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Designing a generic, adaptive protocol resource for the measurement of health impact in cash transfer trials

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Abstract

Introduction

In the context of the COVID-19 pandemic, upstream interventions that tackle social determinants of health inequalities have never been more important. Evaluations of upstream cash transfer trials have failed to capture comprehensively the impacts that such systems might have on population health through inadequate design of the interventions themselves and failure to implement consistent, thorough research measures that can be used in microsimulations to model long-term impact. In this article, we describe the process of developing a generic, adaptive protocol resource to address this issue and the challenges involved in that process.

Methods

We outline two types of prospective intervention based on trials currently under discussion. In developing the remainder of the resource, we establish six key principles, implement a modular approach based on types of measure and their prospective resource intensity, and source (validated where possible) measures and baseline data primarily from routine collection and large, longitudinal cohort studies. Through these measures, we seek to cover all areas of health impact identified in our theoretical model.

Results

We find that, in general, self-reported measures alongside routinely collected linked respondent data may provide data capable of demonstrating comprehensive health impact. However, we also suggest that, where possible, physiological measures should be included to elucidate underlying biological effects that may not be accurately captured through self-reporting alone and can enable modelling of long-term health outcomes.

Discussion

We suggest that while Open Access evaluation instruments are available and usable to measure most constructs of interest, there remain some areas for which further development is necessary. This includes self-reported wellbeing measures that require paid licences but are used in a range of nationally important longitudinal studies instead of Open Access alternatives.

Key Messages

There has been uncertainty about the feasibility of establishing common measures that permit generalisability of findings in specific cash transfer trials and in development of large, longitudinal datasets, due to the broad range of self-reported and physiological measures currently used. We present measures that enable trials to use existing data as a control and to create data that is generalisable to whole populations *and* can be used to model medium and long-term outcomes.

We have included wellbeing measures that require paid licences but facilitate comparison with existing data. However, we recognise that their use will not be feasible for all studies and therefore offer Open Access alternatives, which may be capable of providing comparable data based on establishing common, evidenced, cut-off points for clinical significance or through their adoption on a widespread basis.

In terms of taking forward findings to the design of pilots and main trials, feasibility studies, including the forthcoming Welsh Government trial for Care Leavers, will be necessary to establish a) establish formal power calculations based on the outcomes and demographic groups of interest, and b) the final costs of the intervention and evaluation, which will determine the specific modules and measures included.

Introduction

Some 40 years after The Black Report (Working Group on Inequalities in Health 1980) indicated means of affecting social determinants through tax-benefit policy, welfare has failed to promote health. In 2010, 1.3–2.5 million extra years of life and 2.8 million free of illness or disability were being lost annually in England due to health inequalities (The Marmot Review 2010, 19). Providing support for theoretical work by Grover (2019), IPPR (Hochlaf, Quilter-Pinner & Kibasi 2019) attributed 130,000 preventable deaths between 2012 and 2017 to austerity measures. Health inequalities are worsening (Marmot et al. 2020, 149) and key academic (The Lancet 2020; BMJ 2018) and policymaking organisations (EHRC: Hudson-Sharp et al. 2018) have lobbied for evidence-based reforms to welfare to promote public health. The COVID-19 Pandemic has only increased the urgency of this work.

One of the key under-researched alternatives to the existing system of conditional welfare is Universal Basic Income (UBI), a system of universal cash transfers to (usually adult) citizens or, perhaps pragmatically, residents. It ensures a minimum income but, unlike the UK's Universal Credit (Government Digital Service 2021), is not conditional (i.e., depending on meeting criteria such as being unemployed or disabled to receive benefits). UBI has been presented as a prospective public health measure (Johnson & Johnson 2019) but has not been trialled in ways that permit development of health impact evidence (Johnson, Johnson & Webber 2020). We were funded by the Wellcome Trust to develop a generic, adaptive protocol resource to evaluate health and wellbeing impact comprehensively for two different types of prospective cash transfer trials: a) smaller-

scale pilots for 18- to 21-year-olds with lower-than-average socioeconomic status (SES), as in the current Basic Income trial for Care Leavers in Wales (Welsh Government 2022); b) a large-scale full trial involving all people in a small town. While the project was commissioned within Wellcome's Mental Health Priority area and is informed by Wellcome's 'Active Ingredients' (Pote 2021), the resource seeks to support measurement and evaluation of impact on health and wellbeing more broadly, both because mental health is correlated with physical health and because measuring physical health impact is critical to assessing potential costs and benefits of schemes.

Aims and objectives

In this article, we seek to do the following:

1. Set out key principles of protocol development based on previous theoretical contributions
2. Explore known gaps in evidence on cash transfers resembling UBI to identify the need for a consistent protocol resource
3. Outline the resource and feasibility challenges of some measures, particularly physiological, and how a modular approach to measures banks can address this
4. Examine feasibility issues posed by copyright and paid licensing of measures used in large datasets
 - a. Make the case for bringing widely used measures with paid licencing conditions into the public domain, or identify and implement comparable Open Access alternatives

Existing evidence: Income, health and welfare

There is a broad body of evidence to indicate a causal relationship between income and health. Systematic reviews have presented evidence of associations between income and inequality as determinants of: population health (e.g., Kim 2017; McCartney et al. 2019; Ray & Linden 2018; Kondo et al. 2009; Reche, König & Hajek 2019); child health, wellbeing and educational outcomes (Cooper & Stewart 2021); and adult mental health (Tibber et al. 2021). Indeed, supporting Pickett & Wilkinson's findings (2015), Adeline and Delattre (2017) endorsed both the Absolute Income Hypothesis (a positive and concave effect of income on health) and the Income Inequality Hypothesis (that income inequalities affect all members of a society). As such, the overwhelming body of evidence supports the notion of an increase in income being the 'ultimate "multipurpose" policy instrument' (Mayer 1997, 145).

