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Working with epistemic uncertainties: Emerging entanglements within conditional reimbursement practices

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ABSTRACT

Objectives: HTA agencies are experimenting with conditional reimbursement approaches allowing greater flexibility to cope with epistemic uncertainties generated by new health technologies and pharmaceuticals lacking evidence. While some research into promises and effects of conditional reimbursement is conducted, little empirical research investigates how such policies play out in practice. In this paper, we analyze two cases of conditional reimbursement in the Netherlands.

Methods: Case studies were purposively selected. We conducted document analysis combined with semi-structured in-depth interviews ($n = 28$). We analyzed both case studies together through initial thematic analysis and additional abductive analysis. Results were verified through data triangulation. We performed a member check in which we presented our preliminary analysis during a reflection meeting with key stakeholders.

Results: We identified three tensions in the practices of CED-schemes: proceduralism versus improvisation, steering professionals versus providing leeway, involving patients as data subjects versus legitimate stakeholders. These tensions explicate several sources of epistemic uncertainties that extend beyond methodological and more well-known socio-political pressures such as from industry on regular reimbursement decision-making process. We note the importance of improvisation work, of normative considerations, and of epistemic hierarchies.

Conclusions: We postulate that the emerging uncertainties within the practice of CED-schemes are to an extent unavoidable as they emerge from the necessarily interactive and normative nature of human relations. We conceptualize this with the notion of 'epistemic entanglements', which highlights how normative and scientific dimensions are interwoven in reimbursement decisions. As epistemic uncertainties are difficult to reduce and tame in practice the need for a more reflexive and inclusive approach to conditional reimbursement decision-making becomes apparent.

Public interest abstract: New technologies and personalized medicines can have great health benefits for patients, but often not enough knowledge is available to assess whether these innovations live up to their expectations. At the same time, despite this uncertainty, governments need to make a decision about whether or not to reimburse these innovations. Many countries are experimenting with forms of conditional reimbursement: temporarily reimbursement of technologies until more evidence is collected regarding (cost-)effectiveness in practice. Although much literature addresses potential benefits and drawbacks of conditional reimbursement policies, few studies look into how such policies play out in practice. In our research we study two examples of conditional reimbursement practices. We show conditional reimbursement practices lead to three new tensions. We conclude that HTA agencies would benefit from approaches that recognize that evidence-development and normative considerations are intertwined.

Introduction

The advent of new health technologies and personalized pharmaceuticals offers many potential benefits for affected patients and professionals. At the same time, information on effectiveness in actual medical practice and cost-effectiveness compared to existing technologies and treatments is often lacking or inconclusive at the time a reimbursement decision needs to be made [1]. Decisions about the coverage and reimbursement of innovations in healthcare thus have to be made under considerable uncertainty. For instance, the legitimacy of different

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types of evidence (the extent to which different types of evidence are considered acceptable and strong enough to base decisions on) needed to come to such informed decisions is increasingly under debate [2]. The 'gold standard' of the 'randomized-controlled-trial' (RCT) is not always attainable, in part due to the small patient populations for personalized pharmaceuticals or to the lack of alignment with the often more iterative processes of health technology development [3,cf,4]. Alternatives such as the collection of 'real-world data' are also no self-evident solutions [5, 6].

The developments discussed above thus lead to uncertainties that are epistemic in nature (i.e., they have to do with a lack of knowledge caused either by an absence of studies or by lack of studies of acceptable quality). These are different from regulatory or procedural uncertainties as a lack of knowledge can emerge even when the procedures and regulations for technology assessment are clear. Such epistemic uncertainties create challenges for politicians and healthcare policymakers to make well-informed reimbursement decisions for the long-term [6,7]. Health technology assessment agencies are responsible for assessing and appraising treatments for funding or reimbursement decisions [8]. Often acting semi-dependently at arm's length of the national government, such agencies are nevertheless confronted with high political expectations regarding public service delivery, innovation, technical expertise, and transparency [9]. Agencies in many countries are therefore experimenting with approaches that allow greater flexibility to cope with epistemic uncertainties [10] by allowing *temporary* reimbursement under the condition that more data is being collected to assess real-world effects [7].

