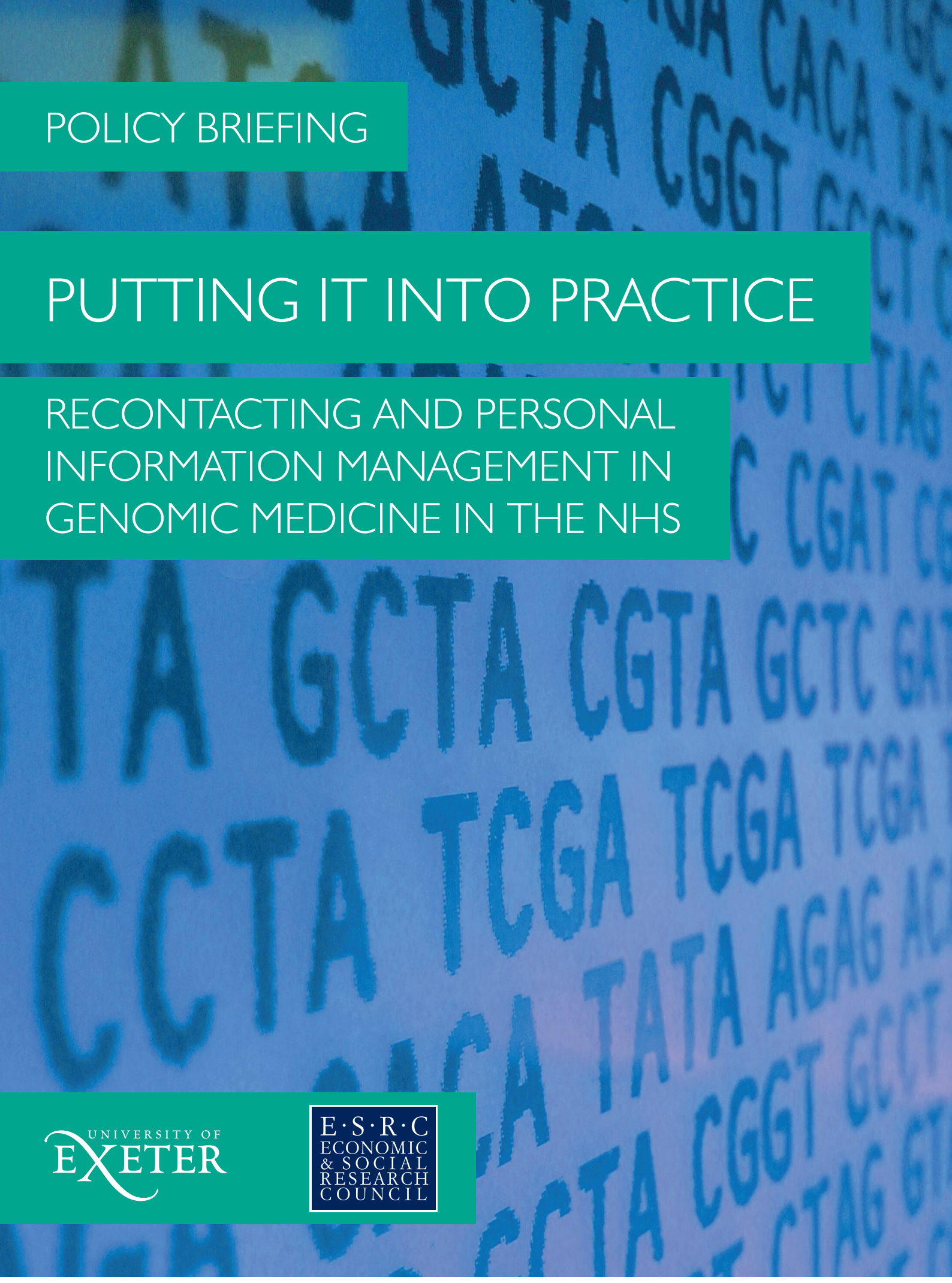

POLICY BRIEFING

PUTTING IT INTO PRACTICE

RECONTACTING AND PERSONAL INFORMATION MANAGEMENT IN GENOMIC MEDICINE IN THE NHS

UNIVERSITY OF EXETER

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

SCuLE Policy Brief No 1

INTRODUCTION AND SUMMARY

In the rapidly evolving world of genomic medicine, understandings of the significance of genomic information change with advances in research. For example, gene mutations may be reclassified from benign to harmful with important implications for risk management for cancer and heritable diseases. This can have significance for the treatment of individual patients, but the process of 'recontacting' them about their treatment is not systematically managed in the NHS or internationally at present. Moreover, recontacting gives rise to important ethical and legal issues associated with the management of genomic information about patients and families. There is growing consensus that questions about recontacting patients will become more pressing as genomics becomes mainstream in clinical practice. Thus there is substantial impact on patient care of recontacting, both nationally and internationally.

