Minimum Unit Pricing in Scotland: Qualitative study of children and young people's own drinking and related behaviour (2017/18 RE003)

Proposal

July 2018

NHS Health Scotland

Contents

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1 Introduction

1.1 This document outlines the study proposal from Iconic Consulting for the Children and Young people: own drinking related behaviour study that is part of the portfolio of studies to evaluate minimum unit pricing for alcohol in Scotland.

1.2 The study will be led by Ian Clark, Director of Iconic Consulting, supported by Dr Briege Nugent and Amber Imran. More information on the team is provided in section 4.

1.3 This proposal was submitted in response to an invitation to tender. It was revised following the briefing meeting and updated in July 2018 to incorporate feedback from NHS Health Scotland's Research Development Group and the MUP Children and Young People Evaluation Advisory Group.

2 Background

2.1 The purpose of the study is to establish children and young people's response to the rise in cost of some alcoholic drinks brought about by the introduction of MUP on 1 May 2018. The study seeks to engage children and young people - and those who work with them – to examine what difference, if any, this has on their alcohol consumption and related behaviours. The study is one element of a research programme assessing the impact of MUP on children and young people. The children and young people's programme is a part of a comprehensive evaluation of the overall impact of MUP which will examine the policy's impact on producers and license holders, the five licensing objectives, and by gender and socio-economic status as well as age. The robustness and extensive nature of the evaluation of MUP has been driven by the inclusion of the sunset clause in the Alcohol (Minimum Pricing) (Scotland) Act 2012 – for the legislation to continue beyond the sixth anniversary of its introduction, Ministers must have evidence of its impact to present to the Scottish Parliament. We appreciate that this study is time critical because the impact of MUP on children and young people is expected to be most evident in the months immediately after its introduction.

2.2 To provide the evidence required, the study will need to deliver on two fundamental issues and our approach outlined in section 3 aims to do so. Firstly, it must engage a cross-section of children and young people. Secondly, it must entail a broad assessment of their response to MUP covering a number of different elements.

2.3 At the briefing meeting, it was agreed that the following characteristics and circumstances will be applied to guide the recruitment of young people (who are already consuming alcohol):

- Age
- Gender
- Socio-economic status (the catchment area of the organisation)

- Location (urban/rural split)

2.4 We will be following NHS guidelines in terms of establishing informed consent from young people. Principles of consent: Children and Young People (Scotland) states that ideally staff with experience of working with children should provide information about the study, which is understandable to them and which explains what is involved including potential risks and benefits.

2.5 The research questions in the study brief identify these key issues as awareness, acquisition, consumption, and harm.

Other issues

2.6 The study aims give rise to some other important methodological issues which are discussed below.

Research ethics

2.7 We have given considerable thought to the issue of research ethics including reviewing the guidance and online decision making tools produced by the NHS Health Research Authority. We note NHS Health Scotland's initial advice from West of Scotland Research Ethics Service is that it is unlikely Research Ethics Committee (REC) approval will be required as participants are not being recruited through NHS services. Having spent some time reviewing the guidance and having experience of a study that required REC approval, the requirement for REC approval was discussed in more detail at the Briefing Meeting. It was agreed that NHS Health Scotland would seek further clarification from West of Scotland Research Ethics Service. If REC approval is required, the additional time outlined in Appendix 1 will be required to manage the process.

2.8 NHS Health Scotland's Research Development Group provided a favourable opinion regarding the study and the proposed methods at their June 2018 meeting.

2.9 We acknowledge that some gatekeeping organisations may have their own ethics procedures which we will also adhere to.

Informed consent

2.10 Informed consent is one of the most challenging aspects of this brief due to the age of potential participants and the subject matter (alcohol).

2.11 In the preparation of our proposal we carefully considered the options and referred to guidance documents including Principles of consent: Children and Young People (Scotland) and Social Research Association (SRA) Ethics Guidelines. Our proposed methods and alternative approaches were discussed at the Briefing Meeting and guidance was sought from the MUP Children and Young People Evaluation Advisory Group which met on 19 June 2018. NHS Health Scotland's Research Development Group were also informed and they provided a favourable opinion on the following approach:

- Set 13 as the minimum age of participation
- Raise awareness of the study with parents/carers.
- Obtain consent from children and young people.

2.12 Our approach – to raise awareness with parents/carers but seek consent from the children and young people – was informed by NHS guidance Principles of consent: Children and Young People (Scotland). The guidance states that children and young people under 16 can give their consent to take part in research if they have the 'capacity to understand the specific circumstances and details of the research being proposed' and their competence to do so may 'be reflected in their ability or otherwise to understand and assess risk'. We therefore proposed that age-appropriate information is available which explains what is involved including potential risks and benefits, and is provided initially by staff or volunteers from the organisations who have experience of working with the children and young people. We will work with NHS Health Scotland to develop processes that ensure children and young people have competence to give

consent and understand the risks associated with taking part, as well as instances they are deemed not to be competent enough to understand the risks and cannot participate.

