**Title:** The ‘Values in Modelling’ framework for patient and public involvement in health economics modelling: development and application in the LEAP model project

**Running head:** The ‘Values in Modelling’ framework

**Authors:** Stephanie Harvard1,2(ORCID ID 0000-0002-9008-2163); Rachel Carter3(ORCID ID/0000-0001-8609-798X); Sian Hoe Cheong3, Tony Lanier3, Zainab Zeyan3, Amin Adibi2,4, Spencer Lee4, Cristina Novacovik4, Mark Ewert4, Eric B.Winsberg5,6 (ORCID ID 0000-0002-8764-0072), Kate Johnson (ORCID ID 0000-0001-7406-2448)1,2,4

1Division of Respiratory Medicine, University of British Columbia (UBC), Gordon and Leslie Diamond Health Care Centre, 2775 Laurel Street, Vancouver, BC Canada V5Z 1M9

2Legacy for Airway Health, Vancouver Coastal Health Research Institute

3Legacy for Airway Health Community Partner Committee

4Faculty of Pharmaceutical Sciences, University of British Columbia, 2405 Wesbrook Mall, Vancouver, BC Canada  
V6T 1Z3

5Department of History and Philosophy of Science, University of Cambridge, Free School Lane  
Cambridge, CB2 3RH, United Kingdom

6Department of Philosophy, University of South Florida, 4202 E Fowler Ave, Tampa, FL 33620, United States

**\*Corresponding Author:**

Stephanie Harvard

Robert H.N. Ho Research Centre, 2635 Laurel Street

Vancouver, British Columbia

Canada

V5Z 1M9

Email: [stephanie.harvard@ubc.ca](mailto:stephanie.harvard@ubc.ca)

**Credit author statement: Stephanie Harvard:** Conceptualization, Methodology,Project administration,Writing - Original Draft; **Rachel Carter:** Methodology, Writing - Review & Editing; **Sian Hoe Chong:** Methodology, Writing - Review & Editing; **Tony Lanier:** Methodology Writing - Review & Editing; **Zainab Zeyan:** Methodology, Writing - Review & Editing; **Amin Adibi:** Methodology, Software, Formal analysis, Writing - Review & Editing; **Spencer Lee:** Investigation, Software, Formal analysis, Writing - Review & Editing; **Cristina Novacovik:** Investigation, Visualization, Writing - Review & Editing; **Mark Ewert:** Software, Formal analysis, Writing - Review & Editing; **Eric B.Winsberg:** Conceptualization, Writing - Review & Editing; **Kate Johnson** Conceptualization, Methodology, Supervision, Project administration, Funding acquisition.

**Competing interests:** The authors have no competing interests to declare

**Word Count:** 6782

**Funding:** Eric Winsberg is supported by a British Academy Global Professorship. Kate Johnson/the LEAP model is supported by a Michael Smith Foundation for Health Research BC Scholar Award and LEAP is funded by a CIHR Catalyst Grant.

**Acknowledgments:** The authors gratefully acknowledge Meghan Roushorne for her participation in the LEAP model project and Emily Brigham (M.D.) for her consultation as a practicing respirologist. Thank you to Isha Joshi, former coordinator of the Legacy for Airway Health Community Partner Committee, and Harry Lee, first author on cited publications about the LEAP model. The authors also thank four anonymous reviewers for their valuable feedback and suggestions, which greatly improved this manuscript.

**Abstract**

Patient and public involvement (PPI) in health economics modelling is an increasingly recommended practice. However, guidelines or ‘best practices’ for PPI in modelling have yet to be developed and modelling teams must determine how to structure the PPI process, track its impact, and document challenges. This is one objective in the Lifetime Exposures and Asthma Outcomes Projection (LEAP) model project, a multi-year initiative to develop a 'Whole Disease' model of asthma. Building on philosophical theory, we developed the Values in Modelling (VIM) framework to help structure the PPI process in the LEAP project and guide future work in this area. In this article, we describe the VIM framework and our process of implementing it in a recent phase of the LEAP project, focused on modelling the cost-effectiveness of high-efficiency particulate air (HEPA) air cleaners for asthma prevention and management. Using specific examples, we illustrate how the VIM framework guided the modelling team’s deliberations and how participators in modelling influenced shared determinations concerning the ‘best’ (most adequate-for-purpose) modelling decisions.

