of work and outputs.

In the first phase (months 1-3), we began by setting up the project administration and seeking ethical approval for the project. Although this is not strictly necessary for public involvement within a research project, in this case we wanted to publish the study findings as academic outputs.

In the second phase (month 4), we conducted a light-touch rapid literature review on two key topics: (i) public involvement in research and (ii) the views of young people in sharing healthy and education data for research, from existing scientific and grey literature. This work was led by the Public Involvement and Engagement Manager overseeing the project, Karen Rigby (Diabetes UK, on secondment from Royal Devon and Exeter NHS Foundation Trust). We established a Young People's Advisory Group of young people living with type 1 diabetes aged 18-30; given the overall rapid 8 month timeframe of the project it was decided that an over 18 age group would be more appropriate. This group was critical in steering and co-producing the project throughout.

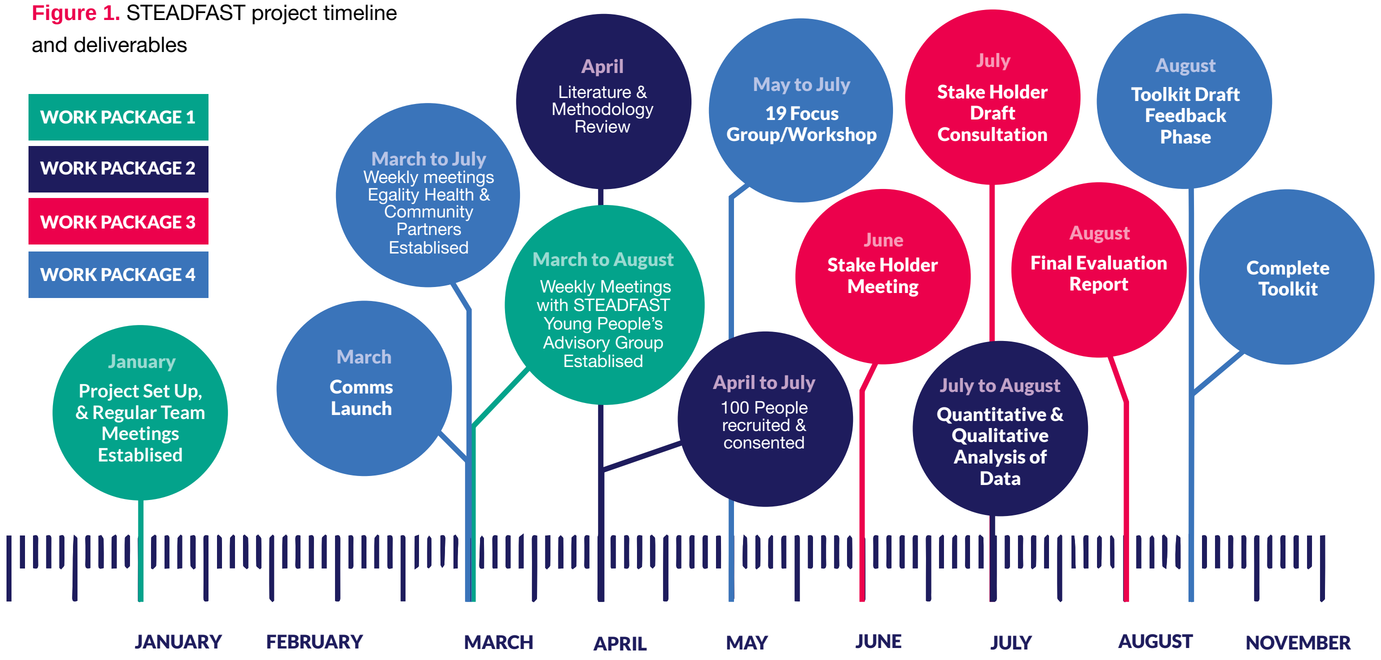
In the second and third phases (months 4 - 7) we began our participant recruitment campaign in collaboration with Egality Health and our Young People's Advisory Group. We co-developed communications materials, including a video from spoken word artist Duke Al Durham, for use on social media and online. We gave young people an ethical incentive, which was to participate in a conversation around type 1 diabetes, health and education which would be of great benefit to researchers, charity Diabetes UK and to policy-makers; and we offered financial compensation of £50. More about the involvement processes we developed and our learning is provided in Part Three.

We invited expressions of interest from young people to participate, and over 400 young people indicated their wish to take part. Following up on the expressions of interest, we asked for demographic information and the participant's postcode, which we linked (anonymously) to publicly available measures of deprivation from England, Wales, Scotland and Northern Ireland. We asked for their informed consent to participate, as well as parental assent for young people under the age of 17. We obtained consent from 100 young people (and their parents where appropriate), of which 70 of these young people subsequently participated in the focus groups.

We ran two stakeholder workshops with researchers, policy-makers and interested groups: one in June 2022 to understand what stakeholders wanted from a public involvement toolkit, and a second workshop in July 2022 to help us put this advice into practice by feeding back on a draft outline.

During August and September 2022 we wrote up the key findings of the workshops, and developed our final report. Between October and December 2022, we finalised the STEADFAST toolkit and a video explaining the project learning, ready for publication.

Figure 1. STEADFAST project timeline and deliverables



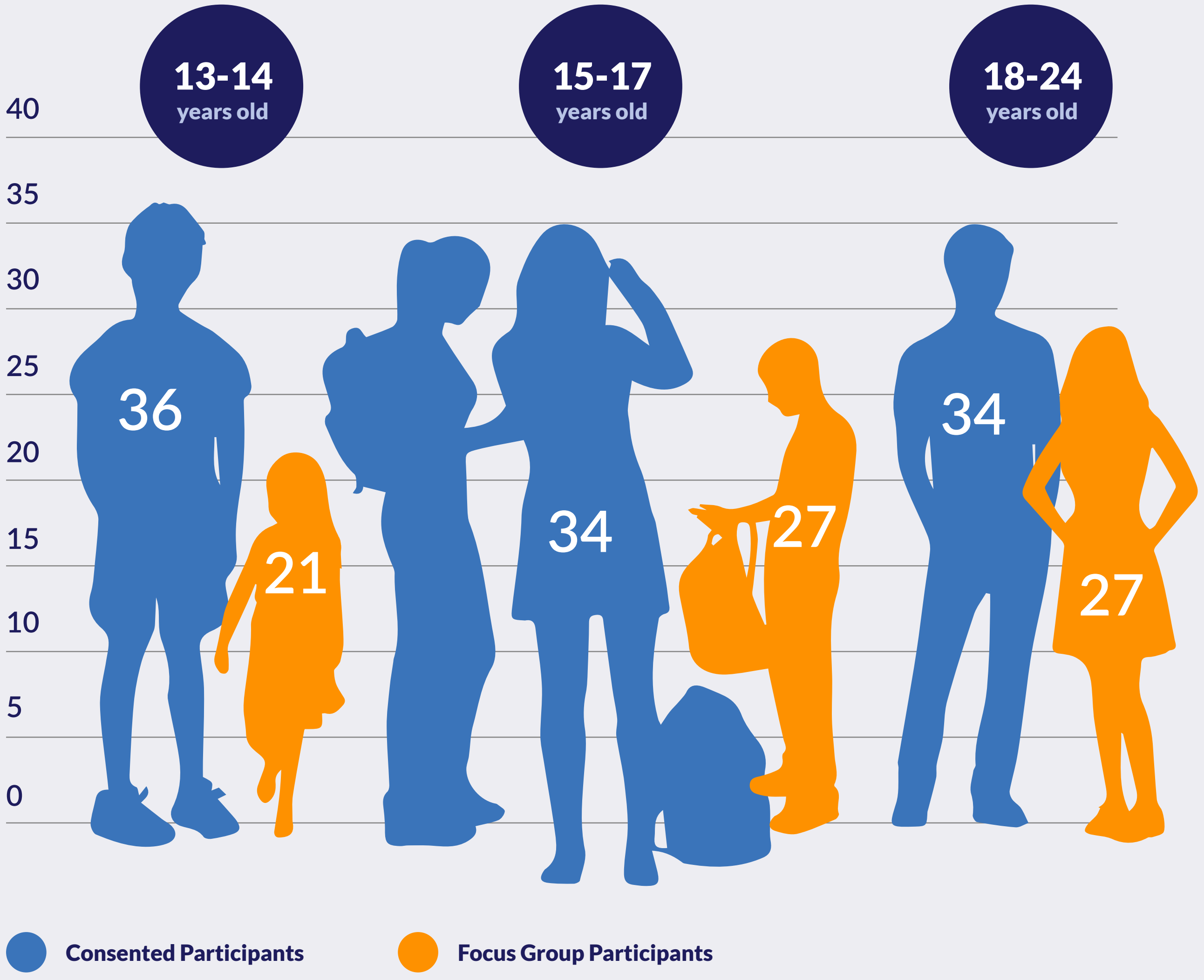
Demographic characteristics of STEADFAST participants

The STEADFAST team hosted 19 focus groups with a total of 70 young people aged 13 to 24 years old. Groups were kept small to facilitate interaction and participation, with between two and five young people in each group. The workshops were facilitated by a lead facilitator and a note-taker, both from either Diabetes UK or Cardiff University. The workshops were recorded and transcribed using Microsoft Teams, checked for accuracy and stored securely by Cardiff University. The key findings are summarised briefly in Section 4.

The tables and charts below illustrate the demographics of our participants in terms of age, gender, ethnicity and deprivation.

Ages of STEADFAST participants

We achieved a roughly equal mix of ages 13-14, 15-17 and 18-24 years old. The conversion rate of consented to participate was 58%, 67% and 79% respectively.



