

# Taking a second look - Reanalysis and a child's previous medical test results



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This paper provides an overview of the issues raised by recontacting patients regarding new medical developments that may be relevant to them. It has been prepared as a briefing paper for a Collaborative for Better Health and Regulation forum at The University of Melbourne

## Introduction

Medical science is advancing rapidly and constantly reshaping the way we interpret medical investigations. Furthermore, with medical records increasingly digitised, there is a growing capacity to re-access and reanalyse patients' test results.

These trends raise the possibility, and potentially the obligation, to reanalyse patients' test results and recontact with new diagnostic or therapeutic information. For example, whilst having their symptoms investigated in hospital, a child may undergo genetic testing that shows them to have multiple genetic changes (or variants) of uncertain clinical significance. Years later, research may show that one of these variants confers significant risk of kidney disease. The child's medical records could then be reanalysed, showing them to have the variant in question, and they may then be recontacted by the healthcare provider. At this later point, the child may have grown to be an adult with no recollection of the original test.

Historically, this idea has been most examined in the field of clinical genetics and thus this is the focus in this paper, but it applies to all fields of medicine. In Australia, recontacting patients is often part of regular practice but there is a lack of standardisation.

This question of whether to recontact patients, and if so, when and how, has numerous ethical, legal, and practical facets that warrant exploration. There would be value in developing a framework of thinking to support good practice in this developing area.

## The ethics of recontact

Medical ethics has historically centred around a set of principles: the autonomy of the patient, doing good (beneficence), avoiding harm (non-maleficence) and social and distributive justice.

In relation to recontact, the principle of autonomy draws attention to the tension between the patient's right to know about relevant developments in their health status and the 'right not to know' (Hunter et al., 2001). An obvious step toward clarifying the patient's wishes is to incorporate recontact into the consent discussion prior to testing (Carrieri et al., 2017a). Whilst a good potential solution, this does not take into account how their stance may change over time, and risks causing needless stress about future recontact that may never occur.

Hospital's electronic portals and electronic medical records may provide opportunities for additional ongoing channels of communication. While issues of unequal accessibility and digital literacy must always be considered, as must the costs of imposing any additional burden on families, there the possibilities of increasing empowerment, allowing dynamic consent, and assisting decision-making remain, even if a diagnosis is not yet available.

The imperative to 'do good' provides a clear mandate to recontact where this will benefit the patient, for example, where a genetic variant is found to carry a significant risk of a serious, treatable cancer. However, this benefit diminishes in correlation with the magnitude and actionability of the information. The other side of this principle is the duty to avoid harm when recontacting patients. Most evidently, receiving a phone call or email regarding a medical issue that was believed to be set aside comes with a significant risk of triggering patient distress.

The principle of just and equitable distribution of resources is also relevant to financially stretched health systems. The economic cost of recontacting patients must be considered (Sharpe, 1999). Clinical and scientific staff are needed to perform re-analysis, select appropriate patients for recontact and then undertake the recontact itself. It also would come with significant administrative work such as chasing up contact details and optimising the IT systems involved. As the scope for recontact grows, resource allocation will become increasingly crucial.

### **What do patients want?**

Recent studies have shifted the focus from ethical principlism to policy formation shaped through engagement with stakeholders who have either been, or may be, affected by recontact. Investigation into the attitudes of patients and patients' families towards recontact shows broad support for the idea of recontact as an important mechanism for expeditiously bringing the benefits of biomedical research to families (Bernard et al., 1999; Carrieri et al., 2017c; Griffin et al., 2007).

One important consideration raised by studies, however, is that receiving new information may trigger any number of complex emotional reactions. As such, recontact by a healthcare provider known to the patient is desirable to tailor the communication, with a personalised letter regarded as the preferred medium (Griffin et al., 2007).

An important special case to consider is parents with children living with rare, undiagnosed diseases. The family psychosocial burden of these conditions is high (EURORDIS & Faurisson, 2009; Smits et al., 2022). Parents of these families are generally willing to be recontacted with new information, even when it may not be clinically actionable, as scientific illumination of the conditions can have a huge psychological benefit for families (Carrieri et al., 2017c).

### **What do healthcare professionals want?**

The studies that have investigated the views of healthcare professionals on recontact show similar support to those of patients but they hold slightly different reservations, often centring around logistical and legal issues (Carrieri et al., 2017b; Fitzpatrick et al., 1999).

As it stands, surveys amongst healthcare professionals in Australia and the United Kingdom show that recontacting patients is already common practice but is done on an *ad hoc* basis (Carrieri et al.,

2017b; Vora et al., 2022). On the one hand, concerns around resource allocation are commonly reported and automated means of identifying and recontacting patients would be necessary to keep costs feasible. However, the benefits of the lack of automation present in most genetic counselling services is that recontacting can be tailored by the clinician, allowing greater sensitivity to the patient's needs (Carrieri et al., 2017b).

A common issue raised by clinicians is the question of where the responsibility to recontact lies. Regarding genetic data, genetic counsellors are the most obvious answer as they are best placed to communicate complicated genomic information to patients. But the notion of a "shared" model in which patients bear some of the responsibility is commonly raised (Dheensa et al., 2017). Empowering patients to take responsibility for their health and reducing workload for the health system would be two benefits of this. However, concerns around a hugely diverse capacity amongst patients to take the initiative to recontact were commonly cited, with psychosocial issues and neuro-disabilities important qualifying factors.

### **What are the legal aspects?**

When surveyed, many clinicians cited liability as a major deterrent against establishing a framework around recontact. Indeed, it is foreseeable that medical professionals may be held responsible by patients for withholding medically relevant information. The contrary, that patients could hold clinicians responsible for recontacting them without consent, is also plausible but has been examined less in the literature.

In Australia at present, there is no legal duty to recontact and it is not standard of care under Australian practice guidelines (Vora et al., 2022). Furthermore, the discussion around setting recontacting policies which may prove unrealistic raises concerns that healthcare professionals may open themselves up to liability (Hunter et al., 2001; Letendre & Godard, 2004).

Medical liability rests on the idea of the clinician's duty of care and elucidating its limits. In the past, for example, this duty has been judged to include notifying patients of previously unknown risks of their current medications (Letendre & Godard, 2004). To what extent this duty applies to recontact may well hinge on the pertinence and actionability of the new information.

## Key questions

- To what extent is there an ethical responsibility to recontact patients in response to new information about their health?
- Who should be responsible for initiating the recontact of patients?
- How do we incorporate the possibility of recontact into the discussion of consent for medical testing?
- What magnitude of potential impact on the patient's health should trigger a recontact?
- How do we find a balance between maximising efficiency and coverage and retaining a personalised, tailored recontact process?
- What are the limits of the clinician's duty of care with regards to recontact? And how does this impact any potential liability of the institutions involved?

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