Crucially, despite the clear evidence of a relationship between income, welfare and income, Benzeval et al. (2014, 52) have argued that there is 'less clarity regarding the particular role of income as a health determinant or the mechanisms by which income modification interventions might affect health'. Based on the literature, we have presented three pathways to health through welfare (Johnson et al. 2021a), which we represent in Fig. 1.

Where welfare increases:

- i) size of income, it can reduce poverty, thereby improving quality of resources by which to satisfy basic needs (Johnson, Degerman & Geyer 2019).
- ii) security of income, it can reduce stress associated with exposure to threat of destitution (Johnson & Johnson 2019).
- iii) predictability of income, it can reduce 'extrinsic mortality cues' and promote longer-term thinking conducive to health promoting behaviour (e.g., substance use and relationship formation) (Pepper & Nettle 2017).

A safety net that reduces 'health inequalities and the structural conditions that put people "at risk of risks"' (Thoits, 2010, S47), can, therefore, potentially serve as a significant public health instrument. However, conditional welfare systems like Universal Credit are often associated with poor outcomes. Receipt in high-income countries is associated with worse health outcomes (Shahidi et al. 2019), increased psychological distress prevalence (Wickham et al. 2020) and reduction in activity (Johnson & Spring 2018). Our model suggests several explanations: current welfare schemes are 'insufficient to offset the negative health consequences of severe socioeconomic disadvantage' (Shahidi et al. 2019); conditionality (requirements such as being unemployed or disabled to receive benefits) and assessment inflicts stress (Dwyer et al. 2020) and creates perverse incentives for health-diminishing behaviour (Johnson et al. 2021a, 5); and focusing on the poorest fails to mitigate broader determinants that affect society as a whole (see Marmot Review 2010, 16). It is for these reasons that organisations, parties and commentators have called for evaluation of alternatives (The Lancet 2020).

Evidence on alternative systems, such as UBI, is less clear by virtue of the absence of representative trials and the failure to evaluate health impact in a consistent and generalisable manner within previous cash transfer programmes. Gibson, Hearty & Craig's (2020) scoping review examined interventions similar to basic income. Where transfers reduced poverty, research found increased birth weight (Chung, Ha & Kim 2016), illness and injury reduction (Beck, Pulkki-Brännström & Sebastián 2015), and decreased hospital admissions (Forget 2011). Where schemes reduced conditionality, qualitative studies found improved adult mental health (Hannan 1978; Kangas et al. 2019, 24), fibromyalgia and coeliac disease (Hamilton & Mulvale 2019). Where schemes increased predictability of income, studies showed reduced substance misuse (Costello et al. 2010).

However, the schemes from which the evidence was drawn were unrepresentative of prospective trials in the UK as payments were either not applied to entire populations, were contingent on ethnicity, made to heads of households, were periodic or too small (Johnson, Johnson & Webber 2020). Moreover, the trial protocols have failed to secure comprehensive generalisable data on health impact for a number of reasons, such as that they: a) focus solely on mental health measures with regard to the role that stress plays rather than accompanying physical health effects; b) consider outcomes that would be anticipated solely from poverty reduction among the very poorest rather than health impacts across the population; c) fail to measure a broad range of measures of stress and subjective socioeconomic status that affect those broader sections of society (Johnson, Johnson & Webber 2020). The consequence of inadequate design and evaluation in previous trials is that assessments of UBI are likely to have underestimated health impacts and overestimated net costs.

In terms of understanding long-term population-level outcomes, even comprehensive, systematic reviews and meta-analyses of available data, like Romero et al.'s (2021), are unable to provide the data required for microsimulation. This is because microsimulation estimates distributional outputs and studies must report not just the average effect of the intervention but the disaggregated distributional effect as well. For example, ideally, data should report the intervention's differential impact across different age groups, sex, and income deciles. This would enable a more realistic simulation of the potential policy impacts and in-silico experimentation of multiple policy implementations.

With regard to prospective cash transfer systems, Randomised Controlled Trials (RCTs), and other experimental designs, are crucial as they play the following roles:

1. Identify the causal mechanisms between income (including quantity and quality) and health
2. Prove risk reversibility, i.e., that cash transfer interventions can reduce the excess risk of living in material deprivation. This is crucial for policymaking as it would justify cash transfer policies
3. Quantify the impact of the intervention
4. Identify the most effective intervention designs

Given rising interest among policymakers in UBI, as well as other cash-transfer upstream interventions, there is genuine need for research protocols capable of being deployed effectively in different trial conditions. However, it is perhaps unfeasible that a single RCT could fulfil all the roles above because it would require too large a sample size and a long observation period that may not be feasible in the current political and academic environment. Therefore, multiple RCTs may be required to explore the issues and produce much-needed data on efficacy. This makes the consistency of outcome measures between trials essential. In this regard, the abundance of observational and experimental studies requires evidence synthesis. Simulation modelling is uniquely positioned to synthesise all available evidence and estimate what cannot be directly observed. Microsimulation specifically can simulate the causal pathways between income and health and quantify the distributional impact of policy-relevant what-if scenarios.