**Key Points**

* The Values in Modelling (VIM) framework identifies the purpose of patient and public involvement (PPI) in health economics modelling as to help ‘manage’ the value-laden decisions that arise in the process
* In the LEAP model project, the VIM framework was used to structure the PPI process, track its impact, and identify challenges and outstanding questions
* The VIM framework and underlying theory helped clarify what should be addressed throughout the PPI process and reported for items 21 and 25 of the CHEERS checklist

**Introduction**

Patient and public involvement (PPI) in health economics modelling is recommended, with the 2022 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) asking authors to describe their approach to engaging patients or others affected by the study [1]. Recent contributors have reported various approaches to PPI in health economics modelling and a range of positive outcomes, including improved understanding of the decision problem, better alignment between model objectives and end-user needs, and increased transparency [2–5]. However, guidelines or ‘best practices’ for PPI in modelling have yet to be developed [2–4,6,7]. Progress toward this goal is complicated both by empirical uncertainties—such as the impact of PPI on model results, users’ trust in the model, and real-world capacity [8]— and normative questions, including the appropriate level of patient and public influence and the ‘right’ price to pay for the benefits of PPI [6,9].

Pending the development of formal guidance, modelling teams must determine how to structure the PPI process, track its impact, and document challenges.This is one objective in the Lifetime Exposures and Asthma Outcomes Projection (LEAP) model project, a multi-year initiative to develop a 'Whole Disease' model of asthma [10–12] and involve numerous “participators” [8] in modelling various asthma-related policy decisions. The LEAP project presents an opportunity to study and improve PPI over time, but also a need to justify the initial process. Given promising but varied approaches to PPI in health economics modelling [2–5], we used philosophical theory to help design and justify a PPI process to implement and adapt over time in the LEAP project.

Recently, Harvard [13] and Harvard and Winsberg [6,9] have argued that the purpose of PPI in health economics modelling is to give patients and members of the public a role in managing value-laden decisions, i.e., decisions that are flexible from a scientific perspective and could have downstream social or ethical consequences [14]. Understanding PPI as ‘managing values’ may help unify the numerous goals and benefits linked to PPI (e.g., upholding democratic principles, improving research quality and relevance, gaining public support for funding decisions, increasing trust [15–19]) and clarify the function of PPI, fostering support for it in health economics modelling. Furthermore, this theoretical foundation [9] provides a clear justification for PPI throughout the modelling process, anticipates likely challenges, and identifies potential strategies to manage them. For these reasons, we viewed this theoretical foundation as appropriate to inform a framework to structure the PPI process in modelling and guide future work in this area.

In this article, we describe key aspects of our work in developing a theory-informed framework to structure the PPI process in the LEAP project, along with insights gained from its preliminary application.

1. **Framework development**
   1. *Theoretical Foundation and Aims*

Framework development was led by the first author (SH) and informed by a review and analysis of philosophical theory on ‘managing values’ in science [9]. According to theory, value-laden decisions are expected to arise in any scientific modelling process, regardless of the specific characteristics of the model [20]. Value-laden decisions have been characterized in detail elsewhere, but generally pertain to establishing the purpose of the model, deciding what should be represented in the model and how (given the model’s purpose and the problem of uncertainty), and determining whether/when to draw factual conclusions based on model results— acknowledging that these decisions have potential ethical consequences [14,20–22]. As value-laden decisions are not ‘purely scientific’, many philosophers suggest these decisions are equally relevant and important for scientists and non-scientists to deliberate [9].

We assumed that a framework for PPI in modelling should support a “meta-ethical process” in which modelling teams consider how they will make value-laden decisions and what the consequences of those decisions might be [[9] p.7]. This process raises distinct questions, including (but not necessarily limited to) i) how to identify value-laden modelling decisions and structure deliberation about them; ii) how to select participators to join modelling teams; iii) how to collaborate effectively with participators in modelling. Our primary aim was to address the first question specifically, by developing a theory-informed framework for managing value-laden decisions in modelling — regardless of the particular model or participators involved. This broad focus was intended to ensure the framework could be applied and refined in future phases of the LEAP project, while creating the potential to adapt the framework to contexts beyond LEAP. Formal investigation of the other questions was outside the scope of the project (see Discussion), though we sought to describe the framework’s preliminary application in the LEAP project and record insights from the team.

