Randomised Controlled Trials in the Social Sciences
Twelfth Annual Conference

Department of Health
Department for Work & Pensions
NHS England

Designing a cross-departmental social policy RCT in a locally driven healthcare setting

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Introduction

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- A little about me
- And the Work and Health Unit
- The rest of this presentation

The case for action

Evidence shows that appropriate work is good for our health

Good work → Good health

Worklessness → Poor health

Disability-free life expectancy at birth also varies across England

	Male	Female
	72 years	72 years
	55 years	53 years

Access to timely treatment varies across areas

Average waiting times for mental health treatment can differ as much as 12 weeks across England and some evidence suggests treatment for musculoskeletal conditions can differ as much as 23 weeks.

Ill-health among working age people costs the economy

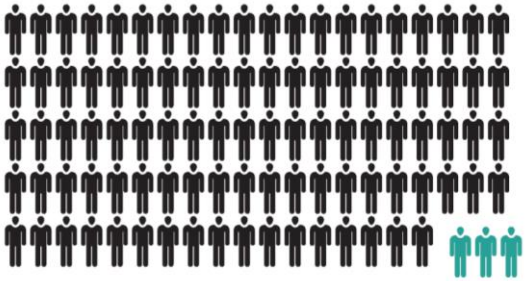
£100 billion and sickness absence costs employers £9bn a year.

Reducing long term sickness absence is a priority

1.8 million employees on average have a long-term sickness absence of four weeks or more in a year

8% of employers report they have recruited a person with a disability or long term health condition over a year.

Only around 3 in 100 of all Employment and Support Allowance claimants leave the benefit each month.

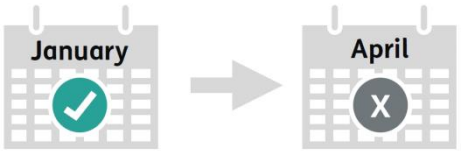


Disability has been rising

over **400,000** increase in the number of working age disabled people in the UK since 2013 **taking the total to more than 7m**

Compared to non-disabled people, disabled people are less likely to enter employment so preventing them from leaving work is important

Between two quarters as many as 150,000 disabled people leave employment.



The health-led trials

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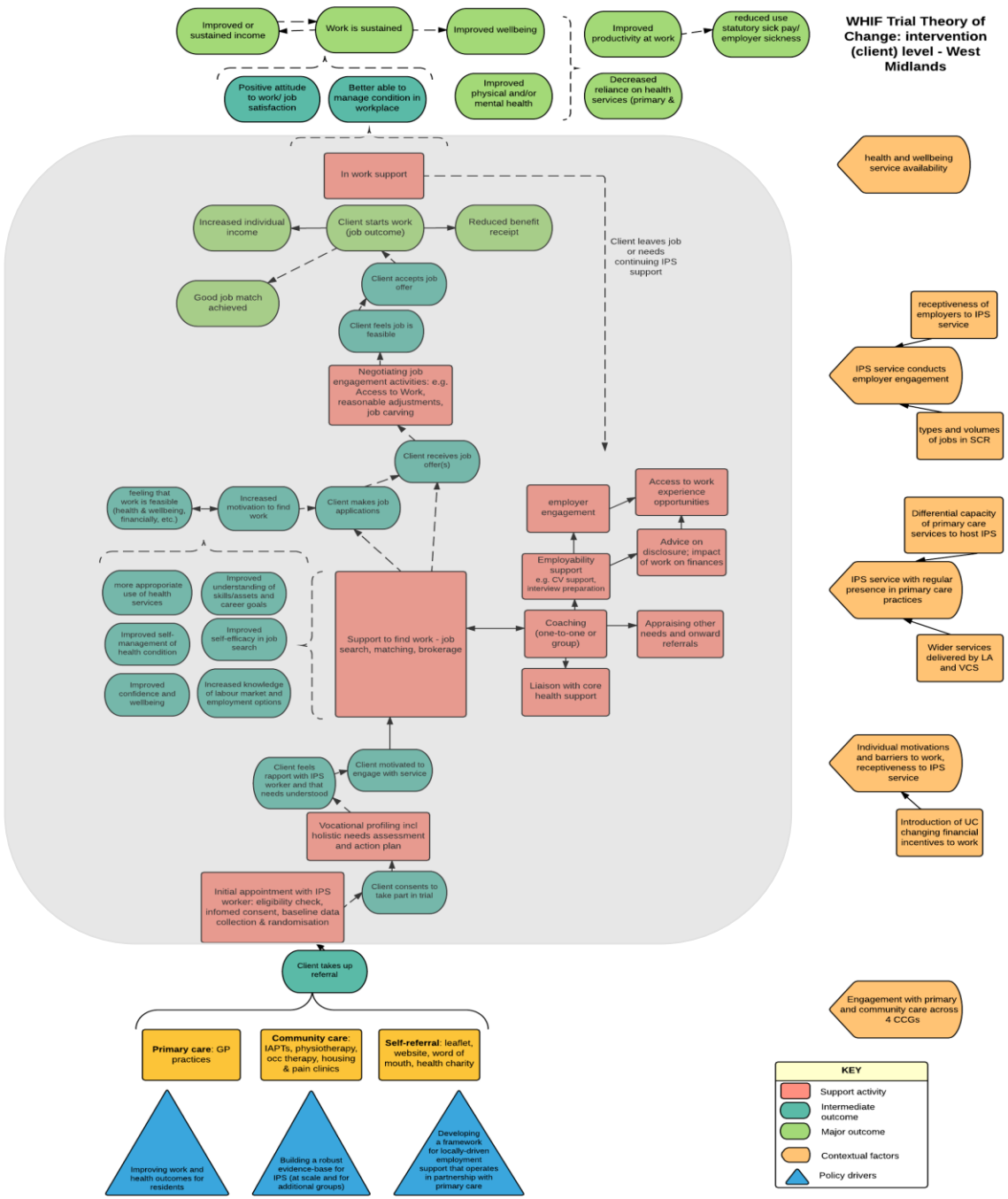
- The health-led trials contribute to addressing that challenge by being one of the ways in which we are trying to establish what effective policy solutions might look like in this space