Quantifying the potential effectiveness, cost-effectiveness, and equity of a proposed cash transfer interventions (e.g., UBI) through modelling requires the simulation of two counterfactual scenarios: the baseline scenario (i.e., UBI is not instituted) and the policy scenario (i.e., UBI is instituted across a nation). The baseline scenario needs to be informed by existing population-representative observational studies, such as longitudinal cohort studies (e.g., Understanding Society and the Millennium Cohort Study). The policy scenario needs to be informed by RCTs of the proposed intervention, although modelling based on observations based on income can aid understanding of the potential impacts cash transfers could have ahead of representative RCTs. Therefore, outcome measures of the RCTs need to be harmonised with the measurement instruments of the population-representative observational studies.

Given this background, there is a need to produce a generic, adaptive protocol resource capable of being deployed in very different types of trial. In this article, we outline development of the resource for two types of trial being considered by policymakers that operate at significantly different scales: a) smaller-scale pilots for 18- to 20-year-olds in urban areas with lower-than-average socioeconomic status (SES); b) a large-scale full trial involving all people in a small town. There are tangible proposals relating to these types of trials (see 'Trial duration and regularity of data collection' below), but we wanted the resource to be sufficiently generic and adaptable to be of use in most possible situations, at least within a UK context. The two trial types necessarily differ according to scale and measures used. The former establishes feasibility in terms of ethics, payment and proof of research concept. The latter is necessarily broader as the impact of the intervention would be broader and would focus more clearly on establishing collective-level efficacy and broader socioeconomic outcomes.

Methods

We have previously established a number of limitations to the existing data (Johnson, Johnson & Webber 2020), guidelines for developing trials designed to promote public health (Johnson, Johnson, Nettle & Pickett 2021) and means of modelling long-term population-level health and economic impacts from trials (Johnson et al. 2021b). Our findings informed some broad underpinning features for pilot design, which we discuss in the results section below. Our development of generic adaptive protocols proceeded according to principles established in Johnson et al. (2020):

1. Routine collection ought to be the foundation for baseline comparison of society-level outcomes

2. Measurement ought to capture wellbeing in its broadest form
3. Only measures validated against morbidity and mortality be deployed
4. Self-reporting requires simplicity and limits on respondent load to ensure accuracy
5. Cost ought to be minimised where similar outcomes can be produced via cheaper procedures

We have added a sixth principle to this in light of the risk of research misuse on the subject of welfare (see impact of reforms in Watkins et al. 2017):

6. Where possible, questions ought to be the result of co-production with, or reflect the assessment of, people most vulnerable to welfare reforms

Upholding these principles ensures a range of measures are available that provide comparability between data sources and a structure that facilitates use in microsimulation modelling. The design of protocols for adaptive use in cash transfer trials is necessarily generic and broad as projects will vary substantially depending on context aims and resource available. As such, we structured our enquiry around evaluating and collating four modular components for studies:

- 1) Essential administrative data
- 2) Available comparative data from routine collection and national surveys
- 3) Self-reported substantive measures
- 4) Physiological measures requiring more intensive collection methods and analysis

Given the need for data to administer the intervention and evaluation, control data where interventions have been provided to everyone within a locality and the needs for substantive, efficient, health outcome data, we held a working assumption that modules 1), 2) and 3) would be essential to completion of any study, while module 4) could be included or omitted depending on resourcing.

We began by reviewing the scale, scope and accessibility of data from routine data collection and national surveys such as the Census, Public Health Profiles (and its sources), Family Resources Survey, Crime Survey for England and Wales and NHS activity. We looked at the possibility of using linked patient data, given that it has the potential to reduce respondent load and enable substantial data gathering that might otherwise be required through self-reporting in a trial measuring health outcomes.

We then reviewed the literature to establish the scope, validation and licensing status of survey questions deployed in large longitudinal cohort studies, including the Millennium Cohort Study, Next Steps and Understanding Society. While recognising that results from observational studies may underestimate strength of association (Cooper & Stewart 2021, 981), we supplemented the review with statistical analysis of the relationship between some commonly used mental wellbeing measures and diagnosis of anxiety and depression. Using data from Understanding Society (wave 10), our analyses showed that among 14- to 24-year-olds, self-reported diagnosis of anxiety or depression was predicted better by SF-12 (OR: 3.12, 95% CI: 2.57–3.78) than GHQ-12 (OR: 2.18, 95% CI: 1.85–2.56), using standardised measures of these predictors to make results comparable. This work served two functions. First, it built into the protocols capacity for comparison with large datasets and, second, it enabled assessment of the viability of adopting solely Open Access questions in order to comply with principle 5. The cohort studies also provided key demographic and administrative questions that could be employed.

We examined measures requiring an interviewer and sought to identify alternatives suitable for self-reporting. Finally, we looked at physiological measures in order to establish whether there was strong case for their inclusion or whether self-reported alternatives would be sufficient.