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Gender of STEADFAST participants

We took particular steps to encourage participation by young males, as they tend to be less well represented in research studies than females. Our methods are explained further in Section 4.

For comparison we reviewed statistics from the National Diabetes Audit (NDA)[14] and National Paediatric Diabetes Audit (NPDA)[15], the audits conducted by NHS England and the Royal College of Paediatric and Child Health on the use and effectiveness of NHS type 1 diabetes services. Because of the age range of participants and the varied ages that young people in different regions transfer into adult type 1 diabetes services, data on young people may be recorded in either of the audits. Figure 2 below demonstrates that males were under-represented compared to the audit datasets, despite our best efforts at encouraging young males to participate, however we are confident that without the specific steps we took, their representation would have been lower. Participants in the focus groups could also identify with gender categories not listed as options in the type 1 diabetes audits, these are not included in the comparison below.

Figure 2 - Gender of STEADFAST consented and focus group participants

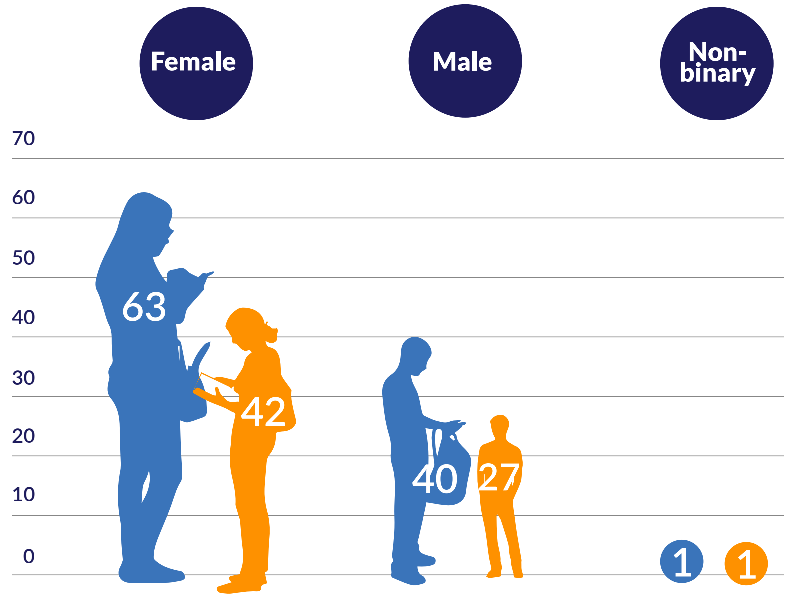
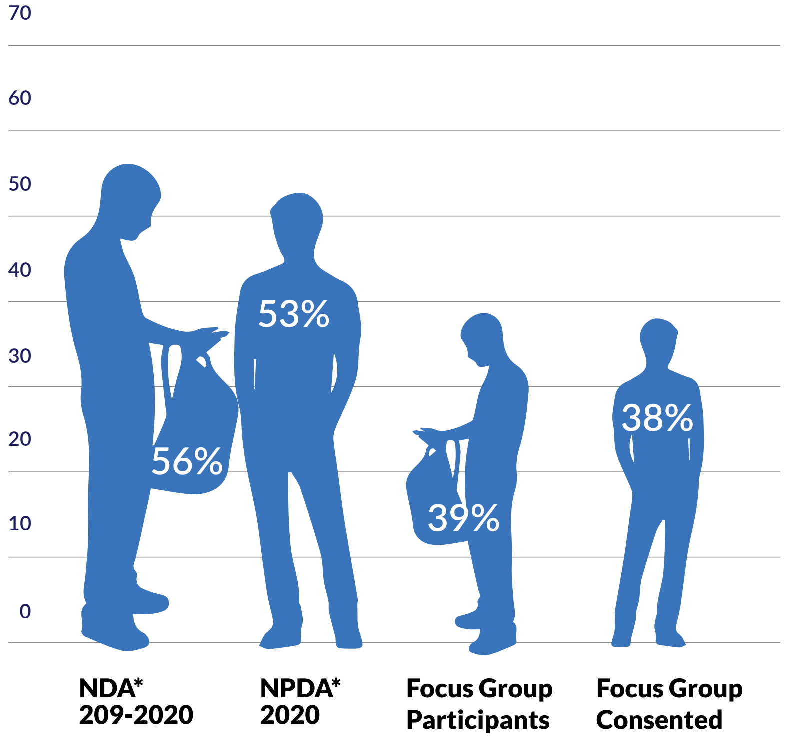


Figure 3 - Gender of STEADFAST consented and focus group participants compared to the percentage in the NDA and NPDA

Note: One STEADFAST focus group participant identified as non-binary, however there is no equivalent group in the NDA/ NPDA.



Ethnic background of STEADFAST participants

Whilst the majority (81%) of our focus group attendees were from white backgrounds, 19% were from ethnic minorities, which is shown in more detail in the table below. We achieved slightly higher representation from ethnic minority backgrounds than the National Paediatric Diabetes Audit and the National Diabetes Audit.

	TOTAL CONSENTED	TOTAL AT FOCUS GROUPS	TOTAL AT FOCUS GROUPS %	National Diabetes Audit 2019-2020	National Paediatric Diabetes Audit 2021
ASIAN OR ASIAN BACKGROUND	5	4	6%	3.5%	6.7%
Any other Asian Background	1	1			
Bangladeshi	1	1			
TOTAL Indian	2	2			
Pakistani	1	0			
BLACK, BLACK BRITISH, CARIBBEAN OR AFRICAN BACKGROUND	6	4	6%	2.3%	4%
African	5	4			
Any other Black, Black British or Caribbean	1	0			
MIXED OR MULTIPLE ETHNIC GROUPS	5	3	4%	1.1%	3%
Any other Mixed or multiple ethnic	3	2			
White and black African	1	0			
White and Black Caribbean	1	1			
OTHER ETHNIC GROUP	1	1	0.1%	1.1%	2.3%
Any other Ethnic Group	1	1			
WHITE	87	57	81%	82.6%	79.3%
Any other white background	4	4			
English, Welsh, Scottish, Northern Irish or British	82	52			
UNKNOWN	1	1	0.1%	9.5%	4.7%
TOTAL	104	70			

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Section 4:
Attitudes of young people with type 1 diabetes to use of their health and education data in research - summary of key findings

There was a variety of support for young people with type 1 diabetes at school in managing their condition, with universities usually offering better support. Best practice was often associated with the school's previous experience in managing type 1 diabetes.

The day-to-day treatment and management of type 1 diabetes requires an exceptional degree of maturity and autonomy from young people to ensure that blood glucose levels remain in range (e.g., access to mobile phones and other technologies to monitor glucose alarms and insulin delivery). Conflicts in negotiating this flexibility between teachers, support staff and students, amid the stress of managing type 1 diabetes, were discussed. When teachers engaged with young people about their condition, they felt better supported and safer, knowing their condition was being taken seriously.

Motivations for young people to be involved in research

We had a really enthusiastic response from the young people involved in our focus groups and most said that they would like to be involved in type 1 diabetes public involvement initiatives in the future. Some of the motivations for the young people to be involved in research were: financial reasons (they were compensated mostly with a £50 voucher, but some requested bank transfers); helping to improve their management of their condition; helping others; engaging with others about shared experiences; learning about data and research.

Attitudes to the use of linked data for research

National diabetes audits

Very few of the participants knew their data were used for the National Diabetes Audit. While most young people were happy for their data to be shared and used for the audit, many wanted to see more effort made to communicate and inform them about this use, beyond posters in GP surgeries which most participants had not seen.

Attitudes to sharing health data, education data and anonymised data

Young people were generally not happy to share identifiable health data as well as identifiable education data with future employers, social media companies, teachers, advertising companies or online contacts. However, over 80% of participants were generally happy to share these identifiable data with Diabetes UK, manufacturers of Flash/Glucose Monitors, parents or guardians, researchers, their GP, and NHS consultants. Nonetheless, on health data, they showed some mistrust of GPs, type 1 diabetes consultants and others, some of whom they felt did not understand type 1 diabetes. There were also some types of sensitive health data that they were less willing to share, such as mental health data, and many expressed the need to have their quantitative data explained within the context of their experience.

Attitudes did not vary significantly by age, although the younger age group was even less likely to feel comfortable sharing identifiable health data with teachers compared to the other age groups. There was a lack of knowledge about the fact that routine data could be used for research without consent, but most young people could see the benefit of this.

Anonymisation of data was generally viewed positively: removing identifiable details made young people more likely to share data with people and organisations that were less trusted.

PART THREE

Our Learning and Recommendations

Introduction

Our stakeholders told us that researchers wanted clear guidelines on how to engage and involve young people from diverse backgrounds, with specific best practice examples of how this involvement could work in practice. Based on this feedback, we have structured the STEADFAST Toolkit in the following way; each section covers a different key topic related to the involvement of young people and discusses:

(i) What we did - a summary of our approach, methodology and outputs

(ii) What we learned and our recommendations - aspects that went well, the things we would do differently next time, and our suggestions for involving young people in data-driven research.

While our case study focuses on public involvement for unconsented data-driven research, specifically education outcomes for young people with diabetes, linking individual data on education outcomes and health records without consent, we aimed for the STEADFAST Toolkit to be more widely applicable for any research project which uses data from young people for the public good.