2.13 Our approach has also been informed by SRA guidance on protecting the interests of social research participants (SRA Ethics Guidelines, p. 35). Some of the children and young people are engaging in an activity (consuming alcohol) that their parents/carers may not approve of and could have involved the law being broken in the purchasing of the alcohol. The aim of this study is to gather views and experiences of those young people consuming alcohol following the introduction of MUP, it is not the aim to stop it or even to influence it. Seeking parental/carer consent could, in some cases, potentially change the situation and could involve consequences for the young person.

2.14 Although we do not propose to seek consent from parents/carers, we recognise they have a duty of care for their children and it was agreed at the Briefing Meeting that parents and carers should be made aware a study was taking place that their child could, potentially, be involved in. We will therefore work with NHS Health Scotland to develop an information sheet to be distributed to parents/carers of all children and young people involved with the organisations in advance of the fieldwork. The sheet will inform parents/carers that research commissioned by NHS Health Scotland is taking place in the area with young people about the introduction of MUP. The sheet will be generic and not addressed to specific parents/carers. Our contact details will be included should parents/carers have any questions. The aim of the sheet is to inform parents/carers the study is taking place and their child may be involved, however, it is not a request for parental consent. At the outset of the study we will agree an approach with NHS Health Scotland on how to respond should parents/carers object to their child's involvement.

2.15 The above will be applied flexibly following our initial discussions with each organisation so that the approach is tailored to the specific circumstances. Discussions will cover topics such as parental support, and alternative

approaches to awareness raising if the staff/volunteers suspect that children and young people at that particular organisation may not pass on the information to their parents/carers. These issues will also be discussed with NHS Health Scotland during the preparatory phase of the study so that alternative approaches can be offered to organisations.

Encouraging participation

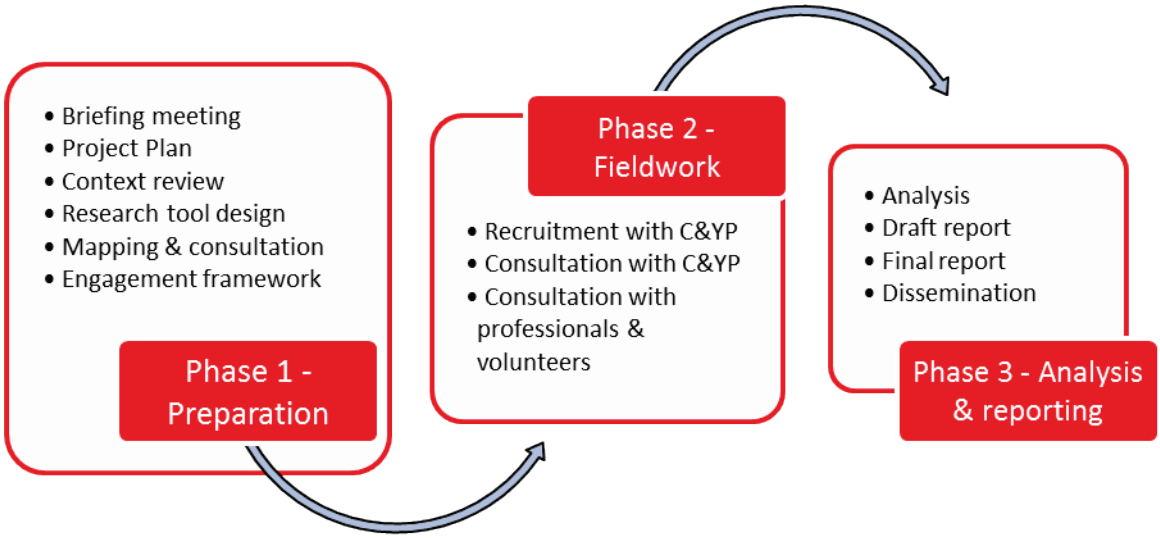
2.16 Following discussions with the Research Commissioning Panel it was agreed we will make a donation to each organisation that assists with the recruitment of young people. It was agreed a flat rate donation would be the fairest option, and we propose this is set at £100 per organisation. The money is to be used by the organisation, in an appropriate manner, for the benefit of all young people not only those who take part in the study.

Research methods

2.17 This is a qualitative study, with flexibility as to size of interview group to provide young people with opportunities for them to take part in the research in a way that they feel most comfortable with. In a practical sense this will entail offering individual, paired, or small group interviews.