Results

Routine collection and baseline data

We identified several core sources of data from routine collection and national surveys that could be deployed in trials within England, Wales and Scotland. First, UK Census data is available from the Office for National Statistics' (2022c) Nomis covering demographic categories and socioeconomic status along with self-rated global health and social model of disability by small administrative areas. It is, fundamentally, the sole major source of such data that is drawn not from a sample but instead contains responses from almost the whole population. 2011 data is currently available, which, unfortunately, does not cover the substantial changes in socioeconomic circumstances that have taken place under austerity policies of the last decade. Full 2021 Census data will, however, be available from March 2023 (Office for National Statistics 2022a). Further official labour market statistics are available through Nomis from a range of, usually annual survey, sources, including the Annual Population Survey. Finally, more detailed, and up-to-date socioeconomic data is available from the Department for Work and Pensions, Office for

National Statistics & NatCen Social Research's (2021) Family Resources Survey, which is of significant importance with regard to tax-benefit microsimulation modelling.

We also located a number of sources of routine and national survey health data. This included the Office for Health Improvement and Disparities' (2022) Public Health Profiles (which collate population health and health behaviour data for England at local authority level), the Scottish Public Health Observatory's (2022) ScotPHO Online Profiles Tool (which presents similar data for Scotland at national, NHS health board or local area level depending on measure) and Public Health Wales' (2022) Observatory which presents similar data but is currently under development. Further physical activity data at local authority level is available for England at through Sport England's (2022) Active Lives Online, while the relevant data for Scotland through the Scottish Government's (2022) Scottish Health Survey is only available at national level.

In terms of crime statistics, which we considered to be a key indicator of broader wellbeing, recorded crime in England is available by Community Safety Partnership level (Office for National Statistics (2022d) – which broadly equate to local authority areas – and by local authority level in Scotland (Scottish Government 2021a). Crime and crime perceptions data are available from the Crime Survey for England and Wales at police force area level (Office for National Statistics 2022b) and the Scottish Crime and Justice Survey at Police Division level (Scottish Government 2021b).

The key sources of health data that have the potential to be compared against that produced through cash transfer evaluations form two groups. First, there are large cohort studies, both longitudinal – such as Understanding Society (Institute for Social and Economic Research 2022), the Millennium Cohort Study (Centre for Longitudinal Studies 2022a), Next Steps (Centre for Longitudinal Studies 2022b), Whitehall II (Institute of Epidemiology & Health Care 2022) and the English Longitudinal Study of Ageing [ELSA] (English Longitudinal Study of Ageing 2021) – and cross-sectional, primarily the Health Survey for England, Scottish Health Survey and Welsh Health Survey. In general, these studies provide large-scale, comprehensive health data from self-reported measures and, in the case of Understanding Society, Whitehall II and ELSA, physiological measures such as biomarkers. Unfortunately, the data from the majority of these studies is often underpowered to explore associations at subnational (or subgroup population) level, with regional data available in the Health Survey for England. It does provide comparison data by demographic groups, however, such as socioeconomic status, so is of significant use in, for example, microsimulation modelling. Most self-reported data is publicly available in some form, while physiological measures sometimes have data-sharing requirements. The second source of health data is NHS activity data at both primary and secondary levels. Tracking changes in activity is possible in England at Clinical Commissioning Group (CCG) level for primary care (NHS Digital 2022a) and, to some extent, at secondary care level (NHS Digital 2022b). Scottish hospital data are available at NHS Board level (Public Health Scotland 2021). Fewer sources of Open Access primary care data appear available (Public Health Scotland 2022). However, the Clinical Practice Research Datalink (2022), which requires a paid licence, provides data based on patient electronic health records from a network of GP practices from across the UK.

Finally, in some areas, and for some research studies, linking respondent data with their patient records or other data sources may be possible. In Bradford, for example, Connected Bradford (Sohal et al. 2022) has been implemented to streamline this process. In London, the boroughs of Tower Hamlets (Thiru, Goldblatt & Hogarth 2018) and Barking and Dagenham (Care City 2020), have also created anonymised/pseudonymised datasets drawn from a range of health and local authority data.

With these routine and comparative data sources identified, we moved on to develop the self-reported questions component of the measures bank.

Self-reported questions

In considering which measures to include in our bank, we again prioritised those in large, national longitudinal cohort studies, both due to the validation status inherent in such measures and their ability to provide comparative data that can be used in microsimulation modelling to fill any gaps in the evidence collected during trials. In addition to administrative questions, we looked for measures in three broad themes.

Demographics

Due to harmonisation efforts by the Government Statistical Service (2022), demographic measures are, on the whole, sufficiently consistent at national statistics level and at least comparable in other large datasets. We therefore prioritised England and Wales 2021 Census measures for this section, particularly as it will provide up-to-date, accurate data at very small administrative area level. While it does not contain comprehensive health and wellbeing data, it is very useful as a means of populating microsimulation models with data that has not been estimated. Some measures, such as gender and assigned sex have been taken from Understanding Society as the previously agreed Census measure guidance was changed by court order (Topping 2021) resulting in potentially inconsistent wording with regard to sex and gender identity.

From a theoretical perspective, it was important to ensure that measures were included for all potential demographic sources of socially determined inequalities in health. It is plausible that different groups, based on gender identity, cultural background, religion or sexual orientation might be impacted differently by socioeconomic interventions. For example, women and LGBT people might disproportionately benefit from independent economic security that could enable escape from domestic violence or intimidation and secure reduced stress and increased wellbeing and flourishing.