Section 5: Summary of our public involvement approach - co-production and involvement across the research lifecycle

Section 6: Outreach, engagement, recruitment and inclusion of young people

Section 7: How we facilitated conversations with young people

Section 8: Legal and safeguarding Issues: How we kept young people and their data safe

Section 9: Acting on public involvement: how we aimed to develop meaningful impact

Section 5:
Summary of our public involvement approach: Co-production and involvement across the research lifecycle

Co-production and involvement at all stages of the Research Lifecycle

Study Design and Funding

Protocol development

Investigation and Analysis

Writing Up and Dissemination

Leadership, Management & Governance

Administration

Innovation in Public involvement

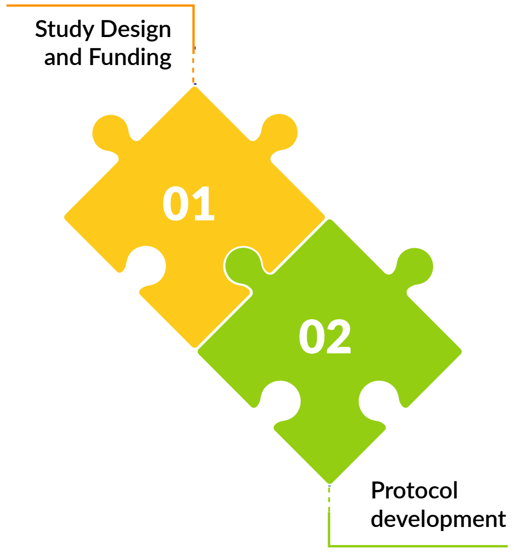
Co-production introduction

Co-production enriches public involvement and gives greater strength and insight to research. This is especially the case for research using unconsented data at scale, which requires evidence that the research is in the public interest, and that the public are involved and are aware that the research is taking place. This section of the STEADFAST Toolkit summarises our co-production approach at each stage of the research lifecycle.

How we approached co-production

Co-production and partnership. STEADFAST was established as a partnership between charity Diabetes UK and Cardiff University and two further contracted partners, Egality Health and Helix Data Innovation. We established the STEADFAST Young People's Advisory Group to guide the project. Diabetes UK led on communications, recruitment and consent and delivery of the focus groups with young people. Cardiff University led the research processes, overall research leadership and sponsorship from the Clinical Trials Unit within the School of Medicine, initial rapid scoping literature reviews, supported the focus groups and led the qualitative analysis, alongside the Diabetes UK Public and Patient Involvement and Engagement Manager. Egality Health led the engagement and outreach to diverse communities to recruit participants, in collaboration with several community groups. Helix Data Innovation organised and led two workshops with research stakeholders to understand what stakeholders wanted from a Public Involvement Toolkit. Diabetes UK's communications and safeguarding teams supported the project along the way. Knowledge exchange with Public Involvement leads across the DARE programme, HDRUK, and NIHR was invaluable for overall team idea generation and learning.

In these stages of the research, we recruited young people with type 1 diabetes, ages 13-24 with a particular emphasis on aiming to reach typically under-represented groups in research, i.e., people from areas with high levels of deprivation and from diverse ethnic groups (we talk more about outreach and engagement in Section 7).



We then developed focus group discussions. We initially structured the project as a series of focus groups across each of three topics, requiring young people to attend three focus groups, although we evolved this plan in response to feedback. We aimed to explore critical issues we had previously identified when submitting our proposal to DARE UK:

- Information governance framework issues;
- Types of data, challenging data, and future use of data;
- Public benefit and trust.

We built on these issues further by conducting two rapid reviews identified by the STEADFAST team:

- Management and support of type 1 diabetes for young people in educational settings;
- Young people's perspectives on the use of sensitive data in research.

We received feedback from the STEADFAST Young People's Advisory Group, Egality Health and community partners, Diabetes UK's Type 1 Lead and the Diabetes UK safeguarding team that it was unrealistic to expect young people to attend three separate workshops, that age groups needed to be separated, that our consent process was too complicated and that it was important to provide ongoing opportunities for research involvement. Co-production resulted in three sets of amendments to the focus group protocol:

1. The addition of online consent using a web form to facilitate the process between initial engagement and consent and to reduce drop-out between expression of interest and consent.

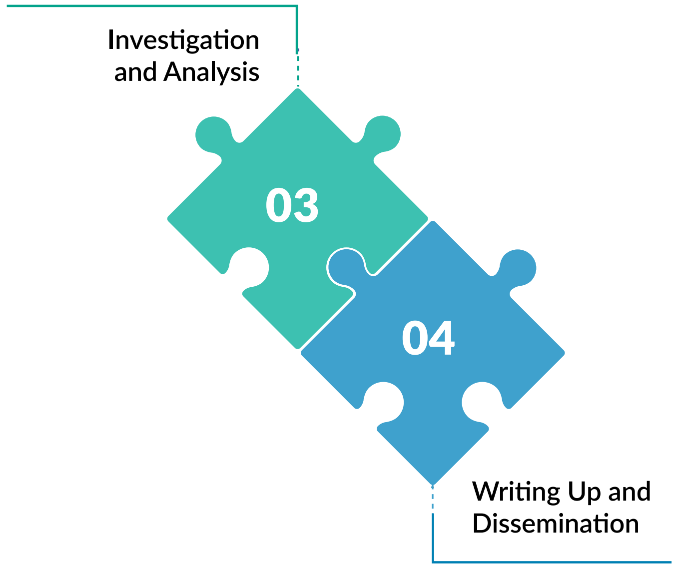
2. We restructured focus groups into separate sessions by age group, to ensure age-appropriate discussions and to ensure participants were engaged by and inspired by their peers. We offered further sessions for 16 and 18-year-olds who were not able to participate in the scheduled sessions due to exam clashes over the summer.

3. We increased the total capacity of the focus groups from 60 to 100 in response to demand; we provided an option for a one-to-one interview as an alternative to focus group participation on request; we included a question on whether participants would be interested in being part of a public involvement group beyond the project; the maximum number of participants in a focus group was reduced from ten young people to six, to encourage more active participation.

The STEADFAST Young People's Advisory Group co-produced first drafts of the focus group protocol, further commented on and improved later drafts and provided input to a focus group 'dress rehearsal' before the first focus group discussion took place. This co-production was invaluable and ensured focus group discussions were engaging, interesting, fun, and useful for participants, resulting in positive feedback.

Co-production of STEADFAST Toolkit with research stakeholders. We held two workshops with approximately 10 research stakeholders per workshop to co-produce the STEADFAST Toolkit. The first was held in June and the second one in July 2022. Discussions with stakeholders enabled us to talk through issues (e.g., diversity, disability, barriers to data sharing) to be considered in the development of recruitment materials, methodologies and best ways to disseminate public involvement findings.

Qualitative Analysis. Transcripts were coded for initial themes and then discussed with the Young People's Advisory Group for accurate interpretation. Young People's Advisory Group involvement optimised our approach through suggestions of themes and interpretation from lived experience perspective and other demographics which could impact experience (e.g., age of diagnosis, input from parents, level of understanding from care providers).



STEADFAST Public Involvement Toolkit. The Toolkit layout and first draft were reviewed by stakeholders. The final toolkit was redrafted incorporating stakeholder feedback. The key points raised by stakeholders were:

- Public involvement should feel like a conversation that delivers insight which is acted upon and made evident to members.

- As for any health condition, people have very different personal experiences and views that would not be incorporated into research design without meaningful, representative public involvement.

- Getting people's voices into research requires a range of perspectives from a range of backgrounds.

- Being involved in public involvement activities is fun and as an involved person, you get to see how new treatments, guidelines and knowledge come about.

Furthermore, Egality and Community Partners stressed the importance of keeping the STEADFAST Toolkit a living tool with regular reviews; adding infographics to make the Toolkit more readable and informative; and ideas for impact creations, such as sharing outcomes with after school groups.

Dissemination. A plan for the dissemination of the Toolkit was developed in collaboration with Egality Health and community partners, Diabetes UK's communications team and the STEADFAST Young People's Advisory Group. Co-production in this phase resulted in an extension of the Advisory Group for input to the STEADFAST final report, the qualitative analysis (for which the summary was reported in section 4 of this Toolkit) and the STEADFAST Toolkit itself.

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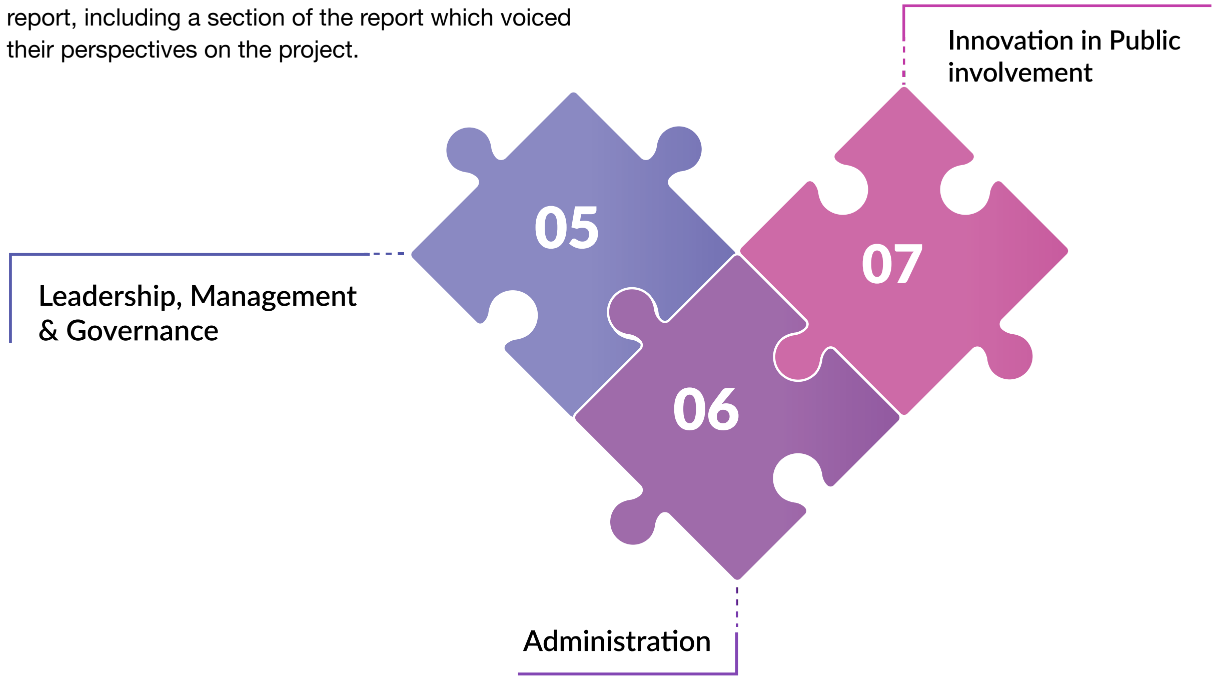
Co-production of Terms of Reference by the STEADFAST Young People's Advisory Group. The STEADFAST Young People's Advisory Group Chair was present at all STEADFAST project team meetings and collaborated to develop agenda items for discussion with the Advisory Group. Meeting notes were circulated to the project team after each STEADFAST Young People's Advisory Group meeting. The Advisory Group also contributed to the final report, including a section of the report which voiced their perspectives on the project.