3 Methods and timetable

3.1 In this section we describe our proposed methods and timetable which have been designed to directly meet the study aims and questions. We draw on our understanding of the subject matter and our previous experience. In summary, the methods consist of the three interlinked phases shown below.



Phase 1 – Preparation

Project plan

3.2 Following the formal award of the contract, we will prepare a detailed project plan summarising the agreed methods, milestones, and timescale for the study. The Plan will be a key reference point for our ongoing management of the project.

Context review

3.3 At the outset of the study we will contextualise the study by undertaking a document review and stakeholder interviews. This will ensure the research is built on a thorough understanding of the main issues and will also directly inform the development of the research tools. The document review will focus on relevant

literature regarding alcohol misuse among children and young people including their means of acquisition, purchasing, consumption, and harms. This will include evidence regarding the impact that specific characteristics/circumstances have on children and young people's alcohol use. The document review will focus primarily on evidence from Scotland although it will extend to research from other parts of the UK as well. This will be complemented by discussions with key stakeholders who we envisage will include members of the Research Commissioning Panel and MUP Children and Young People Evaluation Advisory Group.

3.4 At the end of this task, we will produce a summary of the key findings.

Research tool design

3.5 Research tools will be drafted for review by the Research Commissioning Panel and, if appropriate, the MUP Children and Young People Evaluation Advisory Group.

3.6 The main tool will be a semi-structured discussion guide for the consultation with children and young people. It will be based on the context review and stakeholder interviews and will align with the aims and key themes of the study. Children and young people will also be involved in developing the guide. At this stage we envisage the key themes will be changes in:

- Availability, marketing and price of alcoholic drinks.
- Acquisition and purchasing decisions.
- Consumption – volume and type, drinking patters, frequency.
- Harms.
- Other factors.

3.7 We will also design a Participant Information Sheet and Consent Form. Paper copies of the sheet will be handed to all face-to-face participants or summarised for telephone consultees should anyone express a strong preference for such an approach. The sheet explains why the study was commissioned, who we are and

why we are carrying out the research, what it will entail, how personal information and views will be treated, and what happens with the information and findings. We will follow NHS Health Research Authority Guidance and will draw on previous experience of preparing such tools for clients including NHS Health Scotland, NHS Lanarkshire and NHSGG&C (see section 4).

3.8 We will also develop the awareness raising material highlighted in section 2. The material is likely to include leaflets and posters explaining the purpose of the research, what it will entail, and who it is aimed at. We will emphasise that the research is targeted at children and young people who are already consuming alcohol and will summarise the screening criteria. Our contact details will be included to enable potential participants to contact us for further information.

3.9 Development of a participant screening tool will require careful planning to make sure it is relevant and appropriate. At this stage we do not envisage this being a form that young people have to complete as that would be unnecessary and potentially off-putting. Instead it could be questions posed as part of the awareness raising around the key criteria for taking part in the study e.g. Are you aged under 18 years of age? Have you consumed alcohol more than once over the last year? (to make recruitment most effective) Are you interested in answering some questions about drinking among young people?

3.10 The content of all research tools for use with young people will be assessed using The Writer - an online readability checker - to ensure they are easily understood and appropriate to the intended audience. If necessary, awareness raising material and discussion guides will be translated into other languages to maximise the accessibility of the research process. One member of our team, Amber Imran, is fluent in Urdu and she can translate the documents or conduct interviews in the language if required. Document translation or interviews in other languages will involve an external translation or an interpreter.

3.11 A semi-structured discussion guide will also be produced for the consultation with people working with children and young people. This will gather their views and

experiences of if, and how, MUP has influenced children's drinking behaviour with particular relevance to product price, availability, marketing, purchasing/acquisition, consumption, harms, and other factors.

Mapping and initial consultation with organisations

3.12 We will use the key characteristics/circumstances agreed at the Briefing Meeting to identify potential organisations to help engage study participants. This process will draw on discussions with the Evaluation Advisory Group and desk research. It will also draw on our own experience of almost 20 years' social research in Scotland. For example, Liber8 Lanarkshire could be a potential partner to engage children and young people in disadvantaged socio-economic areas (urban and rural). We will ensure the research engages hard to reach children and young people including, if relevant, those looked after and accommodated and those who tend not to engage in groups by approaching various detached youth work providers (a number of which have been funded by the Scotch Whisky Action Fund we recently evaluated). We will identify several organisations for each key characteristic/circumstance to ensure we engage a reasonable cross-section of participants.