Socioeconomic status and household composition

Our review highlighted the difficulty of deploying a single set of questions to establish household and socioeconomic baselines for the broad range of cash transfer trials that might be undertaken. Household grids are used in large surveys like the Census, Family Resources Survey, Millennium Cohort Study and Understanding Society. However, in respect of principle 4, they are extremely cumbersome and time consuming. For example, Understanding Society's Household Grid module contains a potential 115 questions (Institute for Social and Economic Research 2020a). In keeping with principle 6, co-production with young people as part of the Born in Bradford: Age of Wonder project, resulted in the development of a three-question household composition question. In that project, however, evaluation is primarily focused on individual young participants. A cash transfer trial may look at impacts on one individual in a household alone (as in Kangas 2021, 52), but, as we have argued (Johnson, Johnson & Webber 2020), it is important to consider the effect of such interventions on households, communities and society as a whole. Measurement on the basis of heads of household alone is likely to replicate issues identified in several previous interventions. For the measures bank, we developed a new grid system for use online for completion by a head of household that facilitates cascading individual questionnaires. In future testing, we intend to undertake primary research and co-production to understand the impact on respondent load and response accuracy of these options.

A factor in the need to reduce respondent load and simplify administration is measurement of objective and subjective socioeconomic status (SES). Although an individual is unlikely to answer all of these, Understanding Society (Institute for Social and Economic Research 2020b) has a total of 169 possible questions relating to SES. That study is sufficiently large and well-funded to support this kind of administration. However, for smaller projects, and even the larger of our two theoretical studies in which more than annual collection would be needed, this is unlikely to be feasible. We therefore decided to focus on the most fundamental and replicable measures of SES based on our analysis of datasets and the requirements we have identified for modelling (Lansley et al. 2022).

We have shown that within- and between-individual variations in net equivalised household income are associated with greater prevalence of clinical-threshold level symptoms of poor mental health through measures such as SF-12 (Parra-Mujica et al. 2022 [forthcoming]). We therefore developed a simplified measure of household income developed from the Institute for Fiscal Studies' (2021) 'Your household's income: Where do you fit in?' tool. This only requires four questions to be answered by the head of household/benefit unit to obtain sufficient net household/benefit unit income data. We also include guidance about calculating net income for self-employed people and questions on receipt of benefits, since engagement with welfare has a substantial relationship with the subject of cash transfers.

Importantly, we include subjective SES questions from the Millennium Cohort Study (MCS) associated with poorer mental wellbeing. In young people aged 16–24, the MCS measures were more monotonically associated with poor mental health than average household income (Villadsen et al. 2022 [forthcoming]). They were also strongly correlated among parents of cohort members in the Millennium Cohort Study. The two MCS questions, with headline associations with indications of anxiety and depression, are:

1. Compared to your friends, is your family richer, poorer or about the same? Richer, poorer, the same (reported by cohort member at age 11).

a) At age 14, prevalence of clinical levels of depression on the Short Moods and Feelings Questionnaire (SMFQ) (Angold et al. 1995) was 24.7% among those who reported that their family was poorer compared to 13.8% in those who reported their family to be richer.

b) At age 17, prevalence of clinical levels of distress on the Kessler 6 (Kessler et al. 2003) scale was 25.3% among those who reported that their family was poorer compared to 13.8% among those who reported their family to be richer.

c) Prevalence of clinical levels of distress on the Kessler 6 scale among parents of cohort members was 12.8% for poorer families compared to 5.2% of richer families.

2. How well would you say you yourself are managing financially these days? 1. Living comfortably, 2. Doing alright, 3. Just about getting by, 4. Finding it quite difficult, 5. Finding it very difficult (reported by parent of cohort member at ages 9 to 14 years, with measures across years combined and grouped in quintiles).

a) At age 14, prevalence of SMFQ clinical levels of depression was 18.7% among the quintile managing least well compared to 11.7% in the quintile managing the best.

b) At age 17, prevalence of clinical levels of Kessler 6 distress was 18.9% among the quintile managing least well compared to 10.4% in the quintile managing the best.

c) Prevalence of Kessler 6 clinical levels of distress among parents of cohort members was 14.8% amongst the quintile managing least well compared to 1.0% in the quintile managing the best.

We also included a third question from Understanding Society which covers similar ground and will provide comparable subjective measures of SES.

3. On a scale of 1 to 7 where 1 = 'Completely Dissatisfied' and 7 = 'Completely Satisfied', please tell me the number which you feel best describes how dissatisfied or satisfied you are with the income of your household. 1. Completely dissatisfied, 2. Mostly dissatisfied, 3. Somewhat dissatisfied, 4. Neither satisfied nor dissatisfied, 5. Somewhat satisfied, 6. Mostly satisfied, 7. Completely satisfied.

We have supplemented these measures with a range of questions based on job satisfaction and work environment, including autonomy and security. Proponents of UBI have suggested that these areas, in particular, should be impacted significantly by cash transfers that shift the balance of power away from employers and towards workers (Johnson & Johnson 2019). There are also indications from meta-analysis of a relationship between these areas and health, with strong correlations between job satisfaction and mental health, in particular (Faragher, Cass & Cooper 2005). We also included questions covering material deprivation and food security.