In the Netherlands, 'conditional reimbursement' is the main policy instrument that allows for temporal forms of reimbursement for expensive yet uncertain technologies and pharmaceuticals [11]. The idea behind this policy instrument is that innovations are included in the basic benefits package for a given period of time, under specified conditions, one of which often is the collection of real-world data on costs and effectiveness to enable better informed decisions at a later point – potentially leading to withdraw the reimbursement [1,11]. This is not only expected to reduce initial epistemic uncertainty regarding real-world effectiveness and cost-effectiveness, but is also increasingly seen as a useful instrument to alleviate pressure on the sustainability and accessibility of the Dutch health system in the line of rising costs and decreasing workforce [12]. Despite their potential, existing literature has addressed several limitations and problems, which ultimately raises questions about the usefulness and success of such policy-instruments [7,11]. An important element in this critical assessment relates to the normative and political dimensions in conditional reimbursement, as the reassessment process can be complex and politically sensitive [1,10].

While the examples above show that some research into promises and effects of conditional reimbursement has been conducted, there has been a surprising paucity of empirical research investigating concretely how experiments with CED schemes play out in practice. In this paper, we therefore explore two case studies of conditional reimbursement in the context of Dutch healthcare. We focus on the work of the Dutch National Health Care Institute (Zorginstituut Nederland; in this text HCI), a semi-autonomous regulatory agency and crucial advisor to the Ministry of Health regarding the basic benefits package (BBP), who, amongst other tasks, determines whether specific health technologies meet the requirement of effectiveness [8]. For this purpose, the HCI traditionally works with well-established procedures through which effectiveness, cost-effectiveness, feasibility (including budget impact considerations), and necessity are assessed [6]. Conditional reimbursement not only implies changes in these procedures and in the use of different types of ('real-world') evidence, but also implies different relations to patients and care professionals in gathering data, requiring commitment and cooperation of such actors [11].

Our main research question is: how do experiments with conditional reimbursement play out in the practice of Dutch healthcare? We analyze two experiments with conditional reimbursement in the Netherlands, focusing abductively on three key tensions that emerge in these policy practices [13]. These tensions show that conditional reimbursement experiments, ostensibly aimed at reducing epistemic uncertainties, in practice lead to new sources of epistemic uncertainty. We make sense of such uncertainties through the notion of 'epistemic entanglements: the emergence of new interactions between legitimate(d) evidence, stakeholders and policy [cf. 14]. In the discussion, we reflect on how this notion helps us to better understand the various ways in which normative and scientific dimensions become interwoven in reimbursement decisions.

Our sociological and explorative approach to epistemic uncertainty differs from the way in which uncertainty is traditionally conceptualized in methodological studies in HTA on conditional reimbursement. Although the issue of epistemic uncertainty is recognized in HTA, the primary aim of much work in this field is to *categorize the different types of uncertainty in existing evidence* according to evaluation schemes as developed by the ISPOR-SMDM Taskforce, the TRUST tool or the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach [15,16]. The idea behind such work is that a clearer identification and categorization of the various kinds of uncertainty can lead to more informed and transparent decision-making and can be helpful in developing more suitable and targeted CED-plans to collect relevant data. Our sociological approach to epistemic uncertainty does not seek to classify upfront the various uncertainties in evidence, nor does it repute the merit and relevance of such work, but emphasizes how CED-schemes play out in concrete practice, focusing on the socio-political aspects of such practices. We thus focus on the understanding *the process of how CED-schemes are executed in practice* according to the various stakeholders involved.

Methods

We have selected two case studies in which the reimbursement of the treatment is linked to the condition that patients and healthcare providers collect or share data for the purpose of determining (cost-)effectiveness. The case studies have been purposively selected in consultation with HCI reflecting not only different care contexts, but also in particular due to their expected informative nature regarding challenges in practice. We do not consider them to be representative of all CED-schemes, but do expect that their differences and visibility offer 'most-likely' cases to be informative for an exploration of how ideas about conditional reimbursement work out in practice.