- The trials are taking the concept of Individual Placement and Support (IPS) and testing it with new groups of people and different health conditions

- The trials will run between this autumn and 2020

- They are a joint endeavour between: DWP, DH and NHS-E and two large local sites: the West Midlands Combined Authority and Sheffield City Region



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Our logic model:

it's complicated,

but not necessarily complex?

But there's lots inside the black box

Our approach to evaluation

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To get the maximum learning from the trials they will be robustly evaluated using a mixed methods approach to ensure that we have high quality evidence to inform future decision making.

We expect the trials to include:

- A quantitative assessment of impact.
- A process evaluation
- A cost-benefit analysis
- Consistent health and employment outcome metrics across all the trials

We are currently in the design phase and the remainder of the presentation focuses on the work we have done to date to prepare for live running and reflecting on how that has gone

The building blocks in place

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Early evaluation design	Modelling of ROI	Site selection	Site protocol design
Evaluation contractor recruitment	Senior clearance and release of funding	Theories of change	Contamination and outcome measures
Site service delivery design	Local stakeholder engagement	Data and IG development	HRA application

What have been the key areas of activity? Analytical team

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- Advising on initial design – methods, size, research questions
- Assessing plans against methodological viability and deliverability
- Developing an economic model of likely outcomes to understand financial risk ranges
- Developing initial views on expectations
- Procuring evaluation contractor and developing series of work packages
- Working closely with evaluator and quality assuring all products
- Briefing to senior staff on progress and quality
- Arranging external evaluation specialist critique of progress
- Providing advice on all aspects of evaluation work across methods proposed
- Coordinating work on contamination risks
- Coordinating comments on various documentation
- Project managing contractor and all related finance/invoicing

What have been the key areas of activity? Evaluation contractor

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- Coordinating activities of consortium partners
- Developing detailed evaluation methodology for impact, process and economic evaluations
- Developing theories of change for each site
- Conducting supporting literature review
- Providing technical advice on contamination to support policy and local site work
- Exploring randomisation tool options and procurement
- Advising on power calculations
- Leading on developing trial documentation, eg research protocol, outcome measures, research instruments and consent documentation
- Leading on drafting the IRAS application, responding to (multiple) rounds of comments from range of stakeholder, finalising and uploading application
- Developing implementation documentation to ensure consistent service delivery
- Advising on how to collect informed consent and baseline data