Finally, we included a question on care from the 2021 England and Wales Census. This is crucial, as the ability to undertake activity that is not traditionally remunerated is regarded both as a potential benefit of UBI (Standing 2019, 24), an observed feature of previous trials (Ståhl & MacEachen 2021) and an important issue in gender equality, as women are much more likely to undertake both paid and unpaid care (Women's Budget Group 2020; Standing 2019, 23).

Self-reported health and wellbeing

Our assessment of associations between SES and mental wellbeing provided a foundation for development of the measures bank relating to self-reported measures of health and wellbeing. A range of mental wellbeing measures have been employed by large longitudinal cohort studies. For example: the Millennium Cohort Study includes the Short Moods and Feelings Questionnaire (SMFQ) (Angold et al. 1995) at 14, Kessler 6 (Kessler et al. 2003) and the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (Tennant et al. 2007) at 17, while parents answered the Malaise Inventory (Rutter, Tizard & Whitmore 1970) when their child was 9 months old; Next Steps uses the General Health Questionnaire 12 (GHQ-12) (Goldberg 1978) at 25; and Understanding Society employs GHQ-12 and Short-Form Health Survey (SF-12) (Ware, Kosinski & Keller 1996), and WEMWBS (in particular waves). This does facilitate analysis of the measures most closely linked to clinical outcomes, but also means that many measures are only comparable through relatively complex, and sometimes insufficiently validated, calibration and mapping. Some of this work has been undertaken by McElroy et al. (2020) with regard to mental wellbeing measures used in the six cohort studies managed by the Centre for Longitudinal Studies at UCL. It found that while some measures have good precision and reliability for assessing mental health at the high end of psychological distress other measures perform better at the lower end of and are more reliable at capturing wellbeing than distress. Further calibration work for measures at age 10/11 was undertaken by Gilbert et al. (2019) and covers the longer SF-36 and WEMWBS. This study found that there was at least a 'moderate-high correlation (> 0.60)' between different measures, but this varied substantially (Gilbert et al. 2019, 2) and leaves open questions about the degree to which data can be usefully compared and mapped so as to enable use in microsimulation modelling.

In terms of measures that enable clearer assessment of clinical mental health problems, the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer & Williams 2001) and Generalised Anxiety Disorder Assessment (GAD-7) (Spitzer et al. 2006) measure depression and generalised anxiety disorder according to DSM-IV symptoms. The short version PHQ-8 eliminates a question on self-harm. This is because it is not possible to guarantee support and safeguarding for respondents were they to report history of or plans to self-harm. For young people aged 8–16, we have proposed using RCADS (Francis 2000) as a validated measure. While these measures have not been used in the major longitudinal studies under consideration, they are now the International Alliance of Mental Health Research Funders' (IAMHRF) recommended measures for mental health and will likely be more widely used in future (Farber, Wolpert & Kemmer 2020).

An alternative measure for adults is the Revised Clinical Interview Schedule (CIS-R) (Lewis et al. 1992; Lewis 1994). There is a case to be made for the inclusion of CIS-R as it is the main measure used in the official mental health condition prevalence study in England (McManus et al. 2016) and has no licencing conditions. The measure used in the corresponding children and young people prevalence study (NHS Digital 2021) is the Development and Well-Being Assessment (DAWBA) (Goodman et al. 2000; Youthmind 2019b), which does have paid licence conditions (see 'Discussion' below). While both can be completed through computerised versions, assessment of results by clinicians is still usually indicated. We have not recommended CIS-R and DAWBA over wholly self-reported alternatives as the latter would result in lower respondent load and administrative resource, are validated, and have sufficient sensitivity and specificity.

A number of self-reported measures of physical, or all-round, health are used in large cohort studies in the UK. Global self-rated health, broadly, 'how is your health in general?' usually with five options that vary between studies, is validated as an independent predictor of mortality and is very quick and easy to administer (Idler & Benyamini 1997). The version we selected is that used in the England and Wales Census, since it is the largest, most-comprehensive source of data available, but versions are included in most of the cohort studies, whether independently or as part of SF-12.

Measuring the impact of disability as defined by the social model, is also essential, and in keeping with principle 6, as disabled people now comprise 19% of working-age people and 22% overall (Department for Work and Pensions 2021, Table 4.1) and face a range of intersectional determinants (Rhode et al. 2012; Activity Alliance and IFF Research 2020, 118–123). Disabled people are also disproportionately affected by welfare and reforms to welfare systems (Johnson & Nettle 2020). We have proposed the harmonised ONS version, as it is most-commonly used in national statistics (including the Census) and variations are included in major cohort studies.

We have supplemented these measures by including questions covering conditions diagnosed by a health professional and health service use from Understanding Society. There is strong evidence that the higher disease burden among people with lower SES is not matched by appropriately higher levels of diagnosis and treatment compared with higher SES individuals (Steel et al. 2014) and it is important to understand these access-to-healthcare issues and how they might be affected by cash transfers. In addition, it enables further analysis of how self-reported and physiological measures of health are associated with professional diagnosis.