Methods for public involvement were co-designed by the STEADFAST Young People's Advisory Group to optimise focus group discussions so that they were flexible and could be adapted, based on the participants themselves and the direction of the conversations.



Innovation in Public involvement

05

07

Leadership, Management & Governance

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Administration

What we learned and our recommendations

Public involvement with community partners and advisory group representatives should be considered as early in the process as possible, enabling the co-production of participant-facing materials and communications to maximise opportunities for meaningful engagement.

Flexibility and adaptation are the key to successful collaboration: methodologies need to be open to change and have the capacity for protocol amendments based on advice from collaborators.

Building strong relationships between community partners and research teams will help continued input and recruitment of diverse young people as representatives to advise on subsequent projects. Other suggestions for engagement included recruiting public involvement ambassadors in schools, attending outreach events through community groups and faith networks: all ways community partners can help support continued public involvement.

Regular feedback of diversity statistics and engagement successes is important for community partners to measure their own organisational targets.

Take time to listen, and thus to build relationships that are truly collaborative, through which young people can be involved in decision making.

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.
egality
DARE UK
CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
National Diabetes Audit Programme
NHS Digital
CAHN
British Heart Foundation Data Science Centre
Led by Health Data Research UK
RCPCH
Royal College of Paediatrics and Child Health
Imperial College London
UK Research and Innovation
Helix Data Innovation

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Section 6:
Outreach, engagement, recruitment and inclusion of young people

This section of the STEADFAST Toolkit explains the methods we used to reach out to, engage with, recruit and include young people with type 1 diabetes for our project. The role of Egality Health and community partners was to ensure community-appropriate messaging and to ensure broad outreach to young people from diverse communities. As a result, we were able to recruit a cross-section of voices representative of young people with type 1 diabetes nationally.

How we approached outreach, engagement, recruitment and inclusion

Our involvement strategy aimed to target young people from disadvantaged communities and ethnic minority groups across the four nations of the UK (England, Wales, Scotland, Northern Ireland). Collaboration with the Diabetes UK communications team, community partners and Egality Health, and the STEADFAST Young People's Advisory Group, supported user-driven engagement and helped us to successfully recruit participants.

Egality Health mediated relationships with community partners, action groups and type 1 diabetes ambassadors. We received 400 expressions of interest to participate in STEADFAST from young people within four weeks. The STEADFAST Young People's Advisory group, recruited from both the Diabetes UK Young People's Advisory Panel and directly through our involvement work, was both culturally diverse and motivated to support future projects.

STEADFAST Community Partners

Working closely with Egality Health and community groups, recruitment communications were targeted to appeal to a diverse range of cultures and shared widely across all community and individual networks. We noted the content, times and media channels which received the most engagement. Participant recruitment communications were placed on Twitter, Facebook, LinkedIn, Instagram, and STEADFAST was signposted in a podcast. Whilst Twitter and TikTok were identified as most popular with young people, Facebook was a successful source of engagement with parents and support groups. We used multiple strategies for targeted recruitment including asking influencers to access communities. Parent members of support groups, specialist nurses, clinicians and other charities were asked to, and were happy to, share our engagement materials.

We concentrated our efforts in ethnically diverse communities and we targeted deprived areas of major cities. For instance, clinics in those areas were asked to share advertisements with patients and community partners and outreach events and with youth workers. Diabetes UK's regional network enabled us to reach type 1 diabetes group and parents in Scotland, Wales and Northern Ireland, as well as England.

Duke Al Durham @DukeAlDurham · Jun 15

Check out the teaser of an upcoming project I was involved in with @EgalityHealth I will be sharing the full video soon! Please read the post below 💙

Egality Health @EgalityHealth · Jun 15

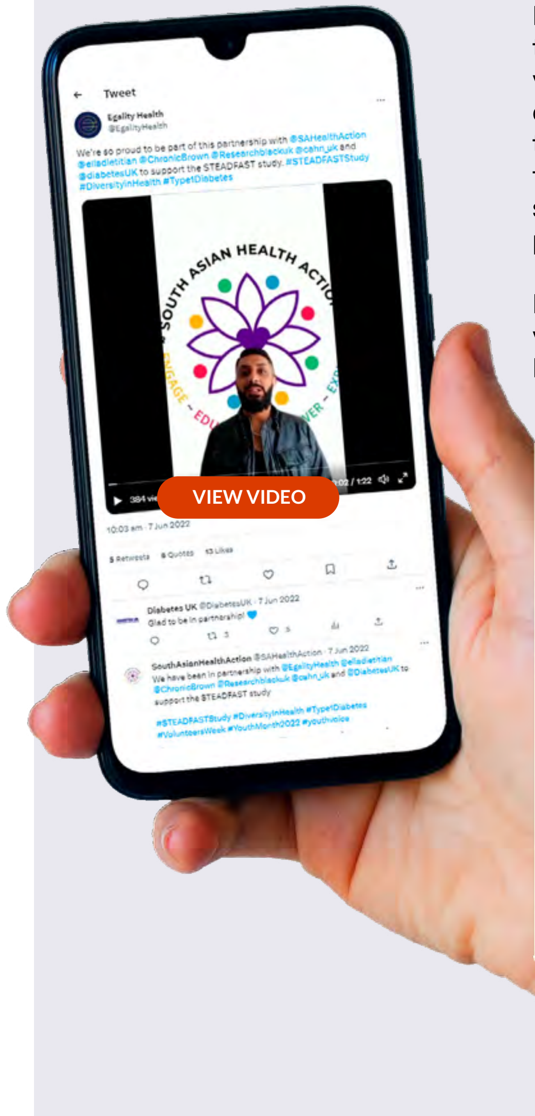
In #diabetesweek we wanted to share this teaser featuring @DukeAlDurham, spoken word artist with #type1diabetes. We worked on a project to engage young people from different backgrounds with #type1diabetes in focus groups about their health and education data.

Show this thread

Creative engagement through video

We experimented with creative engagement strategies, particularly through video: for instance a short TikTok video from Dietitian Ellouise. The community partners and Egality health also got together to produce a STEADFAST video advert which featured all community partners to speak to all communities using voices from those communities (Please see video link in the mobile phone image)

Egality Health developed a video 'Can you relate?', with Duke Al Durham, a spoken word artist who lives with type 1 diabetes, with specific emphasis on recruiting young males; this video was produced by FreshRB, a digital media social enterprise which uses creative communications to give a voice to people with long-term health conditions. A short teaser video was shared on social media with links to a longer version hosted on the Diabetes UK YouTube channel. At the time of writing, this video has been shortlisted for the PM Society Award - Diversity & Inclusion in Creative Communications.



Tweet

Egality Health @EgalityHealth

We're so proud to be part of this partnership with @SAHealthAction @elladietitian @ChronicBrown @Researchblackuk @cahn_uk and @diabetesUK to support the STEADFAST study. #STEADFASTStudy #DiversityinHealth #Type1Diabetes

10:03 am · 7 Jun 2022

5 Retweets 8 Quotes 13 Likes

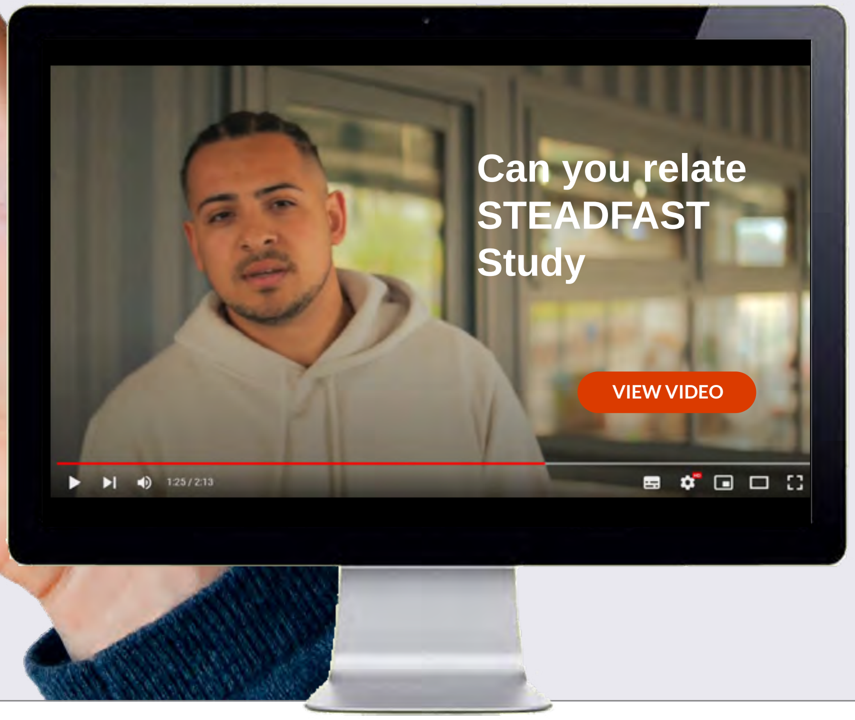
Diabetes UK @DiabetesUK · 7 Jun 2022

Glad to be in partnership! 💙

SouthAsianHealthAction @SAHealthAction · 7 Jun 2022

We have been in partnership with @EgalityHealth @elladietitian @ChronicBrown @Researchblackuk @cahn_uk and @DiabetesUK to support the STEADFAST study