3.13 We will contact all of these organisations to seek their co-operation in the study and children and young people's participation will be encouraged through gatekeeping organisations. An initial e-mail explaining the purpose of the study and our planned approach will be followed up with a telephone call to provide a more detailed explanation. If required, we will visit the organisations to discuss matters further. We will develop a concise memorandum of understanding setting out respective roles and responsibilities for organisations that agree to assist with the study. We will work with the organisations to identify appropriate awareness raising strategies and ways of recruiting specific target groups such as girls under 16 who may be putting themselves at risk of harm. We will also identify an appropriate room within the organisation's venue where confidential interviews/focus group can take place. We will also establish, and take into account, the organisation's own safeguarding and ethics procedures.

3.14 In addition, we will identify independent support agencies that research participants can be signposted to should they become distressed or raise any sensitive issues during the consultation. Leaflets, a named contact and emergency numbers will be sourced for all relevant organisations. We successfully used this approach during our research with hard to reach adults with substance misuse issues in Lanarkshire which required REC approval.

Engagement framework

3.15 Phase 1 will culminate with the development of a framework setting out how we will engage children and young people in the research. It will confirm the organisations across Scotland that have agreed to support the research and identify which of the key characteristics/ circumstances they will help to recruit. It will include indicative numbers of children and young people to be engaged. It will also include a provisional timescale which will be based on our discussions with the various organisations.

Phase 2 – Fieldwork

Recruitment of children and young people

3.16 To engage children and young people, we will prepare an awareness raising and recruitment pack (consisting of material such as posters and leaflets) for each organisation we are working with. All material will be age appropriate and will clearly explain the purpose of the study, what it will entail, the confidential nature of the study, and how children and young people can take part. It will also include the screening questions to ensure participants meet the study criteria. The organisations will be briefed to enable them to answer any questions locally, and on the process for recording interest among children and young people. We will provide hands-on support throughout including, if necessary, being on-site to help impart information about the research and answer any questions. Potential participants will be asked to specify a preference for an individual, paired or small group interview. Ongoing communication with the organisations will ensure

the recruitment addresses the framework, as far as possible, and reacts to any issues that arise. We will also firm up a timescale for the consultation.

3.17 Our aim is to engage up to 45 children and young people in the study. To do so we will aim to recruit approximately 70 to allow for drop-outs. Our value for money approach allows us to target such a number and our track record proves that we will deliver not only on engaging them but also on producing high quality outputs.

Consultation with children and young people

3.18 Using a combination of individual, paired and small group interviews we will gather the views and experiences of young children and young people who are already consuming alcohol. Ideally, we will spend several hours at each organisation consulting with a number of children and young people. This is likely to include evening and possibly weekend work which we can accommodate.

3.19 Before the consultation starts, children and young people will also be asked to confirm they meet the study criteria. Any potential participants who do not meet the criteria will be politely informed that they cannot take part in the study. For those who do meet the criteria, we will recap the purpose and nature of the research. All participants will complete a consent form at the start of their interview/focus group. They will confirm they are under 18 by ticking a relevant box but will not need to provide their date of birth, they will sign the form and print their name but not need to provide their address or any other contact information. They will also confirm they have received and understood information about the study, and have voluntarily agreed to participate in it. Approval to digitally record the interview will also be sought and noted, alongside an explanation of how the recording will be used and subsequently stored and destroyed.

3.20 The consultation will use the semi-structured discussion guide developed during phase 1. The semi-structured nature of the interview allows the children and young people to discuss issues in a natural, conversational way, with prompts

from the interviewer where necessary. We will also use age-appropriate techniques to engage participants and encourage them to open up such as props and games. For example, we will print pictures of some alcoholic drinks popular with children and young people and a series of price stickers, and ask participants to pin the right price to each drink; the exercise will lead into a discussion about whether the price has gone up recently and by how much and what difference, if any, this has had. We envisage the consultations will take between 30 and 45 minutes for individual discussions, and up to an hour for group sessions. Food and drink will be provided for participants.

3.21 Notes will be taken by the researcher during the consultation. These notes will be added to afterwards while the researcher listens back to the recording to ensure a comprehensive record of each session is available for analysis.

3.22 At the outset, we will emphasise that participants should only discuss issues they are comfortable sharing. Should any participants become distressed during the interview we will allow them to take a break. If they are happy to resume we will sensitively re-start the interview taking care not to raise the issue which led to their distress in the first place. If they would rather not resume the interview we will not apply any pressure and we will establish if there is someone they would like us to contact. We will also provide the information on local and national support agencies. Further details on our approach to dealing with distress are provided in paragraph 5.24.

3.23 In cases where participants disclosure they have suffered physical, mental or sexual abuse or are in immediate danger of abuse we are duty bound to protect them and we will need to contact relevant authorities such as Social Work or Police Scotland. If participants disclose other information that the researcher considers to be harmful we will sensitively offer to signpost them to appropriate support. For example, if they disclose harmful drinking we will highlight that support is available and provide details of local support agencies. These procedures will be contained in our Participant Information Sheet which all participants will receive in advance.

