Assembling the Data Jigsaw

Powering robust population research in MSK disease

Patient and Public Involvement and Engagement strategy

Centre for Epidemiology Versus Arthritis

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Salford Royal NHS
NHS Foundation Trust

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Contents

Purpose

This document sets out the approach for patient and public involvement and engagement in Assembling the Data Jigsaw (*Jigsaw)*, demonstrating the importance of PPI to the research programme. The strategy has been led by Joyce Fox Patient and Public Involvement and Engagement (PPIE) lead and co-developed with input from our core patient/public advisory group (CPAG) members (Lynn Laidlaw and Jane Taylor) and members of the research team (Will Dixon, Louise Cook, Caroline Sanders). The document is intended to provide an overview for research staff, public contributors (see also additional role description document), external partners, expert advisors, funders and other interested parties.

Background

Arthritis and musculoskeletal (MSK) conditions (from here on referred to as MSK conditions) are a leading cause of disability with significant impact on quality of life. However, lots of gaps remain in our understanding of MSK disease. For example, exactly how common it is, how it progresses, what treatments are optimal in terms of comparative effectiveness and safety, and who needs which services and when.

Research using routinely collected health data can answer such questions, as long as the right data is accessible for a given research question. But in MSK disease, progress is often hampered by lack of availability of the right data. This can be for three key reasons.

1. Despite all the necessary data items being in existence, these data items are not yet available altogether in the same dataset (siloed).
2. Data is not formatted in a way that makes them suitable for research (unstructured). And
3. The data items do not yet exist within the health and social care system (absent).

Examples of siloed, unstructured or absent data are commonplace in MSK conditions. There is, surprisingly, no national system for recording diagnoses in hospital outpatient clinics, nor a standard way of tracking disease severity and therefore long-term disease outcome. Outpatient letters sometimes include this information, but typically it is hidden in a jumble of words making it difficult to analyse. Other pieces of the “data puzzle” exist, such as social care use (a common need in patients with arthritis), but social care data is rarely linked to health data and is inaccessible for research. This means, for example, that we have no knowledge of social care service use in patients with arthritis.

The aim is to “assemble the data jigsaw” in Salford (Greater Manchester), bringing together pre-existing and new health care data to answer questions about arthritis that are important to patients and health care professionals.

Vision

Our vision is that people affected by arthritis, particularly people in Salford and in seldom-heard communities[1], and rheumatology patients at Salford Royal NHS Foundation Trust, are active partners in shaping Jigsaw research to address patients’ priorities in ways that build and sustain public trust.

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[1] Here we acknowledge that ‘seldom heard communities’ are multiple and varied. Our early planning work will scope and map out key communities to engage with, based on an understanding of the population characteristics within Salford (see appendix 3). We will seek to actively include people who have been under-

Definitions

Here we highlight some of the common terms we refer to in this document.

The word arthritis is used to describe pain, swelling and/or stiffness in a joint or joints. Arthritis isn't a single condition and there are several different types, such as rheumatoid arthritis and osteoarthritis. Musculoskeletal (MSK) disease/ condition is a broader term used to describe arthritis and other conditions affecting the muscles and joints, such as fibromyalgia.

When we refer to ''public' or 'patients and the public' this includes: patients, service users, survivors, carers, family members and other members of the public affected by musculoskeletal (MSK) disease.

Patient and public involvement (PPI): We use the INVOLVE definition of doing research 'with' or 'by' people who use services rather than 'to', 'about' or 'for' them. Those involved in PPI are referred to as public contributors (PC), including members of the Core Patient/Public Advisory Group (CPAG).

Public engagement: We use the National Co-ordinating Centre for Public Engagement (NCCPE) definition of engagement as a two-way process, involving interaction and listening, with the goal of generating mutual benefit.

Co-production is defined by Redman et al. (2021) as a collaborative model of research that includes stakeholders such as patients, the public, clinicians, service providers, and policy makers. It is based on shared values and principles, and where sharing of power is key. It is an approach where stakeholders and researchers work together in equal partnership for equal benefit to develop the agenda, design and implement the research, and interpret, disseminate, and implement the findings.

Primary research refers to the collection of original information (data) to answer questions that haven't been answered before. When doing primary research, the researcher gathers information first-hand rather than relying on available information in databases and other publications. In *Jigsaw,* primary data will be collected from patients and health care professionals using interviews and focus groups (qualitative research), as well as collecting data in more structured formats using surveys and questionnaires (quantitative research).