Case study 1: Paramedical rehabilitation after COVID-19

At the beginning of May 2020, the Minister for Medical Care and Sport asks the HCI for advice on the reimbursement of paramedical rehabilitation care after COVID-19 through the basic care package. In view of the limited scientific knowledge about the recovery process after COVID-19, advice is also requested on how a possible expansion of paramedical recovery care as part of the insured care package could be combined with research into the effectiveness of this care. At the end of June, the Advisory Committee (ACP) of the HCI produces a draft advise on rehabilitation and aftercare ('recovery care') after COVID-19 in which the Committee suggests to temporarily include first-line paramedical treatment of COVID-19 patients in the basic insurance. In addition to the need for a quick procedure, care should also be taken to include research that allows the HCI to gain evidence about the effectiveness of this care in the long term. At the beginning of July, the HCI published the 'Package advice for entitlement to first-line paramedical recovery care COVID-19', in which it is advised to "temporarily and conditionally reimburse first-line paramedical recovery care, on the basis of Article 2.1, paragraph 5 of the Healthcare Insurance Decree (Bzv). The conditional reimbursement should be aimed at optimal aftercare and rehabilitation support for patients who have been severely affected by COVID-19 and are experiencing serious consequences in the recovery phase. This arrangement would offer patients the opportunity to receive reimbursement for this care while also investigating its effectiveness (Zorginstituut, n.d., a). In mid-July, the Minister for Medical Care and Sport decides to conditionally admit paramedical recovery care to the basic package, based on the advice of the HCI. With the publication of the temporary entitlement in the *Staatscourant* on 17 July 2020, the arrangement has become definitive: this care has been conditionally admitted to the basic package of the health insurance from 18 July 2020 up to and including 31 July 2021.

Case study 2: Eculizumab for atypical hemolytic uremic syndrome (aHUS)

Eculizumab is a pharmaceutical used for patients with the rare conditions paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic-uremic syndrome (aHUS). Eculizumab was included in the insured package in 2008 for the indication PNH under a specific policy rule for orphan drugs. Since 2012, the indication of eculizumab has been expanded to include the treatment of patients with aHUS. This case study focuses on the use of eculizumab for aHUS: a very rare genetic disease that causes tiny blood clots to form in blood vessels, blocking blood flow to important organs. aHUS can cause kidney failure, heart disease and other serious health problems. While there is no known cure for aHUS, it can be treated. It is estimated that in the Netherlands, aHUS is diagnosed 15–20 times per year (5 children and 10–15 adults). In the Netherlands about 100 patients suffer from aHUS. The HCI has issued advice on eculizumab on several occasions. In December 2016, it advised the Minister to continue to reimburse eculizumab from the basic package for the time being, pending on a number of conditions to be met. Arguments for this are that eculizumab is the only treatment option, is effective and shows significant improvements for patients with aHUS, and that a promising treatment guideline has been developed that leads to a reduction in duration of use of the drug for a large proportion of patients or intensity. Eculizumab for this patient group has been conditionally reimbursed on several occasions and now falls under a specific orphan drug arrangement, in which a set of agreements is made with the medical professionals providing care for this specific disorder, including the establishment of an indication committee, determination and further development of start and stop criteria, and requirements for data collection, evaluation and monitoring (Healthcare Institute, n.d., b). This arrangement was established in 2017 with the Dutch Association of Internists. Involved in the agreements were a national centre of expertise, the patient association, and health insurers. In this arrangement, the emphasis is on gaining insight into the (cost) effectiveness of the treatment in accordance with the Dutch guideline, whereby medication can be discontinued under specific clinical and safety conditions.

For each case study, we conducted a document analysis in combination with semi-structured in-depth interviews ($n = 28$) with patients, healthcare providers, policy makers, researchers, employees of the HCI, insurers and representatives of patient associations. Interviews lasted 45 to 80 min (60 min on average). All participants received information about the study in advance and consented to participate in the study. We used a general topic list, focusing on the background and history of the case, current regulations and experiences with them, the institutional context of the HCI (e.g., relations with field parties and the Ministry), relevant societal debates, and the perceived legitimacy of the conditional reimbursement policies. Each topic list was further specified based on the role and background of the respondent. The document analysis consisted of publicly available documentation from the HCI, such as advice of the ACP, press releases, letters to the minister, presentations and other online information.

We have analyzed both case studies together through initial thematic analysis [17]. Based on our theoretical familiarity with debates on conditional reimbursement, politics of evidence, and the role of regulatory agencies in policy advice, we conducted additional abductive analysis [18] in which we gradually zoomed-in on three central tensions in conditional reimbursement practices. Results were verified through data triangulation of documents and interviews. We also performed a member check in which we presented our preliminary analysis during a reflection meeting with key stakeholders, leading to minor refinements.

Results

We describe three tensions in the practice of conditional reimbursement and analyze how these played out in the two different cases, after which we reflect on the similarities and differences between the two case studies.

Sticking to procedures or improvising

The first tension is between sticking to procedures or improvising in the development and execution of conditional reimbursement policies.