Finally, with regard to subjective measures, we included the EQ-5D-5L (Herdman et al. 2011) for adults and EQ-5D-Y for children and young people (Wille et al. 2010). This enables a broader understanding of respondent health that can be monitored over time. While SF-12 (Ware, Kosinski & Keller 1996) would provide a similarly broad assessment of health and has the benefits of being included in Understanding Society, it requires a paid licence that precludes its recommendation as a part of an Open Access resource (see 'Discussion' below).

In terms of resourcing, we believe that we have been able to assemble a suite of questions that avoid the requirement of using in-person interviewers for the core measures and could be completed online, by post or by phone/video call. We propose, with regard to principles 5 and 6, that there should be both further testing and co-production of these self-reported measures during pre-study preparation as well as the provision of suitable alternatives, such as the option of a phone interview if required for access reasons, should they be required. Family Resources Survey data indicates that, in 2019/20, there were 1.6 million people in the UK with visual impairments, 3.5 million with dexterity impairments, 2.1 million with memory impairments and 1.8 million with learning disabilities (Department for Work and Pensions 2021, Table 4.5). While there is overlap in these numbers, it is clear that if studies are to be truly representative of the public, accessible forms of participation must be available.

Physiological measures

Stress mitigation from cash transfers is a theoretical pathway in our model of impact (see Johnson & Johnson 2019) but remains challenging to measure comprehensively. We include a subjective measure, the Perceived Stress Scale (Cohen, Kamarck & Mermelstein 1988), in the self-report question bank. However, because individuals may perceive their level of chronic stress inaccurately (Brant, et al. 2010) or self-report it differently for social reasons (Simpson, et al. 2008), we examined examples of biological material collection in studies such as Whitehall II and Understanding Society. The challenge of accurate measurement is not solely limited to stress. Chaparro et al. examined the associations between global self-rated health (SRH) – dichotomised to 'good' or 'poor' – with biomarker indices, namely 'visible weight-related', 'fitness', 'fatigue', and 'disease risk' which reflected 'different ways they may make the respondent feel and hence assess their health' (2019, 2). They also assessed whether these associations are modified by age, gender, and/or socioeconomic position. They found that while self-rated global health is 'overall strongly associated with objective measures of health', 'the strength of this association varies by the type of biomarker used as well as by gender, age, and income, though the latter to a lower extent than we hypothesized' (Chaparro et al. 2019, 9). They conclude that while 'SRH is a valuable health indicator, caution should be taken when using SRH as the sole health measure when studying gender, age, and income health inequalities' (Chaparro et al. 2019, 9).

Given this background, principle 5 and the additional ethical burden of biomarker collection in mind, we developed a module based on elements of major longitudinal cohort studies, particularly Understanding Society (Institute for Social and Economic Research 2017) along with others included in CLOSER (Ruiz, Benzeval & Kumari 2017) and Whitehall II (Institute of Epidemiology & Health Care 2019; Kumari et al. 2011). The majority of the physiological and recorded measures section should therefore be regarded as an optional add-on module, but one that deserves strong consideration, particularly for large studies. We have included evidence of association with health outcomes for each area measured and, as such, it is also possible to select from the bank based on particular interests within studies or where self-reported data is insufficient.

Access and licensing conditions

Given principle 5 and a general commitment to transformative science, we sought as fully as possible to produce Open Access protocols. While measures such as PHQ-9 and GAD-7 have no licence conditions attached to them, GHQ-12 (Goldberg 1978) and SF-12 (Ware, Kosinski & Keller 1996) require a paid licence in advance of use in studies, while EuroQol instruments (like EQ-5D) require licences that entail obligations for collaboration. WEMWBS also requires a licence, though conditions are relatively straightforward. Unpaid licences may be compatible with the spirit of Open Access collaboration, but paid licences pose ethical questions, particularly given the deployment of protocols for evaluation of trials intended specifically to mitigate health inequalities. Such interventions ought not to be compromised by the need to pay for survey measures, particularly where the validation process is unclear.

The case for payment lies in the quantity of existing data collected using paid measures that provides comparative, and microsimulation modelling, data for trial evaluations, as GHQ-12 and SF-12 have been deployed for over 10 years within Understanding Society. GHQ's copyright holder also states that 'part of the payment received from permissions is paid as a royalty to the Institute of Psychiatry to fund research' (GL Assessment 2022). While this may support scholarship, it is important to note that there have not been any major updates to the original English version of the measure since its introduction in the 1970s. For example, no child version has been developed by the copyright holder (GL Assessment 2022). Similarly, SF-12, which is used as a measure of wellbeing by the UK Office for National Statistics, was released in 1996 with v2 in 2000 (Mapi Research Trust 2022). Again, the copyright holder has not developed a child version and there is no clear cost on their website (QualityMetric 2022). As such, we

sought to present Open Access alternatives. Our assessment identified a range of options that can be used in place of paid licence measures. In our measures bank, however, we highlight where paid alternatives with substantial comparative data can be sought where resources permit.

Trial duration and regularity of data collection

We included in the resource an adaptable study design for a pilot intervention for 18- to 20-year-olds (see Fig. 2). This reflects projects currently of interest, with the Welsh Government (2022) having announced a cash transfer intervention for care leavers while a scheme is under development in Bradford for young adults living in deprived areas within the UK Prevention Research Partnership-funded ActEarly City Collaboratory (Wright et al. 2019). In both cases, pilot schemes are being considered for 18- to 20-year-olds with the inclusion of life-skills support. Both planned interventions follow previous precedent, such as the Educational Maintenance Allowance (EMA), in being directly aimed at a transitory period with specific intended impacts, particularly with regard to mental health.