3.24 At the outset of any focus groups, we will emphasise the importance of participants respecting the confidentiality of other participants. We will stress that we want participants to be as open and honest as possible during the discussion which may involve sharing sensitive information that should not be shared verbally or through social media with others outwith the group. We have in the past asked focus group participants to set out and agree to 'rules' for the discussion at the outset and this approach could be applied with NHS Health Scotland's approval during this study to reinforce the importance of issues such as confidentiality.

Consultation with people working with children and young people

3.25 Although children and young people are the primary focus of our consultation, we will also gather the views of the professionals and volunteers working with them. We envisage they will include representatives from the organisations assisting with the engagement of the children and young people – such as youth workers, project workers, and residential staff – who will be interviewed during one of our visits. We will also envisage consultees will also include other professionals identified by preliminary desk research and advice from the Evaluation Advisory Group. Others might include guidance teachers, social workers, health professionals, and children and young people's alcohol treatment/support agencies. Consultees will be prioritised and agreed in advance with NHS Health Scotland. A full explanation of the research will be provided to all participants and their consent will be recorded. We have costed for the involvement of up to 20 consultees and we envisage the discussions will last between 30 and 45 minutes.

3.26 The semi-structured discussion guide developed during phase 1 will be used. The interviews will provide an alternative, but still well informed, perspective on children and young people's response to MUP. It may be particularly useful in examining factors other than MUP which could be relevant to any observed change in behaviour, such as cultural shifts in young people's relationship with alcohol.

Phase 3 – Analysis and reporting

Qualitative analysis

3.27 This research will generate a significant amount of information from the document review and consultations with children and young people, people who work with them, and the key stakeholders. We have the organisational and analytical skills to make sense of the information. Our team members are very experienced, competent and confident in this integral element of the research process.

3.28 We will undertake a systematic and thorough thematic analysis of the findings using the study aims and objectives as the assessment framework. As described above, notes will be taken during all interviews. Where participants give their permission, the interviews will also be recorded and this will be used to add to the notes afterwards so a comprehensive record is available for analysis. A summary of each interview will be recorded on an Excel spreadsheet. Overall, we will adopt a thematic approach to analyse the qualitative evidence, and we have developed a rigorous approach that includes coding, prioritising, assessing and interpreting the information gathered. Quality is assured by thorough cross-checking and where necessary re-coding by a second member of the team. Throughout this analysis, we will be mindful of the potential for difference by key characteristics/circumstances to draw out any findings which the evidence shows are more relevant to one specific group than others.

Draft and final report

3.29 Before drafting the report, we will discuss writing approaches with you to ensure that contextual information, views gathered through fieldwork, analysis and conclusions are presented in ways that meet your requirements and preferences.

3.30 Based on the above analysis we will prepare a draft report in early July 2019. The report will directly address the study questions and will therefore:

- Identify any changes in the availability or price of alcoholic drinks observed after the introduction of MUP.
- Examine how MUP influenced children and young people's consumption and acquisition decisions.
- Describe children and young people's strategies for dealing with price increases observed in their favoured drink.
- Assess any change in health or social harms among children and young people following MUP.
- Identify factors other than MUP that might have influenced children and young people's alcohol use.

3.31 We will produce a final report by mid-August 2019. The final report will incorporate feedback on the draft report from the Research Commission Panel and the MUP Children and Young People Evaluation Advisory Group. We will also produce an Executive Summary and a standalone publication description, at this stage.

3.32 The study outputs will be compliant with NHS Health Scotland's Research Report Style and Content Guidelines which we have previously used.

Dissemination

3.33 The findings will be of value to a wide range of stakeholders across Scotland and further afield and we can develop a dissemination plan with NHS Health Scotland, if desired. Accessible research outputs will add value to this study, sustaining its legacy and extending lessons. We are happy to support other communication activities such as draft text for journal articles, news releases or multi-media outputs.

Timetable

3.34 The study timetable is shown below.

	2018					2019							
	A	S	O	N	D	J	F	M	A	M	J	J	A
Start-up meeting	✓												
Project Plan	✓												
Context review													
Develop research tools													
Mapping & initial consultation with organisations													
Engagement framework													
Consultation with children & young people													
Consultation with professionals & volunteers													
Qualitative analysis													
Draft Report												✓	
Final Research Report													✓
Presentation of findings											✓		

3.35 The above timescale is based on the assumption that REC approval is not required. Should REC approval be required the start of fieldwork and all subsequent task, are likely to be delayed by two or three months.