Secondary research uses data that has already been collected, for example within electronic health records, and can take the form of reviewing existing research.

Big data research is a form of secondary research that uses large sets of existing data. In the Jigsaw programme we focus on joining together existing health and care datasets and linking to information produced by our primary research. The methods used to access, link, store and analyse complex datasets is known as 'big data research'.

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represented in previous research and related PPIE but where there will likely be common experiences of MSK disease.

The programme

There are three main work streams:

Assembling the Data Jigsaw

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Work Stream 1 **Clinical Research Questions**	**Work Stream 2** **Data collection, access and processing**	**Work Stream 3** **Public trust and scalability**
• Burden of disease • Multimorbidity • As-yet undiagnosed RA & AS • Effectiveness and safety of analgesics (opioids; OTC)	• Text-mining outpatient letters • Collecting structured EHR data • Collecting data from patients • Linkage to social media data • Piloting linked social care data	• Two-way communication to support public trust in data use • Stakeholder engagement for best design and knowledge mobilization • Evaluating impact

Across *Jigsaw's three workstreams and the nine work packages (Appendix ?2)* each work package has a distinct focus; however there are many links across work packages and some work packages have a key role in underpinning the work of others; these have resulted in *Jigsaw* research being carried out by collaborations across work packages and work streams.

PPI themes

PPI in *Jigsaw* is focused on working with these collaborations, rather than each individual work package, to ensure that PPI can inform the research in a holistic way. This has resulted in three PPI themes, and each falling within one of the three main workstreams. Activities will be specified and regularly reviewed by the research lead working together with the PPIE CPAG lead member for this PPI theme. The three themes are as follows:

1. **Predictive algorithm**

   To develop and pilot an algorithm for the early detection of patients with Axial Spondyloarthritis (AxSpA), and possibly Rheumatoid Arthritis (WP1.2), and to explore options for future deployment of the algorithm.

   Initial activities may include:

   - Sharing lived experience of diagnosis to help inform the development of the algorithm
   - Sense-checking outputs.

   PPI regarding public trust and wider views on the use of predictive algorithms to inform diagnosis will be developed in conjunction with WP3.1 and is shown under PPI theme 3 – Public Trust topic 'e' (See, below).

   See PPI plan for more details

2. **Patient-generated health data (PGHD)**

To understand the acceptability, feasibility and benefit of collecting data from patients (that is not recorded elsewhere in the healthcare system) (WP2.3) to gain insight into:

a. Impact on rheumatic diseases (RMDs) (WP1.1)
b. Over-the-counter pain medication use (WP1.3)
c. Care consumption beyond clinical services, specifically social care services (WP2.4)

Initial activities may include:

- Informing the development and refinement of a set of data items to be collected, including frequency.
- Co-designing guidance and materials to support patients with PGHD collection.
- Assisting in writing Participant Information Sheet, consent forms and other patient-facing material.
- Contribute to the development/ review of protocols and ethics submissions; attend Ethics Committee meetings.
- Help interpret the results.
- Developing materials to help share findings; present findings and aid the distribution of results to public and professional audiences.

PPI regarding public trust and wider views on PGHD will be developed in conjunction with WP3.1 and is shown under PPI theme 3 – Public Trust topic 'd' (see below).

See PPI plan for more detail.

3. **Public trust in the use and linking of healthcare data for research.**

This area of PPI will look at what is needed to develop and sustain the trust of the public in the use of their health and care data for research, specifically in relation to the *Jigsaw* research programme, including:

a. Linking data from different sources (GP records, hospital in- and out-patient records, social care records) (WP1.1, WP1.3, WP2.1, WP2.2, WP2.3, WP2.4)
b. Text mining of hospital outpatient letters (WP2.1)
c. Linking social care data and specific sensitivities (WP2.4)
d. PGHD (WP2.3, WP1.1, WP1.3, WP2.2, WP2.4)
e. Use of a predictive algorithm in primary care to inform the early diagnosis of AxSpa and RA (WP1.2)