#STEADFASTStudy #DiversityInHealth #Type1Diabetes #youthvoice #VolunteersWeek #YouthMonth2022



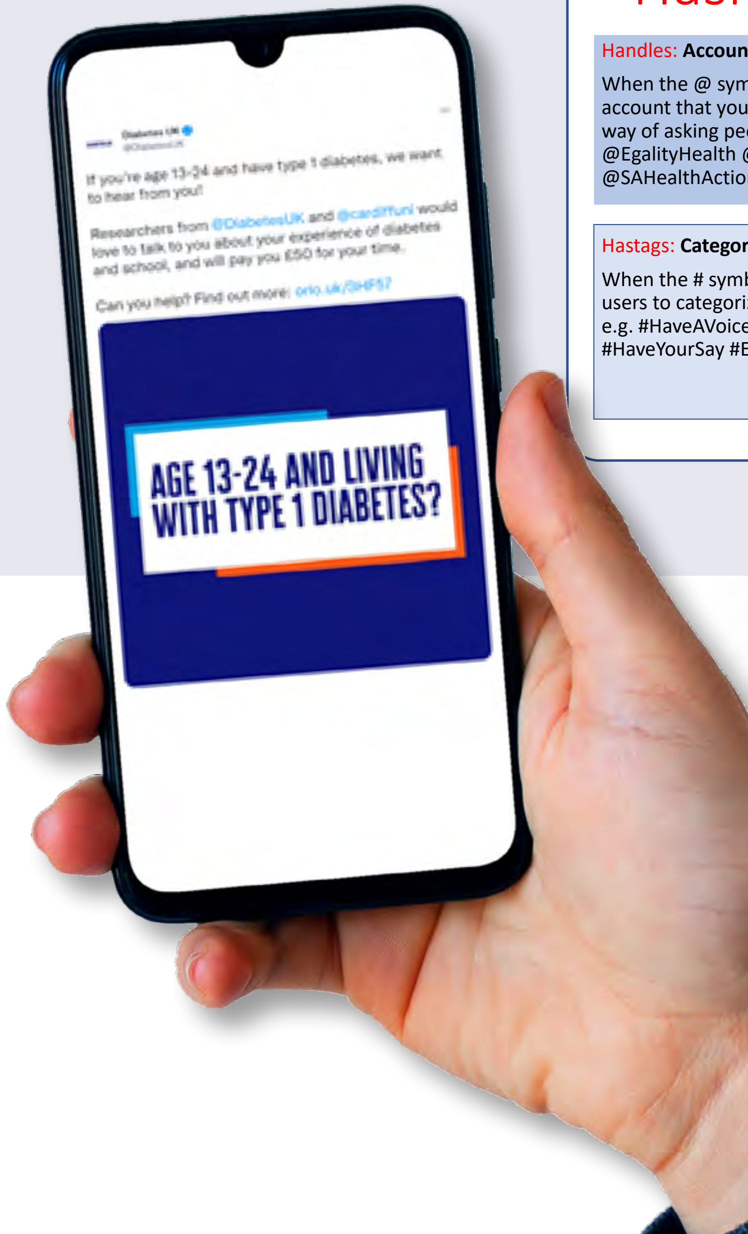
Engagement using social media

Engagement via social media channels, using co-developed messaging delivered by all collaborators had a broad reach especially when trusted branding was applied; we found that Diabetes UK branded adverts using simple graphics or short videos gained the most traction.

We developed a list of appropriate hashtags and handles relevant to public involvement and current campaigns. Collaboration involved weekly meetings to develop, iterate, and evaluate engagement materials, as well as the delivery of messaging together.

Discussions with existing public involvement group leads with expertise in research involvement, such as the Cardiff University young people's health involvement group (ALPHA), NIHR Young People's Advisory Groups (YAGs), and other DARE UK programme teams involving the public in their projects enabled us to learn from examples of best practice. In particular, we optimised our approach around the appropriate language to use, ideas of networks to approach, ways to reach communities who have not been heard enough from and incentives to offer them to participate.

Discussion with Egality Health and community groups led to the development of a simple online consent process.



Diabetes UK
@DiabetesUK

If you're age 13-24 and have type 1 diabetes, we want to hear from you!

Researchers from @DiabetesUK and @cardiffuni would love to talk to you about your experience of diabetes and school, and will pay you £50 for your time.

Can you help? Find out more: orlo.uk/3HF57

Hashtags and Handles?

Handles: Account names for social media accounts

When the @ symbol is placed in front of an account name it alerts that account that you are talking about them with or to them, this is a good way of asking people to share your content e.g. @DiabetesUK @cardiffuni @EgalityHealth @cahn_uk @ChronicBrown @Researchblackuk @SAHealthAction @elladietitian

Hastags: Categorized Content

When the # symbol is placed in front of a theme or message it allows users to categorize their content and make it easily searchable by others e.g. #HaveAVoice #TakePartInResearch #Type1Diabetes #diversityinhealth #HaveYourSay #EveryVoiceMatters

What we learned and our recommendations

Use multiple methods and channels of engagement keeping up to date with trends in social media; for example, develop a set of hashtags and handles relevant to your research topic, target audience, and current campaigns.

Producing video content takes time, so plan this into your schedule.

Collaborate with young people to co-produce engagement materials that are appealing, as well as language and culture-appropriate.

Share your mission and message with as many relevant people and organisations as possible and encourage user-driven recruitment to access other networks.

Engage with people who can reach your target community such as youth workers and youth groups; specialist nurses/clinicians/doctors; schools, teachers, parent and school participation groups; mental health ambassadors; equality & diversity groups; sports groups.

Communicate compensation and reimbursement methods clearly.

Offer appropriate compensation for volunteers' time with some form of payment, and consider the tax or welfare benefits implications of payments for public involvement volunteers. Plan for the limitations of research institutions such as universities or charities to rapidly process vouchers or BACS payments[16].

Develop easily-accessible methods for expression of interest and consent online, incorporating the collection of demographic information for monitoring diversity and inclusion. Collect parents' contact details for under 17s.

Give clear calls-to-action for participation, including deadlines for a response.

Be flexible for communincation methods give all alternative means of contact: Phone, WhatsApp, Email/text to for communication preferences.

Be flexible with types of engagement (online, face-to-face, group and one-to-one, online chats, phone, WhatsApp, email) and with alternatives for the time of day (offer weekends/late afternoons/evenings).

Allow for for flexibility in meeting scheduling to accommodate changes in circumstances.

Over recruit to advisory groups as it is impossible to achieve full attendence at meetings.

Schedule reminders and "availabilty check-ins" to ensure maximum attendance.

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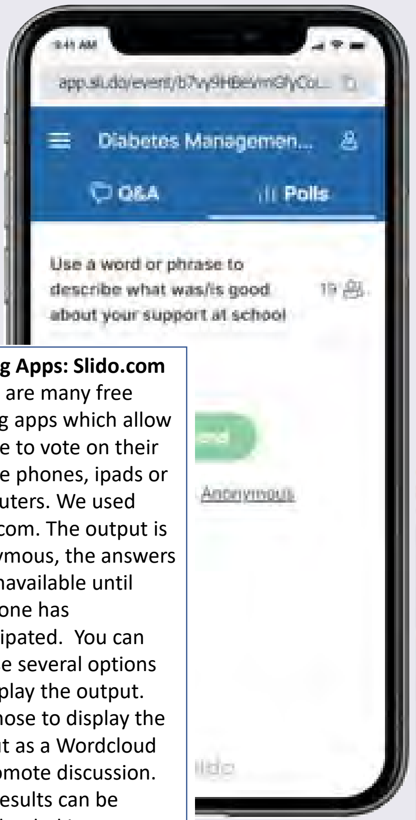
Section 7:
How should I facilitate conversations with young people?

Using the Lundy Model of Participation (Lundy 2007) as a broad framework for participation, we explain how we facilitated conversations with young people. The first few focus groups were run as semi-pilots, and we iterated our approach as the focus groups progressed in response to feedback.

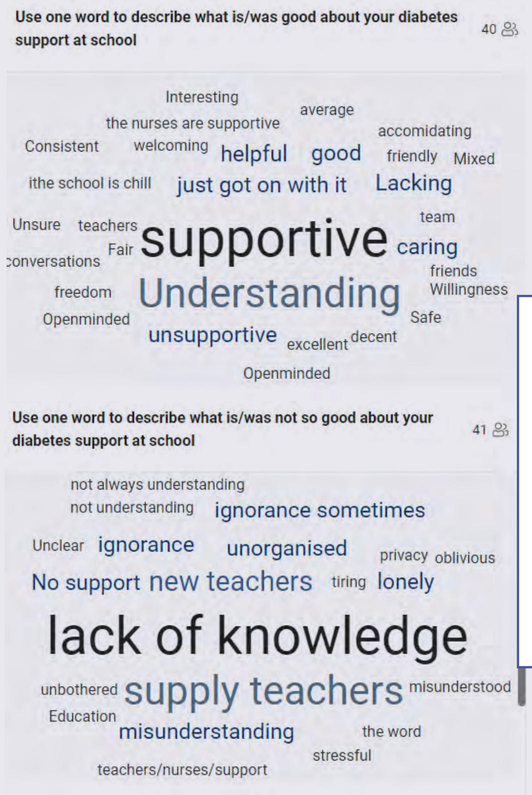
Space: How we developed a safe and trusted place for young people to express their views

We began the focus groups with introductions from the research team and invited young people to introduce themselves, including their age and when they were first diagnosed with type 1 diabetes.