WHY IS RECONTACTING IMPORTANT IN THE NHS NOW?

Recontacting is driven by rapid technological change, when new information about a patient or his/her health, or that of a relative, comes to light. Situations which might give rise to recontacting include: re-evaluation of a genetic variant that has been analyzed and interpreted in the past; new information about the patient's condition has come to light; or new treatment guidelines for the patient's condition have been issued.

Recontacting is an emerging and developing feature of contemporary healthcare, and is governed by norms arising in clinical genetics as well as patient expectations. It occurs where the patient is not under the ongoing care of the HCP, and it is distinct from routine follow-up. At present, it occurs on an ad hoc basis, in some places, by some people and in some situations.

However, there is emerging consensus that recontacting should happen in a more systematic way. With technological innovation, recontacting will become more feasible. Moreover, there is a growing ethical consensus that recontacting should happen in certain situations. Finally, there is emerging professional consensus about the ways in which recontacting should happen (see *Existing Guidelines*). It is therefore important that the NHS develop a clear and transparent policy on recontacting. In the context of the reorganisation of genetic/genomic services in the NHS, the development of policy is timely; questions about recontacting are arising in clinical situations, but local practice is still emerging and is amenable to central policymaking.

KEY OBSTACLES TO RECONTACTING POLICY

Although there is emerging consensus about the importance of recontacting in clinical practice, there remain many competing views about whether, when and how recontacting should occur in particular situations. In this respect, recontacting is no different to other areas of genomic ethical, legal and social issues such as feedback of incidental findings, where there remains discussion about the detail of professional duties. Clear, transparent and justifiable policy will help to build consensus.

Key challenges to recontacting in the NHS, which should be considered by policymakers are:

- **Resource constraints:** Like many new developments in clinical care, recontacting will have resource implications. However, while relevant, resource constraints should not be determinative of policy in this respect
- **Technical:** At present, technical systems do not make recontacting straightforward. However, technical obstacles are often amenable to technical solutions, and such solutions can be designed in light of NHS policy, which pays attention to the broader social, ethical and legal framework
- **Professional issues:** Challenges include the need for staff training in relation to recontacting. Secondly, discordant practices and professional cultures in different specialities exist, for example in relation to the prioritisation of recontacting, which may present obstacles to harmonisation of practices on recontacting. Moreover, divergence across geographical regions and across specialities is to be expected.
- **Legal:** There is currently lack of clarity in the legal framework.

EXISTING GUIDELINES

European Society of Human Genetics:

OPEN LINK

Published in October 2018, the Recommendations of the European Society of Human Genetics, drafted by academic researchers and the PPPC, set out 13 recommendations for clinical geneticists and the wider genetics community to consider in their practices around recontacting.

American College of Medical Genetics:

OPEN LINK

In December 2018, the American College of Medical Genetics published Patient re-contact after revision of genomic test results: points to consider—a statement of the American College of Medical Genetics and Genomics (ACMG). The document sets out 8 points to consider, and is designed primarily as an educational resource for medical geneticists and other clinicians.

American Society of Human Genetics:

OPEN LINK

The American Society of Human Genetics (ASHG) published their position statement in April 2019. These recommendations focus on the responsibilities of researchers to inform participants of reinterpreted results.

RECOMMENDATIONS – UK POLICYMAKING

It is essential that the NHS develop policy for recontacting in clinical genetics. Such policy may be a standalone policy focused on recontacting, or it may be part of a policy addressing a broader set of ethical, legal and social questions.

Recontacting policy should be developed in consultation with key stakeholders. We consider that this group should include:

- Laboratory managers
- Clinical genetics professionals
- Genetic counsellors
- Representatives of specialities involved in recontacting outside clinical genetics, including for example cardiology and cancer
- NHS commissioners
- Representatives of the Department of Health
- Patients.

It is important that patients are included in the development of recontacting policy. Moreover, different types of patients should be consulted, as their views may be different depending on the nature of their contact with the health service. For example, rare disease patients may have different views to oncology patients or those with contact with other specialities, and policies may need to be sufficiently flexible to accommodate these differences. As the role that the patient plays in taking a shared responsibility with healthcare professionals for their own health increases, the involvement of patients in setting policy is key.

Policies need to evolve in response to changing technology, practice, guidelines and patient expectations. For example, as the genomic medicine service becomes embedded into mainstream clinical care, there will be various different professionals involved at different stages and they will all have different professional ethical obligations and NHS policy will need to accommodate this. Policies should be flexible and be reviewed at regular intervals.

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