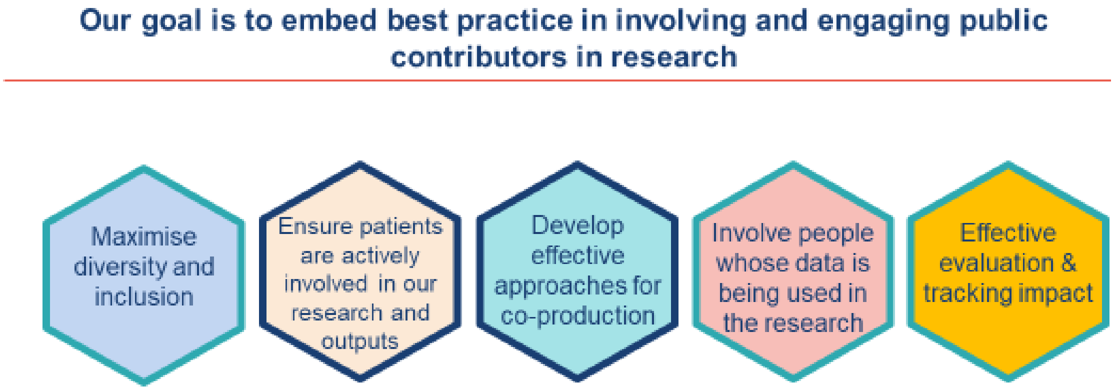
Specifically by:

- Recruiting a patient/public involvement group (PPI Group) to co-develop the research in WP3.1 and ensure ongoing input from a diverse group of individuals and communities.
- The PPI group will:
  - Help review and appraise existing literature and resources relevant to public trust in data sharing.
  - Contribute to the development/review of protocols and ethics submissions; attend Ethics Committee meetings.

- Contribute to the development of the communication plan.
- Co-design supporting materials for focus groups and individual interviews (see WP3.1 document for details of methods).
- Co-facilitate focus groups.
- Co-produce analysis and outputs from qualitative research.
- Work with design partner to co-design a public-facing website and other materials for *Jigsaw* to support public trust and sustainability.
- Co-design methods to evaluate the functioning, usefulness and impact of the website and materials.
- Co-develop materials to help share findings; present findings and aid in the distribution of findings and outputs to public and professional audiences.
- Co-design evaluation methods for involvement and engagement in WP3.1.

See PPI Plan, Terms of Reference for PPI Group, and WP3.1 document for more detail.

Each theme area will have a pre-agreed budget. The academic lead and CPAG lead for each area will work together to plan and define detailed activities within the constraints of the agreed budget.



Approach to PPI

We have used the UK Standards for Public Involvement to guide the development of our PPI Strategy and PPI activities within *Jigsaw.*

UK Standards for public involvement	What the standard means in Jigsaw	How we will meet the standard in Jigsaw:
1. Inclusive opportunities	We offer public involvement opportunities that are accessible and that reach diverse people, communities and groups particularly within Salford (especially those who are seldom heard) who have lived experience of arthritis. Research will be informed by a diversity of public experience and insight so that the research leads to outcomes which address patient/public priorities	• We will develop clear role descriptions (Terms of Reference) for all PPI opportunities. The role description will be sent to people who express an interest in the role. After recruitment, the role description will be reviewed with PPI group members and any agreed amendments made. • We will establish a contact list of relevant voluntary sector organisations and community groups and networks within Salford and establish relationships (e.g. via meetings, presentations and online discussions) to support inclusive opportunities accessible to a diverse range of people (see appendix 3) • We will use plain language and co-produced information to advertise involvement and engagement opportunities, and will advertise widely via established networks (e.g. the GM PCIE forum) • We will ensure accessibility, choice, flexibility and support for people to take part in in involvement and engagement activities and events. For example, people may be happy to discuss research by phone but not online. Others may need support and guidance to participate in an online/ video discussion group. • We will aim to work with one of our community organisations to conduct at least one focus group in another language spoken amongst a BAME community group in Salford

		- We will reimburse people for time spent contributing to research (£20 per hour) and a policy on payments will be shared with researchers and public contributors - Researchers in each work stream will formulate a specific PPIE plan to enable and support diverse and inclusive PPIE for each PPI theme with input from a member of the CPAG.
2. Working together	We work together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships. Our strong partnerships ~~and shared power~~ will ensure research is shaped by lived experience, including co-production of methods to collect and use data, and to build and sustain public trust	- We will work with public contributors to define ways of working together. - We will work with CPAG members and public contributors in the PPI themes to specify clear roles and terms of reference. - We will work with public contributors to identify opportunities to give and receive feedback to support learning together. Together, we will agree what feedback is wanted, and why and how the information gained will be used. - We will listen to ideas and contributions made by public contributors and via wider engagement activities, ensuring these are documented and reflected upon in terms of how these influence subsequent plans and research. - We will acknowledge the key role patient data has had in our research by including a data citation, developed and tested by patients at "Understanding Patient Data", in all publications and stories to acknowledge our research would not have been possible without access to patient data.
3. Support and learning	We will offer and promote support and learning opportunities that builds confidence and skills for public involvement in research We will seek to remove practical and social barriers that stop members of the public and research professionals from making the most of public involvement in research.	- We will support public contributors and staff to identify support and training needs, and agree ways to meet these needs, to enable successful PPIE; - We will provide an introduction session to Jigsaw and public involvement for all public contributors. - We will signpost training courses and resources available for public contributors and staff via University of Manchester (FBMH Social Responsibility team), including the NIHR infrastructure (e.g. NSPCR, ARC-GM, BRC, PSTRC, CRN) - We will collect and share resources with staff (via Jigsaw shared folder) to support best practice for PPIE that are available via national