What have been the key areas of activity? Local sites

- Setting up a local delivery coordination team
- Putting the right local leadership in place
- Relationship building with delivery partners, such as local CCGs, service providers and public health and local council colleagues, JCP
- Developing detailed trial design protocols
- Developing detailed local delivery and service plans for effective delivery within primary and community healthcare setting
- Developing effective local solutions to support trial work
- Working through data requirements with local NHS partners
- Running various engagement activity, for example identifying GP champions
- Procuring service delivery partners

What have been the key areas of activity? Policy team (1)

- Leading on relationship management with sites
- Developing shared narrative and senior commitment across organisations as to the purpose of the trials
- Leading on planning work, including delivery timing and assessment of progress
- Working with sites to develop delivery costs
- Providing assurance on costs, gaining senior sign off arranging transfer of funding
- Working across organisations on issues of contamination with other local or national trialling activity
- Working with sites on all aspects of design development, engagement and stakeholder management
- Liaising with HRA REC panel secretariat
- Acting as the link point between local sites, national evaluator and analytical team and brokering solutions on points of difference
- Quality assuring all materials from a policy perspective
- Briefing relevant senior staff on progress and expected delivery

What have been the key areas of activity? Policy team (2 - data)

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- Leading on data and information governance
- Developing relationships with HMRC, NHS-D and DWP security and data sharing colleagues
- Working closely with data colleagues in local sites to join up local and national processes
- Agreeing scope and use of their data from possible sources
- Agreeing data storage and linking solutions and appropriate levels of data protection, eg ISO27001
- Leading on advice regarding new data protection legislation from next year
- Leading on the agreement of informed consent wording for purposes of data sharing and linking
- Agreeing consent wording with relevant organisations and lawyers
- Developing detailed data flows map of how all unanonymised, pseudonymised and anonymised will move round the system, to whom, when and how

Illustrating data and information governance

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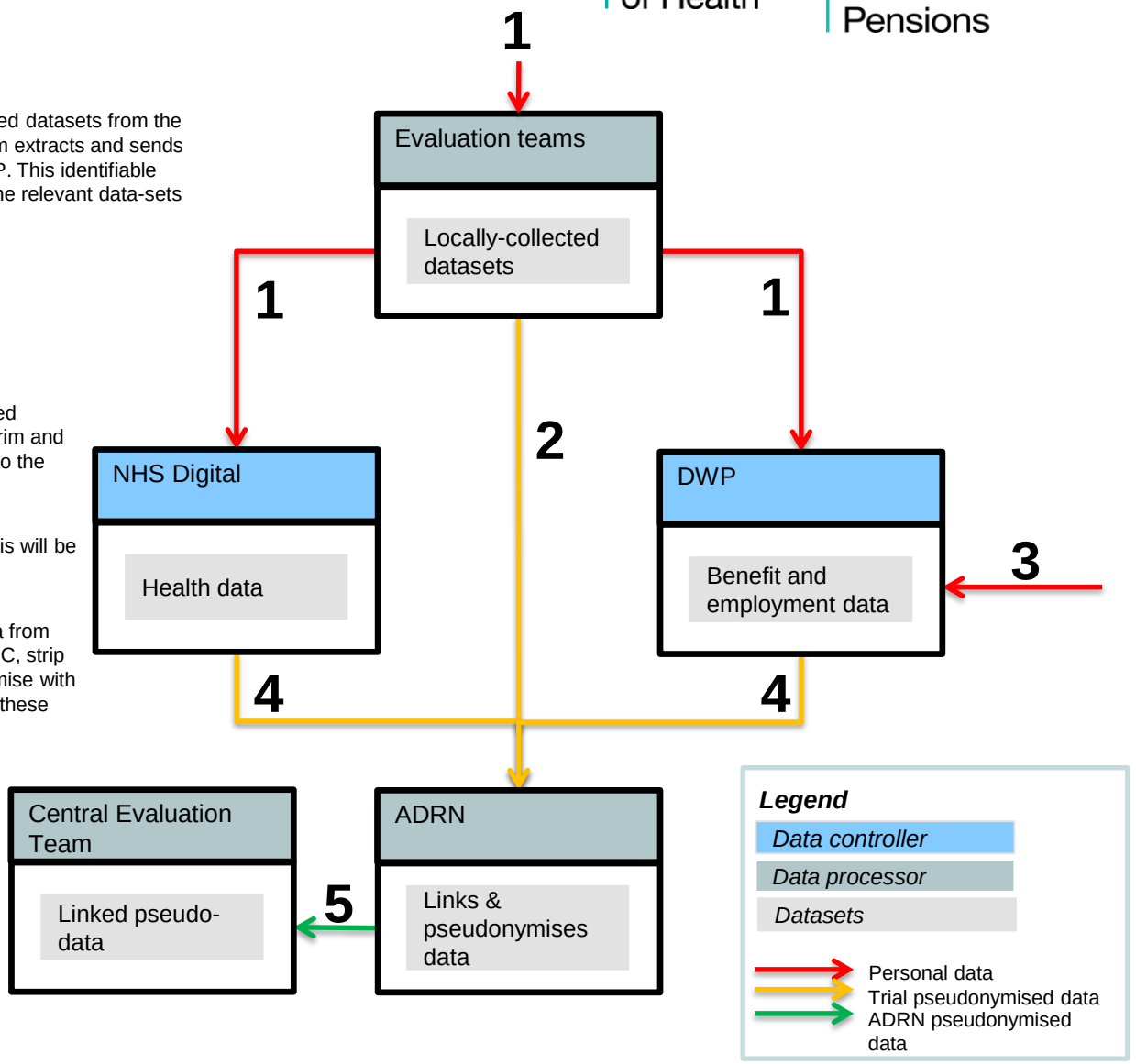
1. After receiving and validating the locally-collected datasets from the service provider, the evaluation monitoring team extracts and sends identifiable information to NHS Digital and DWP. This identifiable information is so they can identify and extract the relevant data-sets needed for evaluation:
   - First name and surname
   - Data of birth
   - Address and postcode
   - Trial identification number
   - NHS number (to NHS Digital only)
   - NINO (to DWP only)