We aimed to support PPI in the full range of modelling decisions, while maximizing teams’ flexibility in implementing PPI in their own context—i.e., to support various levels of PPI in the modelling process, rather than require a specific level. Our rationale was that i) all modelling decisions are in some sense value-laden and PPI is a core strategy for ‘managing’ these decisions appropriately, i.e., for avoiding specific problems associated with value-laden science; *but* ii) PPI is not the only available strategy for this purpose, the ‘right’ strategy is a normative question about which there is no current consensus (nor would consensus definitively close the question), and resource limitations and other practical considerations will likely influence whether and how PPI is implemented [9]. This justifies a framework that centres the role of PPI in managing value-laden modelling decisions but avoids taking a strict view on how PPI should be implemented.

*2.2 Framework Structure*

The ‘Values in Modelling’ (VIM) framework outlines five interrelated steps for modellers (i.e., individuals with expertise in technical aspects of modelling) and transdisciplinary participators in modelling (i.e., individuals with expertise in other areas) to take when working together. Table 1 defines these five steps and their purposes, while Tables 2 and 3 describe the conceptual distinctions that inform them. Figure 1 provides a process overview.

Following the VIM framework, modellers and participators first engage in group discussion to consider relevant ethical questions, including the potential benefits and harms of the health intervention, the potential benefits and harms of the modelling project, and appropriate standards of evidence and ‘adequacy for purpose’ in this context (Table 1, Step 1). Next, modellers consider upcoming modelling decisions and, to the best of their ability, characterize them according to four decision types: ‘Pivotal’, ‘Opaque’, ‘Guideline’, and ‘Informant’ decisions (see Table 1, Step 2, and Table 2 for descriptions). This will inform Step 3 (Table 1), which is choosing between three previously-identified strategies to inform value-laden decisions: *Democratization*, *Pre-identification,* and *Transparency* [9] (see Table 3 for descriptions). Note that each decision-making strategy is generally most appropriate for a specific type of decision (Figure 1).

Tables 2 and 3, respectively, describe the differences between the four types of modelling decisions and the decision-making strategies highlighted by the VIM framework. Table 3 further illustrates how characterizing modelling decisions can help teams select the most appropriate strategies for managing those decisions. For example, for ‘Guideline’ decisions, the team is expected to use the *Pre-identification* strategy (i.e., by consulting the relevant authoritative source): this approach avoids violating well-established scientific/institutional norms and reduces unnecessary burden on participators. For ‘Pivotal’ decisions, the *Democratization* strategy(i.e., involving all team members in a decision) is preferable if feasible, as these decisions are subject to considerable uncertainty/disagreement and may have important consequences. For ‘Opaque’ decisions, practical considerations support the *Transparency* strategy (i.e., having modellers make the decision independently, but transparently). In part because a modelling decision may fit more than one description (e.g., both ‘Pivotal’ and ‘Opaque’), and in part because of resource considerations (e.g., there may be insufficient capacity to use *Democratization* for all ‘Pivotal’ decisions), the VIM framework does not prescribe the ‘best’ approach. Instead, it encourages teams to weigh their options thoughtfully and prepare to justify their chosen decision-making strategies.

Following the VIM framework, modelling decisions to be made following either *Pre-identification* or *Transparency* are labelled ‘Closed’ decisions, while modelling decisions to be made following *Democratization* are labelled ‘Open’ decisions, i.e., to indicate that they will receive input via PPI (Table 3). In deliberating about ‘Open’ decisions (Table 1, Step 4), the VIM framework encourages modelling teams to consider overlapping epistemic issues (e.g., quality of scientific evidence) and ethical issues (e.g., social consequences of modelling decisions) from different team members’ perspectives, while centring the goal of model *adequacy-for-purpose* [23]. In its final step, the VIM framework invites modelling teams to describe the results of the process, including who was involved and who had the highest level of decision-making power (Table 1, Step 5). It further asks participators to address questions relevant to evaluating the model and PPI process (Table 6). The questions reflect the core assumptions that: i) to ensure adequacy-for-purpose, models demand a level of critical scrutiny capable of detecting relevant weaknesses if they exist (cf. [24]); ii) PPI in modelling introduces diverse perspectives that help probe for relevant weaknesses in models, particularly around values, priorities, and real-world implications that might be overlooked in purely technical assessments. Currently, Step 5 of the VIM framework addresses only a subset of issues relevant to reporting and evaluating the model and PPI process—further development is needed (see Discussion).