		organisations (e.g. INVOLVE and now the NIHR Centre for Engagement and Dissemination), including those focused on data science, e.g. HDRUK.
4. Governance	We will involve the public in research management, regulation, leadership and decision-making (Appendix ?1). Public involvement in research governance will be crucial in Jigsaw to ensure: • they are part of decision making • research using health data is transparent and will build and sustain public trust.	• Our PPIE lead (Joyce Fox), a public contributor, will provide overall leadership for PPIE, including leading CPAG, and will be a member of the Local Management Team attending regular LMT meetings. • PPI is a standing agenda item at LMT meetings. • The CPAG will have a key role in the oversight and governance of *Jigsaw* PPI. A CPAG member will provide leadership for each of the three PPI themes. PPIE plans for each theme will be created, and reviewed via regular progress reports (internal and to the funder) by researchers, member of CPAG, and public contributors, to ensure aims are met. • Joyce Fox and members of the CPAG will provide inputs to periodic reports to the funder to report on progress with PPIE relevant to each PPI theme. • Public contributors will provide review and comment on plans developed for ethical approval applications. Public contributors will attend the Spilsbury (implementation) Advisory Group, and our external Jigsaw Advisory Group.
5. Communications	We will use plain language for well-timed and relevant communications, as part of involvement plans and activities. We will be inclusive and flexible in our communication methods to meet the needs of different people.	• We will maintain regular communication with our public contributors, agreeing together the methods, content and frequency to be used. • We will work with our CPAG and three PPI themes to co-produce content to support the communications plan, including our external engagement with wider communities.
6. Impact	We will identify and share information about the difference that public involvement makes to our research. This will enable us to understand the changes,	• We will involve public contributors in agreeing the intended outcomes of public involvement, in deciding what the assessment of impact should focus on, and the approach to take. • We will document all PPI activities and outcomes of activities. • We will consider multiple approaches for evaluation depending on activity, including

	benefits and learning gained from PPIE and will be crucial for building and sustaining public trust in data sharing with implications beyond this programme	written evaluation forms for wider engagement activities, verbal discussion and feedback (e.g. for our core CPAG), and online surveys. • We will include a patient and public involvement statement in the methods section of research papers. We will acknowledge public contributors in the contributorship statement, and seek their permission to name and thank them, clearly identifying them as public contributors (BMJ, 2018) • We will document any new contacts, activities and influences emerging from ongoing PPIE throughout the programme. • Theme PPI documents will be used to devise appropriate ways to evaluate ongoing work and to record response to feedback and impacts of work. • We will keep an overall tracking document to record feedback from evaluation and actions to respond – work package PPI documents will be used to regularly review and populate the overall tracker enabling a record for the programme as a whole

Roles and responsibilities

PPI Lead

1. Provide overall leadership and direction for PPIE strategy and activity.
2. Take part in decision-making as part of the Local Management Team (LMT).
3. Decide on budget allocations with programme manager.

Programme Manager

1. Allocate and monitor budget.
2. Ensure alignment of PPIE activities with the programme and communications plans.
3. Support PPIE lead and the production of strategy and related documents.

Research Project Administrator:

1. Keep records of PPI activity.
2. Maintain spend vs budget spreadsheet.
3. Support the organisation/ co-ordination of PPIE activities (eg send relevant information to new contributors, set up meetings, oversee expense claims etc).

Researchers (PDRA and WP lead)

1. Working with the PPIE Lead and CPAG members, develop a PPI plan for the PPI theme, using template.
2. Co-ordinate and deliver meaningful PPIE activities.
3. Provide support for public contributors and maintain regular communication. .
4. Report on PPI activity and impact.
5. Work with CPAG members and PPIE Lead to review and revise plans to ensure successful involvement and engagement.