In the case of paramedical covid rehabilitation care, the temporary reimbursement arrangement was created in a context of crisis and widely experienced urgency. According to various actors, the scheme for conditional reimbursement was the only option to make this specific form of rehabilitation care quickly available to a large group of people. As the legal principle was not clear from the onset, improvisation work was necessary:

> "This arrangement [regarding paramedical covid rehabilitation care] had to be created very rapidly, and that never leads to the nicest arrangement. So we also struggled with the question how to implement this [arrangement] and how can we explain this." (Respondent HCI)

This sense of urgency came with downsides as well. Advisors of the HCI became aware that privacy legislation (AVG, GDPR) would challenge the legal basis of processing personal data for research purposes. Specifically, the obligation to participate in research in order to be amendable to the reimbursed care was conceived to be problematic. The ethical committee of the University Medical Centre in the lead of the research questioned this obligation. Their main point of critique was that consent could never be fully freely given when patients depend on the care that is reimbursed through this arrangement. After a period of negotiation, a compromise was reached in which the research was divided into two components: a retrospective part based on anonymous data gathered from Electronic Health Records, and a prospective part with questionnaires for which patients needed to provide consent.

The eculizumab for aHUS case study shows another aspect of the tension between procedures and improvisation. The improvisation work in this case is triggered by the perceived necessity of medical experts and patients to anticipate a potentially negative reevaluation of eculizumab given its highly unfavorable cost-benefit ratio:

> "We were told that [the HCI] was going to reassess eculizumab. That the firm submitted the paperwork arguing for lifelong [prescriptions]. We already saw for PNH that the HCI was making a fuss about it. […] So we already felt, all of us together, the patient association as well as medical specialists: this could end badly. And then we proactively said: we are going to do things differently in the Netherlands. Lifelong [prescriptions] we do not agree with." (Medical specialist)

Both medical professionals and patients became aware of the risks that eculizumab would no longer be reimbursed. Anticipating a potentially negative reevaluation of the HCI, the expertise center and the patient association joined forces in the search to an alternative approach, in which the pharmaceutical would no longer be subscribed indefinitely, but only for a period of several months (and in the case of an emerging relapse).

This improvisation work did not emerge out of the blue: importantly, it is intimately tied to scientific literature and substantiated by medical arguments, for instance about the lack of evidence about lifelong subscription, uncertainties regarding long-term side-effects, the gradual character of the condition and the reversibility of the disease process. Moreover: improvisation work was conducted simultaneously with the establishment of new protocols, which included national agreements about diagnosis, administering, and monitoring.

Reflecting on similarities and differences, we see that while clear procedures can create clarity for stakeholders and help in accounting for reimbursement decisions, improvisation work was necessary in both projects. In the practice of CED-schemes, research protocols turn out to be far from static: they can become problematic in practice, requiring improvisation and adjustments. This necessary improvisation work is one 'source' of epistemic uncertainties emerging in the practice of CED schemes. Such improvisation work can be seen as valuable as it is a way of dealing with emerging problems and be accountable to the needs of different groups, but it comes with risks as well: it can lead to a process that is perceived as 'messy' and decisions can be harder to justify on a more general societal level.

Professionals in the lead or under control

The second tension in the practice of conditional reimbursement is about the relation between the HCI and (medical) professionals, and especially about balancing the need to provide strict criteria (e.g., for the collection of real-world evidence in registries, start- and stop criteria for studies) and the need to allow professional leeway (as the HCI does not seek to replace or overrule medical expertise).

In the case of paramedical covid rehabilitation care we see this tension in the way multidisciplinary care is envisaged. In the creation of the arrangement, the HCI emphasizes close professional collaboration between various paramedical disciplines, such as physiotherapy, occupational therapy, remedial therapy, dietetics, and speech therapy. In practice, however, care continued to be provided separately:

> "The arrangement calls for multidisciplinary collaboration. But the arrangement in itself does nothing to actively stimulate this collaboration. You can only reimburse monodisciplinary [care] sessions on an hourly basis. So there is no reimbursement of multidisciplinary meetings or other forms in which you have time to coordinate with each other." (Medical researcher)

Whereas close multidisciplinary collaboration was the ideal, practice turned out differently. Rigid payment structures are experienced as an important obstacle, reducing incentives to provide multidisciplinary care as envisaged. Moreover, contradictory interests and approaches complicated coordination between physiotherapy and occupational therapy. Various occupational therapists for instance criticized the frequency and intensity of treatments by physiotherapists, arguing that this often was detrimental rather than beneficial to this group of patients. In sum, this example shows that putting professionals in the lead is no guarantee for success and can also be frustrated by misaligned institutional arrangements.