Requirements from NHS Health Scotland

3.36 The following assistance from NHS Health Scotland would be welcomed:

- Clarification on research ethics requirements.
- Support with the production of internal and, if required, REC submission documents.
- Contact details for key stakeholders and ethics approval.
- Clarification of reporting requirements.
- Prompt response to ad-hoc queries.
- Prompt payment of invoices.

4 Knowledge and experience

4.1 In this section we outline the knowledge and experience of our study team.

Team members

4.2 Our team consists of Ian Clark, Dr Briege Nugent and Amber Imran.

4.3 **Ian** is the founding director of Iconic and he will take a hands-on approach to leading this study. He has 23 years' relevant experience including 18 years in consultancy during which time he has managed over 200 studies for numerous public and third sector clients. His experience includes designing, managing and conducting social research projects and evaluations covering a range of issues. Ian's skills include communication, project management, and qualitative and quantitative research. He has completed Social Research Association (SRA) training on focus group facilitation and delivered internal training sessions on the subject. He has undertaken depth interviews and focus groups with a range of consultees including professionals, members of the public, project beneficiaries, and trustees. His quantitative research skills include data gathering, managing surveys and detailed statistical analysis. In addition, Ian is a skilled report writer who has completed Plain English and Effective Writing courses, authored many published reports and delivered report writing training for a third sector organisation. He is a member of the SRA, UK Evaluation Society, and Society for the Study of Addiction. He has a MA with Distinction in Urban Policy and Development and a University Certificate with Distinction in Drug and Alcohol Studies. Ian has led all the studies referenced in this section.

4.4 **Briege** is an Associate with Iconic as well as an independent research consultant and Honorary Research Fellow at the University of Salford. Over the past twelve years she has worked for the government, private, academic and third sector. Her experience includes research into children and young people, substance misuse, poverty, homelessness, families and relationships, social inclusion and criminal justice. Briege has extensive experience of qualitative research specifically with

children and young people and alcohol misuse. She conducted a seven-year longitudinal evaluation of Moving On, Action for Children, a throughcare service providing support for young men leaving prison with multiple and complex needs (funded by The Robertson Trust). Her PhD was a qualitative study of the impact of poverty on transitions to adulthood (funded by the ESRC), and involved extensive interviews with young people. More recently, she has completed projects alongside Edinburgh Council's Mental Health Wellbeing Team, interviewing children at both primary and secondary level to assess the impact of their Building Resilience, 1 in 5 Poverty Awareness Raising and Turn Your Life Around programmes. She is currently carrying out a qualitative study commissioned by the Scottish Government and being led by the Scottish Health Action on Alcohol Problems (SHAAP), to explore the contributory factors to alcohol mortality. She has also completed a study exploring the relationship between alcohol, self-harm and suicide using lifecourse interviews (funded by Alcohol Research, UK). She completed her law degree at Queen's University, Belfast, MSc in Criminology and Criminal Justice and PhD both at the University of Edinburgh. She is a member of the Scottish Working Group on Women's Offending and Howard League Scotland.

4.5 **Amber** is a researcher with Iconic who possesses excellent qualitative and quantitative research skills. Amber joined Iconic in January 2017 and has worked on many of the studies referenced below including our ongoing evaluation of Elevate PSP and the CYPFEI & ALEC Fund. She previously worked as a Research Assistant with the school of Education, Social Work and Community Education at the University of Dundee where she supported the Lochee Pathfinder Community Engagement team by conducting interviews, focus groups and ethnographic research with families and workers, policy mapping and literature reviews that ultimately informed the Integrated Children's Services Plan. Amber also gained valuable experience during a placement with Fife Council Youth Service involving engagement with hard to reach or 'at risk' young people. Amber has an MSc with Merit in Social Research Methods, and a BA in Community Learning and Development.

4.6 If additional resources are required we have a pool of associates we can call upon. This includes Dr Margaret Callaghan who would be the first of the associates we would bring into the study. Margaret has twenty-five years' health research and policy experience. She has a PhD in Public Health from the MRC Social and Public Health Medicine Unit at the University of Glasgow. This explored how a smoking cessation service was embedded into an acute unit at a time when such services were in their infancy. She also has a Master's in Public Health with distinction and her thesis was a study of lifestyle factors in heart disease in the North Glasgow cohort of a World Health Organisation project. She has worked in research positions for NHS Lanarkshire and NHSGG&C, the Universities of Dundee, Glasgow and Exeter, HM Treasury (as a health policy advisor) and the Office of the Deputy Prime Minister (as a Senior Researcher in neighbourhood deprivation). She was one of the national evaluators for the Scottish Government and Health Scotland's Equally Well project which explored how mainstream projects and funding could be used to address social inequalities. She has also managed a large number of consultancy project largely in the areas of health, social care and inequalities and carried out many focus groups and interviews with vulnerable groups including young parents, Looked after children and homeless people. Margaret has also taught qualitative and quantitative research and evaluation skills to master's students and health care staff and was recently commissioned, alongside the University of Exeter, by the Department of Health to write an online training resource in evaluation for public health practitioners in England and Wales.