We prompted young people to talk about their type 1 diabetes support at school and to be open to share their experiences. We used the free online slido.com polling app to ask participants to use one word to describe what was good and one word to describe what was bad about their type 1 diabetes support at school. Facilitators with lived experience also shared some of their own experiences. We used ‘chat bombs’ as an alternative if any participants struggled to connect to slido.com.



Use a word or phrase to describe what was/is good about your support at school



Use one word to describe what is/was good about your diabetes support at school

Use one word to describe what is/was not so good about your diabetes support at school

Polling Apps: Slido.com
There are many free polling apps which allow people to vote on their mobile phones, ipads or computers. We used slido.com. The output is anonymous, the answers are unavailable until everyone has participated. You can choose several options to display the output. We chose to display the output as a Wordcloud to promote discussion. The results can be downloaded into a spreadsheet if required.

What is a Chat Bomb
Tell participants that you are going to ask them a question and that you want the answer written in the chat but not sent. Tell them you will count down 3,2, 1 and then all press Send at the same time. This enables people not to be influenced by each other's answers and also builds some excitement.

Voice: How we gave young people a voice, and prompted discussions about data

To visualise and prompt discussions about data sharing we utilised a free online whiteboard tool, Google Jamboard.

We used different coloured post-it notes for each participant (Google jamboard is limited to 5 colours). Participants were asked whether they were happy to share identifiable or non-identifiable health data and educational data with 12 different potential users of data (for example, a teacher or their doctor). They were asked to express their preference by moving their coloured post-it note in one of two headings: ‘Happy to Share with’ or ‘Unhappy to Share with’ areas of the jamboard.

Participants were then prompted to elaborate on the reasons for these choices and we discussed different scenarios to try and ascertain whether the trust in these organisations was conditional using a ‘What if / Who / What / Why’ structure as suggested by the STEADFAST Advisory Group.

1. Who would you be happy to share your health data with, if it included your name, address and date of birth?
(Health data = HbA1c, height, weight, blood pressure, blood test results, urine test results)

We attempted to give young people the information they needed to form their opinions, as the participants were generally unaware what routinely-collected data was and that it could be accessed by third parties. We avoided jargon, and prompted young people to ask questions if there was something they did not understand, and we explained there was no 'right or wrong' answer. We prompted discussions around their perspectives and feelings about researchers accessing data, especially without their consent, by sharing two videos which clarified what routine data is and how and why researchers may access it:

1. A video by the Centre for Trials Research at Cardiff University showing examples of what routine data is and how it is used [17].
2. A video created by the Diabetes UK Young People's Advisory group . The video describes how data from their routine type 1 diabetes appointments is collected, stored, and shared, and how researchers can apply to Data Providers for access according to strict regulations and guidelines.

Audience:
How we tried to allow flexibility so that all voices could be heard

Participant feedback showed that most found listening to others' experiences valuable, with only a few participants expressing a preference for a one-to-one discussion instead of participation in a focus group.

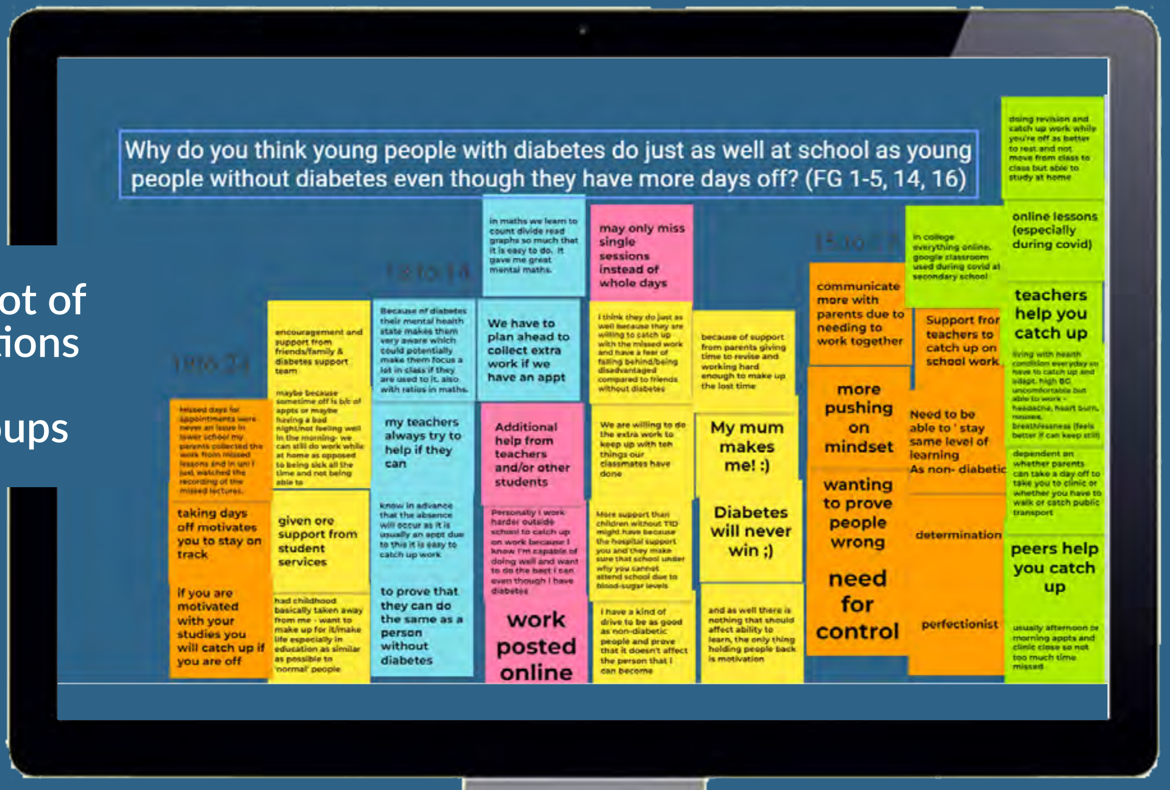
The focus groups were held online, using Microsoft Teams. These online discussions facilitated participation from young people all over the UK. Participants were given the choice of having their camera on or off, to speak or to use the chat to type answers, and to use reactions or emojis or simply a thumbs up or down. Diabetes UK's Public Involvement Manager spoke to all participants in advance, so that we knew who they were, even though their participation in the focus groups was later anonymised.

Following the focus groups, we encouraged feedback by sending out a feedback form with the reimbursement details (£50 shopping voucher or £50 BACS transfer as a form of compensation for participation). We reflected on the feedback forms as we went along, which was a positive way of assessing how our focus groups were working. The feedback form we used is presented at Annex 1.

Feedback from the Young People's Advisory Group and focus group participants highlighted the importance of demonstrating evidence of their contributions and dissemination of the findings.

Results from previous research conducted by researchers at Cardiff University, (French et al. 2022), were shared with participants to illustrate how researchers linked Welsh education and health data to compare GCSE exam results of those living with type 1 diabetes and those without type 1 diabetes, from 2009 to 2016. This enabled the participants to understand how their contribution could help to inform future research. Using Google Jamboards, we were then able to ask participants to share their opinions (using digital 'post-it' notes) on the possible reasons behind the study results. This prompted a group discussion about how young people felt about researchers accessing information about where they lived, what clinic they attended, family structure and financial information. As a result, participants told us that they felt listened to and that their contributions were taken seriously.

A snapshot of contributions from the focus groups



Why do you think young people with diabetes do just as well at school as young people without diabetes even though they have more days off? (FG 1-5, 14, 16)

Missed days for appointments were never an issue in lower school my parents collected the work from missed lessons and in uni I just watched the recording of the missed lectures.

taking days off motivates you to stay on track

if you are motivated with your studies you will catch up if you are off

encouragement and support from friends/family & diabetes support team

maybe because sometime off is b/c of appts or maybe having a bad night/not feeling well in the morning- we can still do work while at home as opposed to being sick all the time and not being able to

given ore support from student services

had childhood basically taken away from me - want to make up for it/make life especially in education as similar as possible to 'normal' people

Because of diabetes their mental health state makes them very aware which could potentially make them focus a lot in class if they are used to it. also with ratios in maths.

my teachers always try to help if they can

know in advance that the absence will occur as it is usually an appt due to this it is easy to catch up work

to prove that they can do the same as a person without diabetes

in maths we learn to count divide read graphs so much that it is easy to do. it gave me great mental maths.

