

# Incorporating litigation costs in economic evaluation

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## Background

Litigation in healthcare can arise for a variety of reasons, with major cost implications for providers. Common sources of litigation can be due to medical negligence, such as misdiagnosis, incorrect medication or surgical error. These arise from issues in relation to the experience of an individual patient-clinician interaction. However, litigation can also arise due to systemic issues, where a programme of care may face litigation from multiple individuals.

The costs of litigation can represent a threat to the sustainability of a healthcare system. In England, for example, the payments for negligence awards come from the same funds that

are used to provide care.<sup>(1)</sup> An escalation in awards will reduce the resources available for delivering care. While it is tempting to argue that the threat or pursuance of litigation may lead to improved quality of care, there is no clear evidence to suggest that this is the case.<sup>(2)</sup> However, the understanding of the impact may depend on whether the root cause relates to the behaviour of an individual rather than a system.

This study explored the impact of litigation and the issues associated with inclusion of litigation costs in economic evaluations.

## Methods

We use a motivating example of the national cervical cancer screening programme in Ireland, CervicalCheck, which has recently been subject to multiple court cases. Established in 2008, the programme initially offered universal cytology screening to women aged 25 to 60 years; it was amended to include HPV triage in 2015 and again in 2020 to include primary HPV screening with cytology triage with the upper age limit extended to 65 years.<sup>(3)</sup> When CervicalCheck is notified that a woman has been diagnosed with cervical cancer, her previous screening history can be reviewed. This process is

formally undertaken as part of clinical audit. Following revelations and significant adverse publicity in 2018, in excess of 300 legal cases have been initiated against CervicalCheck. These primarily relate to the reading of cytology ‘smear’ tests by contracted laboratories and to non-disclosure of the results of a clinical audit (that is, where individuals were not alerted to audit findings that were discordant with those reported in the original cytology examination).<sup>(4)</sup> We outline the potential consequences of litigation for the viability of the service and the potential impact of including litigation costs on an economic evaluation.

## Results

### Who pays?

The successful litigations in relation to CervicalCheck have been primarily directed at the laboratories that processed samples, and costs have generally been covered by the insurance of those individual laboratories. To date, most of the cases taken have not been challenged and were settled out of court without admission of liability. Such settlements will impact on insurance premiums that will be reflected in future tenders to provide services to the programme. The cost of screening can therefore be expected to increase over time in a manner that was not considered when the original economic evaluation of the programme was undertaken. The pool of laboratories willing take on the risks associated with providing tests to the Irish programme may diminish, threatening the viability of the programme. Separately, a policy decision was also taken by the government to establish a redress scheme to provide ex-gratia payments for those affected by the CervicalCheck non-disclosure issue with costs of the redress payments and the running cost of the tribunal accruing to the state.

### Consequences of litigation

The consequences of litigation in cervical cancer screening include a loss of public confidence in screening generally, loss of staff morale, difficulties in recruitment and retention of professional staff, and potentially increased costs in tenders for sample processing. A loss of confidence could lead to reduced coverage with implications for costs and outcomes of the programme, and therefore impact on the estimated cost effectiveness of screening. The uncertainty associated with all of these knock-on effects are highly challenging to estimate, and may have to be considered through scenario analyses with an unclear likelihood of occurrence. Conveying the resultant information to a decision maker would be challenging, and the manner of presentation could introduce a bias in how the data are perceived. A risk averse decision maker, for example, may be unwilling to introduce a programme with a high perceived risk of litigation if the likelihood is over-emphasised.

### Wider implications

The issue of litigation highlights the need for accountability and can impact beyond the health service and into the political sphere. The response to litigation in relation to

CervicalCheck led to policy deviations, such as making free, out of programme screening available as well as treatments that were not otherwise reimbursed. Such discretionary policies impacted on service delivery and treatment costs and created inequities in treatment depending on how a patient was diagnosed.<sup>(5)</sup> To incorporate these considerations into an evaluation would be challenging, as there may be many potential policy deviations that could be implemented in response to legal challenges. Furthermore, policy deviations that discriminate between patients impact not just on cost effectiveness, but also on the ethical and potentially legal domains of a health technology assessment.

### Impact on cost effectiveness

At a programme level, litigation may occur sporadically or there may be concentration of cases over a short period. The timing of cases has implications for the impact on cost effectiveness. To incorporate litigation into modelling may suggest the need for extensive scenario analyses to understand the variety of ways in which it could arise.

Inclusion of litigation costs in an economic model may render the programme no longer cost effective. If the risk of litigation is already incorporated through insurance costs (both in third party processing costs and in overheads), then explicit inclusion may lead to double counting and thus be inappropriate. Furthermore, the likelihood of litigation may be challenging to estimate. The continued risk of litigation is dependent on the actions taken arising out of the first or initial cases; changes to the programme design in response to cases may greatly reduce the risk of further cases. The absence of a clear link between litigation and quality implies that systems do not necessarily respond in a way that reduces the future risk of litigation, but that may depend on whether litigation arises due to a systemic issue or what may be considered the actions of an individual.

### Benefits of including litigation costs

Explicit inclusion of litigation costs in economic evaluation could have benefits. Detailed consideration of litigation costs and where they may occur within the screening process, prior to implementation, may allow for a more thorough consideration of potential risks and thus the establishment of more robust systems to avoid these. Inclusion of litigation costs in modelling could therefore act as an awareness-raising mechanism and stimulate risk mitigation.

## Conclusions

Inclusion of litigation costs in an economic evaluation is complex and potentially creates bias. There are many unknowns regarding litigation. These include the likelihood of litigation, the cost of litigation, the impact on service utilisation and provision, and consequently, uncertainty about how all those issues impact on the estimated cost effectiveness of a service. However, explicit consideration of litigation costs could also highlight when there are risks in a programme and the need to identify suitable approaches to mitigating those risks.

## References

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