**3. Preliminary Application in the LEAP project: Key Aspects**

*3.1 Context, selection of participators, and process overview*

In 2023, work began to use the LEAP model to estimate the cost-effectiveness of high efficiency particulate air (HEPA) filters for asthma prevention and management. To support this effort, five transdisciplinary participators were invited to join the LEAP team: four members of the Legacy for Airway Health (LAH) Community Partner Committee (CPC), all of whom have lived experience of asthma (RC, SCH, TL, ZZ), and one government knowledge user with expertise in air quality, who departed the project early due to a professional role change (MR—see Acknowledgements). This project was the first application of the VIM framework. All team meetings occurred online to increase accessibility—meeting dates and attendance notes are provided in Supp. Mat. 1. Participators were invited to meet with the facilitator (SH) if they had questions or comments following team meetings. Below, we describe selected aspects of the VIM framework’s application and its influence on the modelling process. Due to space constraints, results of Step 1 are not presented.

*3.2 Identification and justification of ‘Open’ decisions*

Following Step 2 of the VIM framework, KJ, SH and EW met to characterize modelling decisions, with KJ ultimately responsible for determining how decisions would be made in modelling the cost-effectiveness of HEPA filters. A total of five decisions were designated as ‘Open’ decisions, i.e., to be made using the *Democratization* strategy (Step 3, decisions are listed in Table 4). The first decision concerned what data sources and methods should be used to project future air pollution attributable to wildfire smoke (specifically “PM2.5”, particulate matter with a diameter of 2.5 micrometers or less). This decision was designated as ‘Open’ for two reasons. First, consultations with environmental scientists reinforced the published view that current data/methods are not adequate for projecting future wildfire [25,26]: the choice of which scenarios to model is ultimately “unforced” by scientific evidence [27,28] and all modelled scenarios will be subject to significant uncertainty. Second, the choice of data sources/methods, including which scenarios to model, could be anticipated to significantly affect model results and/or provoke ethical disagreements among participators (e.g., because of the differing values individuals place on over- versus under-estimating the impacts of climate change, which include changes to wildfire patterns). Given these features, the decision was considered to be ‘Pivotal’ and prioritized for PPI. The four other ‘Open’ decisions concerned what data sources and methods should be used to represent the impact of PM2.5 on asthma outcomes, including asthma control, moderate exacerbations, severe exacerbations, and asthma incidence. Not only were these decisions also considered to be ‘Pivotal’, modellers anticipated that participators with lived experience of asthma could have special knowledge relevant to the decisions.

*3.3. Deliberation 1: Methods for projecting future wildfire-attributable PM2.5*

The first ‘Open’ decision concerned the process to project future levels of PM2.5 due to wildfire smoke. Because this decision involves considerable uncertainty, methodological complexity, and potential consequences for model results and policy recommendations, it shares features with many health economics modelling decisions. PPI in such decisions is supported by theoretical arguments but is often approached hesitantly for a variety of reasons, including doubts about participators’ interest, capability, and influence [8].This section describes how participators were engaged in deliberations, illustrates that participators raised relevant questions and considerations, and demonstrates their influence on the management of uncertainty.

Prior to deliberation, participators were informed about the nature of the decision and why it presents a methodological challenge with ethical significance, including the implications of over- versus under-estimating one of many possible impacts of climate change (see Table 4). Briefly, the facilitator (SH) explained that the first task would be to choose between two data sources to examine historical averages of PM2.5 in Canada. One source is the Canadian Optimized Statistical Smoke Exposure Model (CanOSSEM), a machine learning model which estimates historical PM2.5 levels using numerous predictor variables [29]. Another source is the Regional Air Quality Deterministic Prediction System (RAQDPS), whose purpose is to produce 3-day air quality forecasts across Canada based on meteorological inputs, emissions, and chemical transport, but which ultimately provides records of forecasts that can be used to estimate historical PM2.5 levels [30]. Although both CanOSSEM and RAQDPS provide estimates of historical PM2.5 levels, only RAQDPS is capable of distinguishing PM2.5 caused by wildfire specifically. The second task would be to choose a method for representing the increase in PM2.5 attributable to wildfire smoke over time. One way to do this would be to model a range of possible levels of increase (e.g., 0%, 10%, 25%, 100% etc.), without grounding these numbers in empirical estimates or projections. Another way would be to incorporate the results of one or more modelling studies that attempt to project increases in wildfire and resulting smoke according to climate change scenarios, such as the study by Xie et al.[31]. A third possibility would be to combine these methods, extending the range around projections informed by climate change scenarios.