We have to plan ahead to collect extra work if we have an appt

Additional help from teachers and/or other students

Personally I work harder outside school to catch up on work because I know I'm capable of doing well and want to do the best I can even though I have diabetes

work posted online

may only miss single sessions instead of whole days

I think they do just as well because they are willing to catch up with the missed work and have a fear of falling behind/being disadvantaged compared to friends without diabetes

We are willing to do the extra work to keep up with teh things our classmates have done

More support than children without T1D might have because the hospital support you and they make sure that school under why you cannot attend school due to blood-sugar levels

I have a kind of drive to be as good as non-diabetic people and prove that it doesn't affect the person that I can become

because of support from parents giving time to revise and working hard enough to make up the lost time

My mum makes me! :)

Diabetes will never win ;)

and as well there is nothing that should affect ability to learn, the only thing holding people back is motivation

communicate more with parents due to needing to work together

more pushing on mindset

wanting to prove people wrong

need for control

in college everything online. google classroom used during covid at secondary school

Support fror teachers to catch up on school work

Need to be able to ' stay same level of learning As non- diabetic

determination

perfectionist

doing revision and catch up work while you're off as better to rest and not move from class to class but able to study at home

online lessons (especially during covid)

teachers help you catch up

living with health condition everyday so have to catch up and adapt. high BG uncomfortable but able to work - headache, heart burn, nausea, breathlessness (feels better if can keep still)

dependent on whether parents can take a day off to take you to clinic or whether you have to walk or catch public transport

peers help you catch up

usually afternoon or morning appts and clinic close so not too much time missed

What we learned and our recommendations

Contextualise discussions and make them relatable to lived experience.

Keep language simple and stay away from acronyms; have definitions and explanations readily available.

Online tools to start off and facilitate discussions: polling apps, chat bombs, whiteboards.

Listen to participants' experiences to develop trust, encourage them to ask questions to build rewarding relationships, and allow time for free expression.

Make discussions creative and engaging through specific activities, accessible to all participants through the chat and or individually on own devices and displayed on the online communal whiteboard.

Check the technology before you start; note that free apps often have participant or activity limitations; practice participants' ability to access meetings; record the discussion online and/or through automatic transcription.

Optimise engagement: limit discussion groups to 4-6 participants online or 6-8 in person.

Offer several modes of interaction: face-to-face, online, focus groups, one-to-one interviews.

Information materials co-produced with public involvement from young people are more likely to be well received and understood; we found that audio and video content is more relatable with young people.

Clearly demonstrate contributions from participants in group discussions, for example through word clouds, graphs or verbal summaries of the discussion so far.

Maximise involvement in focus groups, through mixed gender groupings; encourage young people to use the chat if not comfortable speaking; identify any area of support and learning required to make contribution possible (e.g., familiarisation before the session with appropriate online platforms such as Microsoft Teams or Zoom, or online apps).

Consider different health conditions and ages of diagnosis, different treatment regimes and use of technology for managing a health condition in advance, and make sure these are clarified so that young people's comments are not misleading or confusing.

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Section 8:
Legal issues: Keeping young people and their data safe

While we managed and governed STEADFAST as a research project, it is not generally necessary to treat public involvement in research, as research itself. However, even public involvement usually requires the collection and management of personal data, particularly as statistics should be collected for monitoring the diversity of participants.

Data collection and processing must be compliant with the UK Data Protection Act 2018, the UK General Data Protection Regulation 2021 and relevant institutional policies. Furthermore, any involvement with young and/or vulnerable people must be compliant with safeguarding policies. Below we explain how we approached these challenges.

Our approach to safeguarding and data protection

The Diabetes UK safeguarding team was responsible for managing safeguarding issues in relation to focus group participants. Diabetes UK had a designated Safeguarding Lead for the project and a published Safeguarding Policy[18]. All Diabetes UK staff, prior to contact with the study participants, were Disclosure and Barring Service checked, sign-posted to the Diabetes UK Safeguarding guidelines[19], and briefed on how to handle any potentially sensitive situations. In accordance with safeguarding procedures, contact with study participants was limited to members of the team that took part in the focus groups or managed recruitment, consent, withdrawal, and screening procedures.

Participation in the focus groups required consent from young people and, if under the age of 17, parental consent and participant assent [20]. For focus groups participants under the age of 17, we invited their parents or carers to speak to us in advance and available in the background during the focus group.

Focus groups were organised by the age of the participant, into groups for ages 13-14, 15-16 and 17-24, to encourage participation with peers, minimise any safeguarding risks and to ensure that the language used in the focus groups was age-appropriate.

The Diabetes UK Information Governance team supported the research team in developing a Data Management Plan and a Data Protection Impact Assessment (DPIA), as expected by institutional privacy policies, research data management guidelines and in accordance with UK data protection legislation and health research best practice. As required by UK Research and Innovation guidelines, the legal basis for processing data (as STEADFAST was a research project) was public task, rather than consent [21].

What we learned and our recommendations

Researchers do not need, in general, to submit an application to a Research Ethics Committee in order to run public involvement activities although it is good practice to at least develop a protocol to describe how you will conduct public involvement [22]. However, if public involvement results in direct contact with study participants, there may need to be consideration of involvement as part of the research process and protocol. If you are in doubt as to which approach to use, please contact your Research Governance Office or seek appropriate specialist expertise.

Sharing photos, videos or testimonials from public involvement representatives requires specific consent. Talk to your communications or information governance team for advice on the consent and approvals you may require for sharing multimedia content.

Ask public involvement participants to fill out photo and video consent forms or have them on hand during any interactions so that you can celebrate events and outputs.

It is important to clarify what is being asked of public involvement participants, so collaborate with them to establish Terms of Reference for your public involvement group and share these terms with any new members.

We found the NICE guidelines on involvement of young people in research and safeguarding annex [23] a helpful guide for our project.

Read your organisation's safeguarding policy [24], have a nominated safeguarding contact, and undertake a safeguarding briefing to cover potential issues you may encounter and related procedures to follow.

As required by UK data protection legislation, conduct a Data Protection Impact Assessment (DPIA) to understand and document risks relating to data collection, processing, storage and management arising from handling the personal data of public involvement participants. The Information Commissioner's Office has a helpful guide to conducting a DPIA on its website [25]. Your DPIA should include procedures for collection, storage and access to personal data relating to public involvement participants, such as demographic information, consent forms and videos.

Via a conversation, inform young people about your project, the data you will collect and use, how you will keep it safe and secure and how it is managed and governed.

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Section 9:
Acting on Public Involvement: Dissemination and Impact

Our approach to dissemination and impact

The outcomes and impact from STEADFAST are still being realised at the time of publishing the STEADFAST Toolkit; the project team and stakeholders intend to continue impact realisation from STEADFAST as we embed the findings into our future work.

At the outset of STEADFAST, we designed a small number of qualitative and quantitative metrics to measure impact generated by the project. These are reported on, with our self-evaluation, in our final report published on the DARE UK website. In particular, we collected demographic information on the age, gender and ethnicity of participants, and linked home postcodes to publicly available metrics of small-area deprivation to understand whether or not we had met our targets for diverse and inclusive representation. We received over 400 expressions of interest to participate, and would have liked to accommodate everyone, however this was not possible due to time and budget constraints. We exceeded our target for the number of participants, with participation from 70 young people, against the target of 60. However, we did not fully meet our targets for gender representation, ethnicity and deprivation, despite our best efforts. Nonetheless, we achieved diversity which was representative of young people with type 1 diabetes in the general population, and we are confident that this outcome was due to the substantial outreach and engagement efforts made throughout STEADFAST.

All recommendations from the STEADFAST Young People's Advisory Group throughout the project were fed back to our team and implemented. Changes applied to methodologies based on their recommendations were documented to enable us to explain how their involvement optimised our approach within the Toolkit, and to track their impact.

Throughout STEADFAST, as well as engaging with community organisations to share our mission and messages, we engaged research stakeholders (those whom we envisaged would use STEADFAST outputs) in co-design and impact generation activities. We engaged with the Health Data Research UK Alliance of healthcare and research organisations, whose mission is to establish best practice for the ethical use of UK health data for research at scale. Diabetes UK's Public Involvement Manager presented STEADFAST to the Association of Medical Research Charities (AMRC) public involvement forum. We held two workshops with research stakeholders to understand what they wanted from a public involvement toolkit, and to provide input to and feedback on the first draft.

We presented the results of Cardiff University's previous research into education outcomes for young people living with type 1 diabetes (French et al. 2022) with focus group participants, to demonstrate the type of impact that would be generated through their involvement, and its importance to research, policy and young people with type 1 diabetes themselves. We received excellent feedback from participants, with 83% of participants saying they knew a lot more about unconsented data and its research use following the focus groups.

We received completed feedback from 99% of our participants. We asked all participants whether they would be willing to participate in future Diabetes UK and Cardiff University public involvement efforts and gained consent to future contact from the vast majority of participants (86% of those who returned feedback forms). We are hugely grateful to all the young people that took the time to talk to us and share their perspectives.

What we learned and our recommendations

Define potential impacts from public involvement at the start of the project and try to measure these in tangible ways using qualitative and quantitative metrics [26].

Share and disseminate public involvement outputs, outcomes and impacts throughout, even if they were not what was expected.

Offer opportunities for continued or future involvement from participants.