The eculizumab for aHUS case study provides a different insight. This case study shows that putting professionals in the lead can be beneficial, but also that this requires much additional negotiation and justification work that often remains invisible:

> "[The research lead] had to put in much time to get every UMC involved in the national network. For the average professional it remains easier to say in the consultation room: this is the protocol, this is the medication, let's get started. Now we have to explain why we do not follow [the protocol] and that there is a study. […] So it's a lot more work for the professional to handle the medication responsibly." (Program manager hospital)

This quote shows that other University Medical Centers needed to be persuaded to participate in the new protocol developed by specialists of the national center of expertise. This Centre is moreover dependent on other UMCs to deliver the right data. Manually validating and checking this data also requires substantive additional work. Third, patients need to be convinced to participate. The new protocol asks for a large amount of trust, as professionals essentially ask patients to decrease their dose of a life-saving pharmaceutical in opposition to formal prescriptions and internationally established guidelines.

Reflecting on similarities and differences, we see that while on the one hand, the HCI aims to facilitate professionals and put them in the lead, the HCI at the same time wishes to maintain some central control. This second tension thus shows how the collection of real-world evidence requires not only additional time and effort, but also depends on normative and 'political' work: key actors needed to reach consensus, finetune between different hospitals and convince a range of actors about protocol deviations. In the case of paramedical covid rehabilitation care, we see that the CED-scheme is applied differently than envisaged due to the conflicting interests and ideas of different (para) professional groups. In the case of the eculizumab for aHUS project, 'convincing work' that is invisible in the protocols needed to be conducted to get and keep other UMCs on board. A second 'source' of epistemic uncertainties in the practice of CED schemes thus emerges from these normative considerations and convincing work that needs to be conducted.

Patients as data source or legitimate stakeholder

The third tension is about the extent to which patients should have an active influence on the design of conditional reimbursement experiments and accompanying (cost-) effectiveness research. While the HCI values the patient perspective, as can be seen in attempts to involve them via dialogues [19], the exact role of patients remains a source of tension [20].

In the case of paramedical covid rehabilitation care, this tension becomes visible in the gap between the experienced sense of urgency to establish a reimbursement arrangement for a new group of patients and the perceived lack of influence of this group regarding the way in which this arrangement worked out in practice. Exemplary for this gap is that signals about problematic health experiences caused by the specific arrangement of paramedical care did not lead to concrete changes in the protocols:

> "If I can speak on behalf of the patients: they really experienced not being taken seriously. […] And that had everything to do with [the fact] that, especially in the beginning [of the conditional reimbursement experiment], they received quite traditional treatments by physiotherapists, according to the protocols, that later turned out to have a detrimental effect on this group of people." (Representatives patient association).

This quote points towards unanticipated consequences for health conditions experienced by patients, and the exclusion of this specific knowledge of patients in relation to the execution of the CED-scheme in practice.

In the eculizumab for aHUS case study a different role for patients can be seen. Here, an active patient association was able to gain a more influential role in the design of an alternative protocol (in combination with the national expertise center). This initiative was greatly appreciated by the HCI, who explicitly considered this collaboration to be an important factor in the decision to keep the pharmaceutical conditionally reimbursed, even when this went against the grain of pressure by the industry and international guidelines. The close collaboration and longstanding relation with the expertise center provided the patient association with legitimacy in the institutional context of the HCI. This legitimacy is however also dependent upon various serendipitous factors:

> "You also need to have a bit of 'luck' with the ones who happen to get your illness. I brought my managerial experience, [X] brought in her experience as a lobbyist, that's a coincidence, but in this case a fortunate one. And we met two doctors who were very venturous, because do not be mistaken: in the early days we were frowned upon […] at meetings with international aHUS patients." (Patient representative)

Patients need to survive their disease, invest time, expertise, and skills to be able to enhance their influence in this institutional context. These requirements are far from self-evident and strongly dependent upon coincidences, as the example shows.

Reflecting on similarities and differences, we see that in the case of paramedical covid rehabilitation care, the inclusion of specific knowledge of patients in the execution of the CED-scheme in practice remained highly limited. Their experiential knowledge about how the treatment might cause overtreatment did not lead to changes in the protocol. In the eculizumab for aHUS case, hierarchical differences between medical expertise and patient knowledge were partially bridged, leading to changes in the protocol, but this required both extensive substantive knowledge and procedural and political sensitivity. Hence, in both cases, we see how such epistemic hierarchies between 'experts' and patients can be another, third, 'source' of epistemic uncertainties.