To foster group discussion, the facilitator described potential strengths, limitations, and downstream implications of these different methods, informed by KJ’s consultations with environmental scientists and an expert in climate modelling ethics (EW). Group discussion began with questions, which participators raised regarding sources of uncertainty affecting the model. These included questions concerning the level of agreement between CanOSSEM and RAQDPS and the latest data incorporated into RAQDPS. In discussing methods for modelling future increases in PM2.5, one participator spoke in favour of incorporating evidence-informed projections (rather than hypothetical assumptions), but another asked for clarification regarding the source of evidence-based projections. This prompted discussion over the desirability of using Canada-specific projections, and the group asked modellers to search for wildfire projection studies that use data from areas close to British Columbia (BC), where the LEAP project is based. Ultimately, participators suggested using a variety of approaches to estimate future PM2.5 and being transparent about what additional data would be required to reduce uncertainty.

At the next meeting, modellers responded to outstanding questions, confirming that the latest RAQDPS data are from 2023 and the agreement between CanOSSEM and RAQDPS is 0.72, as assessed by Pearson’s correlation coefficient. Reflecting on this level of agreement, modellers noted that the most common interpretation among experts is that RAQDPS overpredicts peak exposure during wildfire events but underpredicts baseline exposure compared to CanOSSEM. In most contexts where the goal is to establish a causal inference, 0.72 is considered on the border between medium and high correlation, but one may or may not consider it 'adequate' agreement between two tools that aim to measure the same phenomenon; therefore, one might still wonder about the impact on the model results of using RAQDPS to estimate historical PM2.5 due to wildfire. If the group wished to explore this source of uncertainty, the facilitator noted, one possibility would be to perform a sensitivity analysis by taking the wildfire-attributable fraction of PM2.5 derived from RAQDPS and multiplying it by the CanOSSEM total PM2.5, which would reduce reliance on RAQDPS. Asked whether modellers should perform this additional analysis, all participators agreed that they should do so, if feasible, to strengthen the methods. The modelling team considered this additional sensitivity analysis a result of the PPI process.

Addressing participators’ question concerning projection studies using more local data, modellers confirmed that such studies are lacking. However, modellers identified a wildfire projection study of Western USA [32], which incorporates the propensity of different regions to burn, given historical wildfire activity, fuel availability, and fire weather conditions, and links observed fire behaviour to near-future trends, making it better suited for the LEAP model’s near-future timeframe (2023-2036). Using this study would result in the LEAP model representing an 11% increase in wildfire-attributable PM2.5 between 2023 and 2036 in the base-case analysis; modellers would then choose 0% as a lower bound for the confidence interval and the midway point between 0 and 11% as the intermediate scenario, i.e., a 5.5% increase from 2023-2036. Asked whether modellers should apply any additional scaling factors (e.g., exploring the impact of assuming even greater levels of increase in wildfires, or of absolute reductions in wildfires), participators all indicated that modellers should *not* apply additional scaling factors, as none had reasons to support doing so (see Discussion).

*3.4.Deliberations 2-5: Methods for representing the impact of PM2.5 on asthma outcomes*

‘Open’ decisions 2-5 concerned how to represent the impact of PM2.5 on asthma outcomes. This section describes how participators were engaged in deliberations about these decisions, including considerations when choosing a ‘concentration response function’ (CRF) to represent these impacts (see Supp. Mat 2). We note that ‘Open’ decisions 1-5 all had a clear connection to participators’ lived experience of asthma, unlike ‘Open’ decision 1 (see Discussion). Discourse on PPI in health economics modelling has emphasized that participators’ lived experience is an important source of factual knowledge relevant to model development, raising the question of whether this knowledge is the most important or even only thing to be sought through PPI [2,6]. Here, we describe how participators contributed not only factual knowledge that may have otherwise been inaccessible to modellers, but also their personal, normative perspectives on what questions the model should address, what potential sources of error should be investigated, and how modellers should represent uncertainties.