2. The evaluation teams also send pseudonymised versions of: the locally-collected trial data; interim and final survey results; and qualitative interviews to the ADRN for linking (as per previous slide).

3. HMRC sends identifiable RTi data to DWP. This will be sent via secure transfer.

4. NHS Digital and DWP extract the relevant data from their systems and the data received from HMRC, strip out any identifiable information and pseudonymise with the trial identification number. They then send these pseudonymised datasets to the ADRN.

5. The ADRN use the trial identification number to link the pseudonymised datasets. Once linked, the ADRN generate a Pseudo ID and use it to replace the trial identification number. The ADRN then sends this pseudonymised linked data-set to the evaluation team for analysis.



Some of the challenges we faced

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The previous slides illustrate a whole range of work needed. But to pull out a few key points where we faced particular challenges…

- Complexity of trial designs in a changing local landscape and across national organisations
- Competing priorities and interpretations of what is to be tested
- Sample sizes – keeping them high enough
- Data availability and approval
- Ethical challenges, including consent
- Contamination
- Agreeing outcome measures
- Pace of delivery

Reflecting on what has worked well – lessons learned

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Any trial of this size and complexity will face challenges but there have been some important lessons learned that have wider applicability to running trials

- Being helpful when you're not driving!
- Getting genuine co-production of the evaluation design between policy colleagues, analysts and the evaluation contractor
- Having the right organisational expertise
- Having a clear articulation of the strategic purpose of the trial, even if the detail changes
- Investing in a proper logic model that sets out what the trial is hoping to achieve – both for consistency of approach and to agree a single narrative
- Having a clear understanding of what is methodologically allowable and what is a compromise too far and being able to back it up in decision making
- Being ambitious with the sample size to have sufficient power, allow for sub-group analysis and protect against low numbers or lower than expected intervention effectiveness
- Getting local and national leadership and commitment in place to drive progress
- Taking decisions on the basis of risk and trying to control the remit of who decides what
- Getting dedicated resource on for data and IG and for the IRAS form
- Getting external challenge
- Allowing time for design
- Getting an evaluation contractor on board early
- Ensuring that from the start evaluation, policy and delivery teams have worked in an integrated team

Concluding remarks

- So much of preparing a trial of this size and complexity is about joint working and good leadership, communications and coordination
- As such the skills of the evaluator, whether in government or provider, are about so much more that just technical evaluation methods
- What is clear though as an evaluator is that you need to understand methodological implications of choice and risk as you step through the various activities needed to design, deliver and evaluate your service
- It is clear to me that the commissioner / evaluator dichotomy is a false one, at least in this type of large scale multi-agency trial
- Each has their perspective to bring, but without both, and the support of local delivery colleagues, the evaluation just wouldn't happen

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Questions?

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