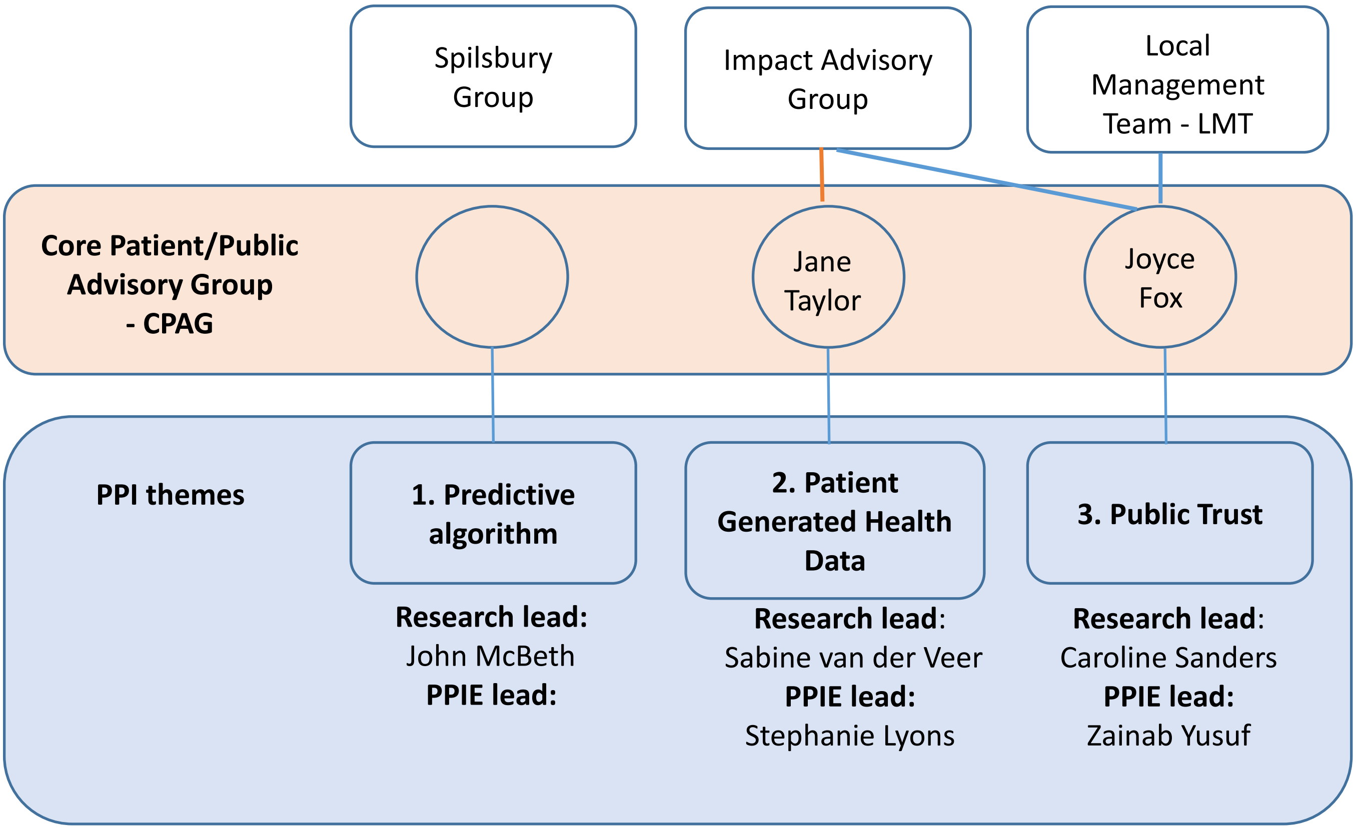
Core Patient Advisory Group

Work with the PPIE Lead and researchers to help develop, support, review and evaluate PPI and engagement plans and activities for the Jigsaw programme and PPI theme.

Public contributors for specific themes across work packages

Roles for public contributors will be different according to which PPI theme they will be working with. A role description for the involvement of public contributors in each of the areas, such as patient-generated health data, will be co-produced between researchers and CPAG.

Appendix 1 Assembling the Data Jigsaw PPI Governance



The Core Patient/Public Advisory Group (CPAG) will have a key role in overseeing and supporting PPI in the programme and ensuring good governance. They will meet regularly to review progress and discuss future plans. Each member of the CPAG will work with a specific PPI theme/research collaboration area to support the development of PPI activities and provide a link between PPI activity in the research and programme level PPI governance.