‘Open’ decision 2 concerned how to represent the impact of PM2.5 on asthma control. Participators were briefed on the decision and informed that KJ’s independent suggestion was to use a BC study that examined the effect of PM2.5 on salbutamol dispensations [33]. To encourage deliberation about this choice, participators were asked *“Are salbutamol dispensations an adequate proxy for asthma control?”.* All participators expressed significant doubts, noting that, in their experience, salbutamol lasts a long time, they often have back stock, and sometimes share within the family (i.e., where more than one member has asthma), meaning they may not see a doctor or pharmacist during a period of high PM2.5 despite being affected. Given these considerations, KJ provided two alternative sources of CRFs to consider, one for adults [34] and one for children [35], both of which use the Asthma Control Test (ACT) as a direct measure of asthma control. KJ summarized the limitations of these studies from her perspective, including that both were conducted in settings considerably different from BC (e.g., weather, housing stock, rural/urban mix), which could affect the relationship between PM2.5 exposure and asthma outcomes. In discussions, it was noted that while salbutamol dispensations would likely underestimate effect of air pollution on asthma control, it was unclear whether or to what extent the studies using ACT scores would underestimate or overestimate impact of air pollution on asthma control in BC. Discussions resulted in unanimous agreement among participators that the ACT is a superior measure of asthma control and the decision to model the relationship between PM2.5 and ACT scores, rather than salbutamol dispensations. Modellers reflected that participators had contributed factual knowledge about salbutamol use that was otherwise inaccessible to them. This input, along with participators’ negative assessment of methods expected to underestimate the effect of PM2.5 on asthma, persuaded the team to model asthma control differently than originally planned.

‘Open’ decision 3 concerned how to represent the impact of PM2.5 on moderate asthma exacerbations. Participators were briefed on this decision and informed that KJ’s independent suggestion was to use a BC study which examined the effect of PM2.5 on asthma-related physician visits [33]. To encourage deliberation about this choice, participators were asked *“Are asthma-related physician visits an adequate a proxy for moderate asthma exacerbations?”.* The central concern raised by participators was whether the billing codes used in the study would capture visits to nurse practitioners, walk-in clinics, and urgent care. Participators stressed the importance of capturing these visits, given a perceived reduction in access to primary care physicians since 2010. Upon confirmation that these visits would normally be captured (so long as the visit was billed correctly), participators agreed that the suggested study [33] was an adequate source to obtain a CRF for moderate asthma exacerbations. Modellers observed that participators had drawn their attention to the issue of reduced access to regular primary care physicians and prompted them to verify that their method would capture other episodic primary care visits. The PPI process had therefore resulted in an additional check for potential error that would not have occurred otherwise.

‘Open’ decision 4 concerned how represent the impact of PM2.5 on severe to very severe asthma exacerbations. Participators were briefed on the decision and informed that KJ’s independent suggestion was to use a recent meta-analysis, which stratified the effects of PM2.5 on asthma-related ER visits into ‘lags’ of 0-4 days [36]. To encourage deliberation, participators were asked to consider the assumption that exposure to PM2.5 has a ‘lagged’ effect on asthma exacerbations (i.e., exacerbations due to increases in PM2.5 do not occur immediately, but 1,2,3, or 4 days after exposure) and *“How should this lag be represented in the LEAP model?”.* At the outset, the facilitator flagged one reason to avoid modelling the 4-day lagged effect, i.e., the corresponding evidence was considered ‘low certainty’, unlike other effects for which evidence was generally considered ‘moderate certainty’. Most participators expressed that lagged effects of 2 or 3 days were the relevant ones to model, as they often try other symptom-control strategies first before resorting to visiting the ER. However, one participator said they tend to visit the ER fairly quickly when experiencing a sudden exacerbation. In light of this discrepancy, participators suggested asking a physician whether it is more common for symptoms to gradually worsen, or whether patients often present to the ER from sudden symptom onset. The physician consulted (see Acknowledgements) suggested that the inflammatory reaction usually occurs within 24 hours but people differ in self-management, comfort, home environments, etc. Given the physician’s input, participators unanimously suggested modelling a range of lagged effects from 1-3 days. Modellers noted that, prior to participators’ input, they were unsure what lagged effect to model (i.e., 0-4 days), but they were inclined to select just one of the four options as this would simplify model results and downstream policy discussions. The PPI process therefore effectively encouraged addressing a greater number of questions, despite the complexity this introduces, and representing a wider array of asthma outcomes relevant to a diverse patient population.