The parameters for the larger trial are less clear. Our model of impact indicates that pathways to health impact from cash transfers depend upon perception of material security and predictability that is unlikely to emerge during short trials. However, we also note that a large intervention in the UK is likely only to be feasible within a period equal to a parliamentary electoral cycle, leaving, at most, three years for the intervention and evaluation (Johnson 2021a, 6). This is because, even if funding were somehow provided privately, government departments, such as the Department for Work and Pensions, would be required to provide approval for payments with tax implications.

If negotiations can be undertaken with prospective governments ahead of elections, so finalised design and contracting could take place immediately following an election, it may then be possible to implement the cash-transfer intervention for the full three years, with principal data collection of health measures completed by the end of the second year. This would avoid measuring effects close to the 'cliff-edge' return to pre-intervention levels of income and conditionality among those in adulthood, though school leavers, for example, do not return to their pre-intervention condition because they would no longer be children. Such duration would still not permit observation of longer-term social changes and the cascading impacts of, for example, participants returning to education. However, evidence from other projects, such as the negative income tax experiments of the 1970s (Gibson, Hearty & Craig 2020, e169) suggests that a 3-year study could provide indications of changes in health behaviours (e.g., Costello et al. 2010) as well as self-reported and physiological measures that can be used in microsimulation to estimate long-term health outcomes anticipated by the model of impact (Gibson, Hearty & Craig 2020); Romero et al. 2021).

Discussion

Our work on the resource has highlighted the large number of measures employed to identify health impacts, the issues in their deployment to evaluate cash transfer trials and, perhaps most importantly, the need for standardisation of measures and new approaches to licencing. A key justification for the kinds of licenced measures that are currently relatively common in health studies is that ownership by organisations and paid licences facilitate the kind of resource-intensive validation, refinement and monitoring of impact that is necessary to ensure they remain relevant to the modern world. One body that licences materials, EuroQol, has invested effort in updating and maintaining its EQ-5D instruments, producing a revised version of the EQ-5D-3L (Rabin & de Charro 2001), the EQ-5D-5L in 2011 (Herdman et al. 2011), and a child version, the EQ-5D-Y, in 2010 (Wille et al. 2010). This has been done while imposing no cost and one condition: that would-be users agree to collaborate with EuroQol researchers in large, > 100,000 participant, studies (EuroQol Research Foundation 2021, 6). Unfortunately, EQ-5D has been used neither in key studies of cash transfers nor major UK epidemiological datasets. Some copyright holders request payment for measures that have not been updated in decades or impose processes that render measures impractical to apply in all studies. For example, regarding GHQ-12, request for translation is subject to approval from the copyright holders, GL Assessment, which, if given, enables the would-be user to request translations separately from the MAPI Research Trust. The lack of public clarity on costs of licences is a significant obstacle to research. While CIS-R has no licencing conditions, use of the online DAWBA assessment tool appears to be charged at £10 per assessment (Youthinmind 2019a) and it is unclear whether licencing conditions allow for administration of an independent online system.

To enable transformative research and data comparability between intervention evaluations and large cohort studies, it would be of substantial benefit for common measures, particularly those used for national statistics, to be brought into the public domain, either through purchase by institutions dedicated to Open Access or through creation and wholesale adoption of Open Access alternatives. Given the diversity of measures presently deployed in large datasets, there is also genuine need for data collected in calibration studies to be used to produce a tool that enables simple comparison between data collected via key measures, such as EQ-5D, SF-12, CIS-R, GHQ-12, Kessler 6. This would be of substantial benefit both in prospective modelling of health outcomes from cash transfers and in assessment of the relationship between income and health more broadly.

We aim for this work to form the foundation for two cash transfer studies currently under discussion, including the Welsh Government scheme for Care Leavers, with piloting and co-production essential to the design of the final protocols. Our hope, though, is that the resource will be used by other researchers and funders as the starting point for their own studies. It is only through this consistent and ongoing work that we will create data capable of assessing the health impact of cash transfer schemes and other socioeconomic interventions.

Conclusion

The design of a generic, adaptive protocol resource for future use in cash transfer trials is necessarily broad as studies will vary substantively depending on aims and resources. We have sought to put together a measures bank that will provide a much greater degree of comparability between data sources and a structure that facilitates use in microsimulation modelling.

The resource is intended as an initial step toward a fully validated system that assists in the design of trials by researchers from a range of disciplines. It presents initial responses to a number of issues we have identified in the existing literature. These responses can only be examined further in co-production with representative participants and through implementation of trials themselves.

It is essential that specialists within the academic community work with members of the public to create protocols that produce widely accessible comparable data. Much greater collaboration, including through public funding of Open Access measures and integration of measures, is required to secure this outcome.

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

EJ conducted background research, integrated measures, produced initial draft. MJ supervised, provided feedback and conducted revisions. CK provided feedback and contributed to reframing. AV provided feedback. KP supervised, framed development of the resource and article, conducted revisions and provided feedback. All authors read and approved the final manuscript.

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Figures

Figure 1

Welfare model of impact (adapted from Johnson et al. 2021 a)

Figure 2

Adaptable study design for pilot intervention for young adults

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