The PPIE Lead for Jigsaw, Joyce Fox, leads CPAG and is a member of the Local Management Team for the *Jigsaw* research programme.

Jane Taylor and Joyce Fox both attend the Spilsbury Group (local implementation group) and the Impact Advisory Group to ensure clear links between PPI internal to the programme and key stakeholders from the external environment in which the programme is operating.

Appendix 2. Assembling the Data Jigsaw Work Streams and Work Packages

Work Stream 1: Understanding the prevalence and burden of MSK disease.

- 1.1 Understanding the incidence, prevalence and burden of MSK disease
- 1.2 Predictive algorithm
- 1.3 Safety and effectiveness of analgesics

Work Stream 2: Data collection, access and processing.

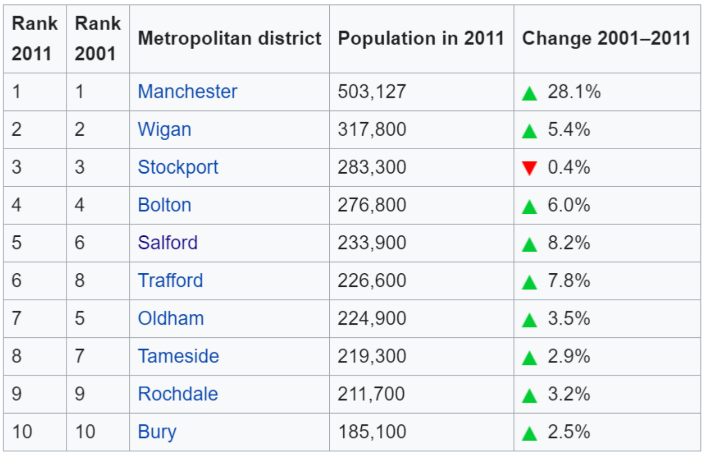
- 2.1 Text mining data
- 2.2 Prospectively collecting structured, research-quality data by clinicians
- 2.3 Patient Generated Health Data
- 2.4 Piloting access and analysis of linked social care data

Work Stream 3: Effective delivery and implementation.

- 3.1 Public Trust
- 3.2 Sustainability and scalability, knowledge mobilisation

Appendix 3. Salford overview

Greater Manchester has 10 metropolitan boroughs: Bolton, Bury, Oldham, Rochdale, Stockport, Tameside, Trafford, Wigan and the cities of Manchester and Salford.



Rank 2011	Rank 2001	Metropolitan district	Population in 2011	Change 2001–2011
1	1	Manchester	503,127	▲ 28.1%
2	2	Wigan	317,800	▲ 5.4%
3	3	Stockport	283,300	▼ 0.4%
4	4	Bolton	276,800	▲ 6.0%
5	6	Salford	233,900	▲ 8.2%
6	8	Trafford	226,600	▲ 7.8%
7	5	Oldham	224,900	▲ 3.5%
8	7	Tameside	219,300	▲ 2.9%
9	9	Rochdale	211,700	▲ 3.2%
10	10	Bury	185,100	▲ 2.5%

Salford is a large metropolitan borough in Greater Manchester, and is one of the most deprived areas in England (PHE, 2017), with a rapidly increasing population:

Different faiths groups and ethnic diversity within Salford are increasing rapidly (Geographies of diversity in Manchester, ?date). From 2001 to 2009, the Salford BAME population increased from 7.4% to 13.5% (ONS mid-year estimates, ?date). Growth drivers for some of the changes include:

- Rapid increase of Orthodox Jewish community: approximately 10,000, 1:30 of all residents, 1:10 of all young people.
- Since 2004 EU enlargement, the arrival of skilled, often well-educated migrant workers from central and Eastern Europe. 2004-2008 there was a 158% increase in NI numbers issued to people in Salford, mainly Polish, Czech and other A8 citizens (Estonia, Hungary, Latvia, Lithuania, Slovakia and Slovenia). (This may have changed as immigration from A8 countries has declined, and numbers of people leaving the UK has increased).
- Increased numbers also from China, Pakistan, India, and Nigeria.
- Salford, along with Manchester and Liverpool, has been one of the region's main gateways for the national programme of asylum seeker dispersal.
  ("Salford Communities", Gemma Pagett, Equalities & Cohesion, Salford City Council, ?date)

Useful summary drawing on the 2019 Index of multiple deprivation for Salford:

https://sccdemocracy.salford.gov.uk/documents/s19853/Intelligence%20Briefing%20-%20Indices%20of%20Deprivation%202019.pdf