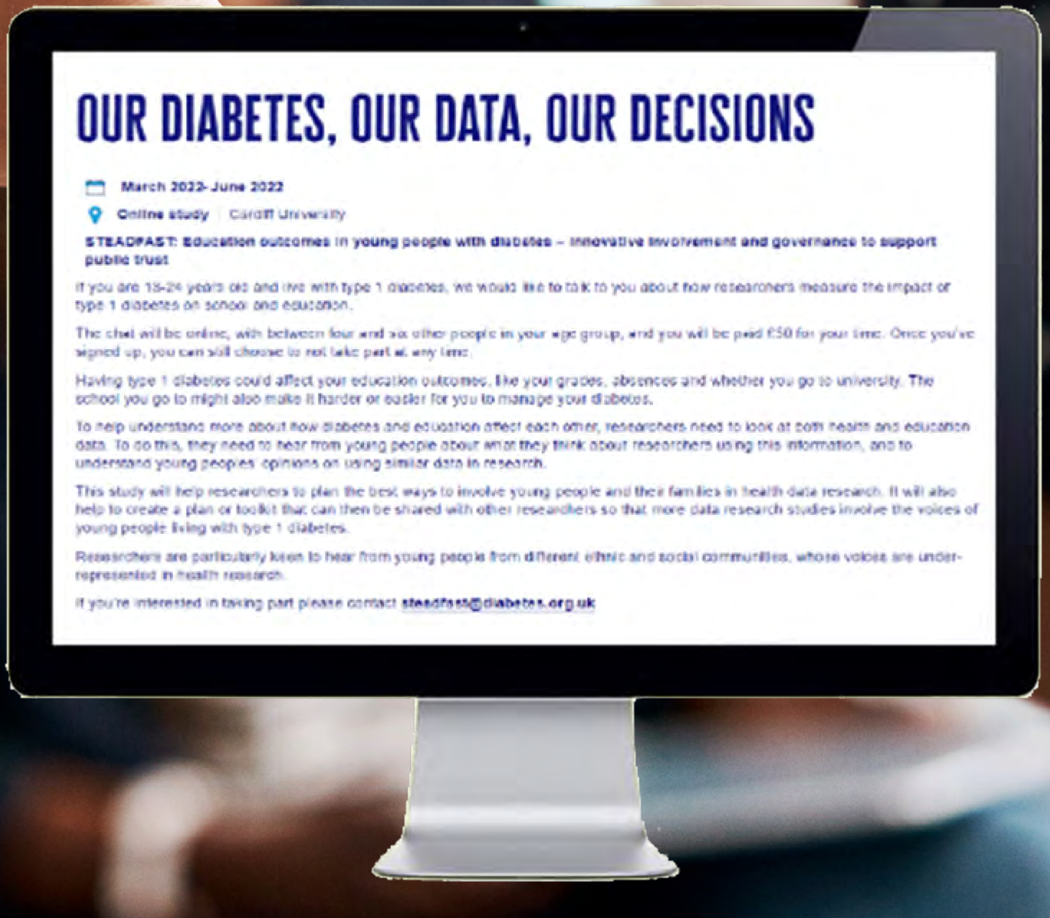
Recognise contributions and ideas from public involvement representatives through proper acknowledgement or co-authorship of outputs as appropriate.

In a research project, get into the habit of sharing public involvement learnings and achievements as well as research findings.

Disseminate research findings and public involvement activities widely to reach young people outside academic circles using a variety of creative formats (e.g., social media, clinics, schools, support groups, charity websites).

Build a culture of using, doing, and building on public involvement within your organisation.

Share evidence of how public involvement contributions are acted on, and therefore the tangible benefits that they bring.



OUR DIABETES, OUR DATA, OUR DECISIONS

March 2022- June 2022

Online study | Cardiff University

STEADFAST: Education outcomes in young people with diabetes – innovative involvement and governance to support public trust

If you are 13-24 years old and live with type 1 diabetes, we would like to talk to you about how researchers measure the impact of type 1 diabetes on school and education.

The chat will be online, with between four and six other people in your age group, and you will be paid £50 for your time. Once you've signed up, you can still choose to not take part at any time.

Having type 1 diabetes could affect your education outcomes, like your grades, absences and whether you go to university. The school you go to might also make it harder or easier for you to manage your diabetes.

To help understand more about how diabetes and education affect each other, researchers need to look at both health and education data. To do this, they need to hear from young people about what they think about researchers using this information, and to understand young peoples' opinions on using similar data in research.

This study will help researchers to plan the best ways to involve young people and their families in health data research. It will also help to create a plan or toolkit that can then be shared with other researchers so that more data research studies involve the voices of young people living with type 1 diabetes.

Researchers are particularly keen to hear from young people from different ethnic and social communities, whose voices are under-represented in health research.

If you're interested in taking part please contact **steadfast@diabetes.org.uk**

Steadfast call for particpants on Diabetes UK website

Appendix 1: Feedback Form

Thank you for taking part in the STEADFAST focus group today. Your input and time were very helpful and greatly appreciated. We hope you found the session interesting and informative.

We would like to ask you a few questions on how you found the session to help us improve and learn.

1. **After the session, do you think that your understanding of unconsented data and its uses is: (Please select one answer)**

   - A lot better?
   - A little bit better?
   - The same as before?
   - Unsure

2. **During the session, would you say that the people attending had: (Please select one answer)**

   - Lots of different opinions about the subjects?
   - A few different opinions about the subjects?
   - Similar opinions about the subjects?
   - Unsure

provided.

3. **Did hearing other participant's views change your views and understanding of the topics? (Please select one answer)**

   - Yes, a lot
   - Yes, somewhat
   - No
   - Unsure

4. **For each of the following statements, please let us know whether you agree or disagree.**

   "During the session, I felt..."

5. **On a scale of 1 to 5, how understandable did you find the content and subject matter of the focus group?**

   With 1 being "I found it confusing and difficult to understand" and 5 being "I found it clear and easy to understand"

6. **On a scale of 1 to 5, how would you rate your experience of participating in the focus group?**

   With 1 being "I found it difficult to participate and get my views across" and 5 being "I could participate fully and I found it easy to get my views across"

7. **What would you change about the session? (Please write your answer below)**

8. **Why did you decide to participate? (Please select as many that apply)**

   - I am interested in the subject matter
   - I wanted to make a difference
   - I was advised to (family member, friend, colleague)
   - £50 voucher
   - Other:

Do you have any additional comments or advice for us?

Would you be interested in being part of a DIABETES UK Public Involvement Group that meets regularly to look at the importance of type 1 diabetes research questions?

- Yes*
- No

*If yes, I am happy to be contacted by Diabetes UK on my email address provided.

	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
Informed (already knew a lot about the subject)					
Confused (subject matter was very overwhelming or hard to follow)					
Angry					
Happy					
Indifferent					
Nervous or uncomfortable (didn't feel like you could talk openly or get your viewpoint across)					

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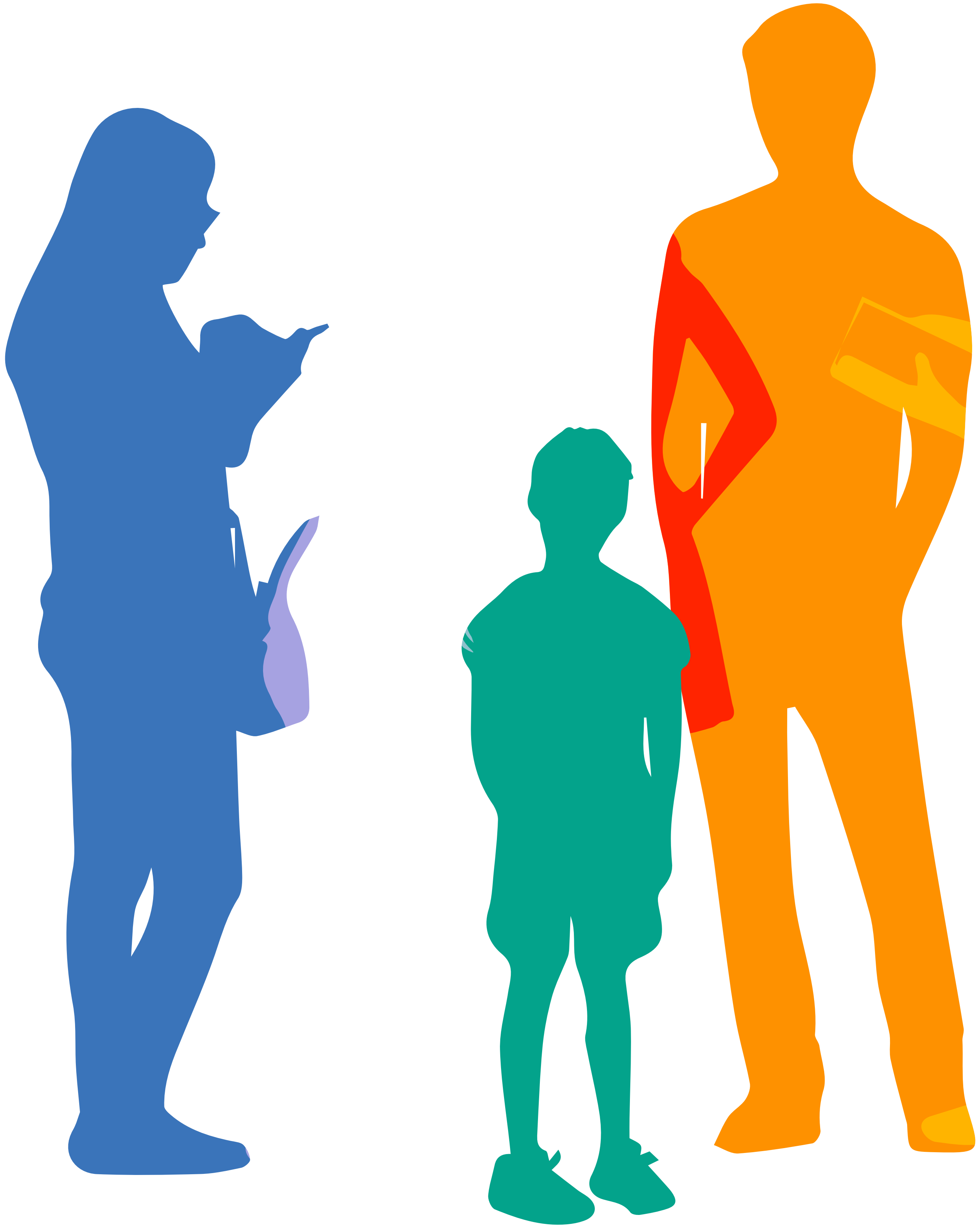

STEADFAST

The STEADFAST Project Team

Cardiff University, Diabetes UK, Egality Health, Helix Data Innovation,
& The Steadfast Young People's Advisory Group

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

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