5 Approach

5.1 In this section we summarise our approach to project management, quality assurance, data protection, equality issues, and research ethics.

Project management including client relations

5.2 This is a complex study involving qualitative research with children and young people, professionals and stakeholders across Scotland. It will therefore require very strong project management skills.

5.3 Iconic's Director, Ian Clark, will lead our team. He is a diligent and experienced project manager who has led over 200 projects for a range of clients during his 18 year consultancy career. This includes the management of major studies for the Scottish Government, NHS Health Scotland and NHS Boards, Scottish Enterprise, numerous local authorities and Community Planning Partnerships, and third sector organisations. Ian has previously managed complex studies such as the four-year formative evaluation of the Better Neighbourhood Service Fund programme for the Scottish Government which involved managing fieldwork in 12 Pathfinders, and the evaluation of Year 1 of the Reducing Reoffending Change Fund which involved fieldwork with 14 PSPs.

5.4 Ian will apply recognised project management principles to the study – these involve distilling key tasks into manageable and controllable stages detailed in the Project Plan and the development of Individual Work plans with key milestones. Continual communication with the study team will ensure progress is adequately monitored and objectives are met, any issues that arise which will be addressed and reported to NHS Health Scotland's Research Commissioning Panel where necessary. To enhance our existing approach to project management we use Microsoft Planner. This provides a shared workspace where the project manager sets out and assigns specific tasks to team members with timelines, and the team can share documents, communicate and keep track of progress with specific tasks and the project as a whole.

5.5 Ian will be the first point of contact and he will be responsible for ongoing client relations. The following procedures will ensure effective communication throughout the study:

- Regular progress updates via e-mail/telephone. Any unexpected and serious issues will be communicated immediately.
- More formal Progress Reports to NHS Health Scotland's Research Commissioning Panel. The frequency and format of these reports will be agreed with you at the outset. We propose monthly reports containing an update on progress against the project timetable, milestones, and performance indicators. Any issues will be reported and accompanied by plans to address them.
- Scheduled client meetings to discuss progress and any issues.

Quality assurance

5.6 Following support from Business Gateway, we have implemented a Total Quality Management (TQM) approach to quality assurance and continuous improvement. TQM is a 'philosophy for managing an organisation in a way which enables it to meet stakeholder needs and expectations efficiently and effectively, without compromising ethical values' (Chartered Quality Institute). We apply the TQM philosophy to all our work and the eight TQM principles are integral to our approach:

- We are a customer-focused organisation.
- Our leadership establishes unity of purpose and direction.
- The involvement of our people is positively encouraged.
- A process approach helps to achieve results effectively by managing resources and activities.
- We apply a systems approach to management which contributes to the effectiveness and efficiency of the organisation.

- Continual improvement is a permanent objective of ours.
- A factual approach to decision making ensures that effective decisions are based on the analysis of information.
- We promote mutually beneficial supplier relationships.

5.7 The following processes will be put in place to ensure quality is established, monitored and maintained throughout this research.

Established

5.8 At the start of the study we will hold an internal team meeting to discuss the research aims, our proposed methods including individual roles, and how the project will be delivered and managed. Quality assurance will be a key part of these discussions and this will include a reminder of our overall approach and specific ways in which the quality of our work will be monitored and maintained.

5.9 Following the contract award, we will develop a Project Plan ensuring that the highest standards are applied at all times including developing research tools, communication, engaging service users, and producing study outputs.

Monitored

5.10 We have internal and external mechanisms in place to monitor the quality of our work. Internally, Ian will oversee the drafting of the study outputs such as research tools, progress updates, and reports. Quality assurance during the analysis stage will involve a second member of the team checking the interviewers coding and interpretation of the findings and recommending revisions where appropriate. All of our study outputs are reviewed by our QA assessor who is independent of the study team. Externally, all study outputs including research tools and reports will be sent to the client for comment and revision.

Maintained

5.11 As part of our approach to ethical research, we inform all research participants about their rights and explain the process of how they can raise any concerns about the quality of the research with us or, if they, prefer NHS Health Scotland. We will take immediate and appropriate action if concerns are raised about the quality of work by the client or a research participant.

Data protection

5.12 Iconic is registered with the Information Commissioner (ref. ZA093188) and we fully comply with the Data Protection Act (1998). In addition, we are fully compliant with the introduction of the General Data Protection Regulation (GDPR) which has applied since 25 May 2018. We have Professional Indemnity Insurance in place and therefore have appropriate provision for meeting the indemnities to NHS Health Scotland for any breach of data by Iconic Consulting during this study. Details can be supplied if required.