Discussion

In the context of increasing epistemic uncertainties in reimbursement decision-making we identified three tensions in the practices of CED-schemes: proceduralism versus improvisation, steering professionals versus providing leeway, and involving patients as data subjects versus legitimate stakeholders. These tensions explicate several sources of epistemic uncertainties that extend beyond methodological and more well-known socio-political pressures such as from industry on regular reimbursement decision-making process [21]. We note the importance of improvisation work, of normative considerations, and of epistemic hierarchies. Our case-studies make clear that the collection of the real-world data comes with much 'invisible work' [22], for instance in relation to negotiating adherence to new protocols, manually verifying the collected data, and lobbying for institutional support to maintain registries and databases. Both cases also show that we cannot assume a static world that operates similar to the closed-system logic that dominates RCT-designs and that is built upon rationalized ideas of efficiency, calculability, predictability, and control [23,24]. Moreover, there can be tensions at play between different stakeholders, whose interests and goals not necessarily need to be aligned. This impacts how the proposed treatments are delivered in practice, and consequentially affects what kind of effects can be shown [cf. 11].

We postulate that these uncertainties within the practice of CED-schemes are to an extent unavoidable as they emerge from the necessarily interactive and normative nature of human relations. We conceptualize this with the notion of 'epistemic entanglements'. The term 'entanglements' is used mostly in contemporary cultural theory to highlight how diverse actors are inextricably bound together in relationships with each other and with various other aspects of the world around them [25]. In science studies and philosophy, the notion connects to the position of agential realism [26] and signals, amongst others, that epistemic acts (producing evidence) do not merely capture aspects of reality, but shape reality (they are performative), and are therefore inherently moral (cf. [27]). In the context of CED-schemes, the notion of 'epistemic entanglements' points to the intrinsic connections between the gathering of evidence in practice, the performative aspects of this process (i.e., how healthcare practices are changed because of it), and the normative considerations that emerge with it.

The notion of epistemic entanglements is not only helpful to better understand the various ways in which normative and scientific dimensions are interwoven in reimbursement decisions, but also comes with practical implications. The underlying question behind the CED development is about how HTA-agencies can come to legitimate decisions on reimbursing innovative medical technologies and pharmaceuticals with inconclusive or insufficient evidence. The notion of epistemic entanglements suggests that approaches seeking to 'purify' processes of evidence development from normative considerations and decisions fall short in this regard [28]. The political, normative and ethical complexities we find in our cases cannot be solved by 'better' evidence alone, but also ask for, for instance, ethical expertise in order to explicate the normative structures of decision-making problems and to reflect on underlying normative assumptions [29,cf,30]. As epistemic uncertainties are difficult to reduce and tame in practice the need for a more reflexive and inclusive approach to conditional reimbursement decision-making becomes apparent. Such an approach builds from the proposition that we need to 'manage and live with, rather than dispel and conquer' epistemic uncertainties [31]. Although the implications for conditional reimbursement policies and the role of HTA agencies need to be fleshed out further, we can take inspiration from fields that have long recognized the intersections of evidence and normative considerations. In Science & Technology Studies (STS), the empirical study of 'boundary organizations' located 'at the interface' between science and policy, such as the HCI, is for instance a central tenet [32,33]. This research recognizes the need for such organizations to balance different accountability demands in a political environment and shows how credible judgement is produced through the ability of such organizations to navigate controversy and mediate among divergent interests, while maintaining a committed focus on science [34]. HTA agencies can benefit from incorporating what Moreira (2005) calls a broader set of 'repertoires' to come to legitimate decisions [35]; not only the technical robustness of the evidence, but also its practical usability, the acceptability of their recommendations in relation to public health policies and stakeholder views, and the adequacy of the process leading to the recommendation. Rather than dispelling and valuing conditional reimbursement practices in light of traditional repertoires of evaluation, e.g. geared towards the best evidence, our findings suggest the need for HTA-agencies the further embrace and explore the epistemic entanglements of which they are an intrinsic part.

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Not required

Patient consent

Not required

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CRediT authorship contribution statement

Rik Wehrens: Conceptualization, Formal analysis, Writing – review & editing, Data curation. **Bert de Graaff:** Conceptualization, Formal analysis, Writing – review & editing, Funding acquisition.

Declaration of competing interest

None declared.

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