5.13 We will apply rigorous procedures to the collection, storage, management and transfer of data during this study.

Data collection

5.14 As described above, we apply the highest standards of ethical research including the principle of informed consent. All participants are provided with information on the purpose of the research, their potential involvement and the reasons for data collection. We do not envisage the need for Privacy Advisory Committee approval.

Data storage and management

5.15 Hard copies of consent sheets, and our interviewer notes will be stored in a locked cabinet at our office.

5.16 A new computer file will be created containing the findings of every interview/focus group. No personal information will be recorded on the file. The filename will be a unique ID number linking the paper-based consent sheet and our interviewer

notes to the anonymised electronic files. The unique ID number will also link the findings to our analysis file. All files will be password protected and should they contain personal information, files will be encrypted as an extra layer of protection.

Data transfer

5.17 The original consent sheets, interviewer notes and all electronic files will be retained by Iconic until the end of the study when they will be securely transferred to NHS Health Scotland, who will retain all project data for a minimum of five years from project completion, with the exception of the unique ID numbers, which will be destroyed immediately after project completion. All transfer and transportation will be by secure file transfer or in person, and where necessary, transportation of the personal and non-personal data will be separated. Under no circumstances will the data be shared with anyone outwith our study team or outside NHS Health Scotland (with the exception of disclosure of harm in exceptional circumstances).

Equality issues

5.18 Iconic is committed to the principle and practice of equality of opportunity and promote this in all aspects of our work. We comply with relevant legislation and policies, most notably the 2010 Equality Act and we will adhere to NHS Fair for All equality standards.

5.19 A range of equality and diversity issues were considered during the development of our study methodology. For example, we will seek to engage a cross section of consultees in the fieldwork and will offer additional support if any potential research participant requires it, and make it clear at the outset that our approaches are fully inclusive.

Research ethics

5.20 Ian is a member of the Social Research Association (SRA) and we adhere to the SRA's Ethics Guidelines and RESPECT Code of Practice. We also refer to the Scottish Government's Ethics Guidance for Social Researchers and the ESRC's Framework for Research Ethics. We have a very robust approach to research

ethics which was enhanced by the requirement for Research Ethics Committee approval for our qualitative research for NHS Lanarkshire.

5.21 SRA Ethics Guidelines note that social researchers are bound by a professional obligation to resist approaches to problem formulation, data collection or analysis, interpretation and publication of results that are likely (explicitly or implicitly) to misinform or to mislead rather than to advance knowledge. We uphold this obligation throughout our work, particularly during the analysis stage to ensure the findings are protected from bias. We do so by triangulating findings from different sources and by challenging interpretations made by colleagues. An indication of the strength of opinion will be stated in the report and minority views will also be presented proportionately.

5.22 Our team members have PVG / Disclosure Scotland clearance. We have a researcher safety guide that all members of the team adhere to during fieldwork.

Distress

It is possible that some participants may become distressed during the interview when talking about their personal experiences of misusing alcohol or related issues. We have an approach to anyone who becomes distressed during an interview.

We also have procedures in place to support staff should they be distressed by the content of any interviews.

Risk management

5.23 The main risks associated with this research are listed below. A risk management strategy has been developed, identifying the likelihood of it arising, the potential impact it would have, the mitigating actions to minimise the risk and the recovery plan should it arise.

- Timescale slippage due to requirement for REC approval (LOW likelihood, MEDIUM impact)

- Difficulty identifying relevant organisations working with children and young people (LOW likelihood, HIGH impact)
- Difficulty engaging staff and volunteers at relevant organisations (MEDIUM likelihood, HIGH impact)
- Difficulty recruiting children and young people (MEDIUM likelihood, HIGH impact)
- Children and young people becoming distressed during or after the interviews (LOW likelihood, HIGH impact)
- Difficulties regarding parents/carers involvement (LOW likelihood, HIGH impact)
- Focus group participants sharing confidential information with others (LOW likelihood, HIGH impact)
- Perceived conflict of interest regarding our evaluation of the Scotch Whisky Action Fund (LOW likelihood, LOW impact)
- Insufficient time allocated to research tasks (LOW likelihood, LOW impact)
- Substandard quality of research and study outputs (LOW likelihood, HIGH impact)
- Inability to analyse the volume of evidence gathered (LOW likelihood, HIGH impact)
- Loss of research data (LOW likelihood, HIGH impact)
- Staff turnover or absence (LOW likelihood, MEDIUM impact)
- Timetable slippage (MEDIUM likelihood, HIGH impact)