‘Open’ decision 5 concerned how to represent the impact of PM2.5 on asthma incidence in children and adults, respectively. Participators were briefed on the decision and informed that KJ’s independent suggestion was to use two separate meta-analyses, both of which compiled evidence from diverse geographical settings [37,38] At the first two meetings, participators were asked to consider: 1) asthma is difficult to diagnose in children under 5 and what is considered asthma in this age group could vary across studies included in the children-focused meta-analysis; 2) asthma diagnosis was often self-reported, and could therefore be uncertain, in studies included in the adult-focused meta-analysis. A follow-up brief circulated by email highlighted additional considerations and asked *“Do you think we should use the two meta-analyses above as the sources for the CRFs for asthma incidence in adults and children, respectively? If we do use them, will you trust the model results?”.* The brief also provided examples of alternate/complementary strategies that modellers could take, e.g., using only Canadian studies or studies meeting other important criteria, conducting sensitivity analyses around the CRFs obtained from meta-analyses, and/or taking extra measures to communicate the uncertainty in the CRFs. At the final meeting, the facilitator presented additional information concerning the quality of evidence included in the meta-analyses.

Contemplating this decision, participators expressed different perspectives. Two participators said the decision should be made by modellers familiar with the meta-analyses in question and that they were not qualified to decide which option is best and why. However, one expressed the view that CRFs from meta-analyses should be adequate, as researchers who conducted the meta-analyses would ‘weed out’ poor studies so that the average would be appropriate. Conversely, another worried that meta-analyses would not reflect actual asthma incidence, noting that many children may remain undiagnosed due to barriers in accessing specialized care and self-reported asthma could introduce inconsistencies based on differences in healthcare access, cultural factors, and awareness levels across regions. This participator also questioned whether variability in study locations would affect how well the CRFs from meta-analyses would reflect asthma risk in BC/Canada. Accordingly, the participator expressed a preference to use specific studies selected to represent the local context. While they thought it was reasonable to use the CRFs from meta-analyses, they said they would feel more confident in the model’s results if additional steps were taken to account for uncertainty.

Given these differing opinions, deliberation gravitated towards using a range of CRF values and presenting multiple results. One participator suggested asking the modeller most familiar with the meta-analyses to identify specific studies that would be particularly suitable for representing BC/Canada. For the CRF among adults, this modeller recommended two large, high-quality cohort studies with PM2.5 concentrations comparable to Canada [39,40]. Considering the various suggestions made, KJ made the final decision to model not only the CRFs obtained from the meta-analyses but the CRFs from the two above recommended studies as well [39,40]. Modellers reflected that the PPI process, following the VIM framework, prompted the team to more closely consider the complexities of selecting a single CRF to represent the impact of PM2.5 across all policy settings that may be informed by the LEAP model. This effectively encouraged modelling a wider range of uncertainty.

*3.5 Reporting and evaluation*

As described in Table 1 (Step 5), the VIM framework invites modelling teams to describe their process and demonstrate to what extent value-laden modelling decisions received input from transdisciplinary participators. While model results are outside the scope of this article, Table 5 describes the decisions required to model the cost-effectiveness of HEPA filters and indicates which decision-making strategies were followed to make each one, including who was involved in specific decisions and who had greatest decision-making power. Table 5 shows the proportion of decisions designated as ‘Open’ versus ‘Closed’, highlighting that the PPI process involved participators in a very small proportion of total decisions in this phase of LEAP model development. Table 6 describes participators’ answers to VIM framework questions relevant to evaluating both the model and PPI process (see Discussion). As VIM framework questions do not cover personal experiences, participators were also asked to complete the Patient Engagement in Research Scale [41] (see Supp. Mat. 3). This was done to obtain a general impression of participators’ experiences and identify any serious issues that should be addressed before undertaking future work using the VIM framework. The results indicated that one participator had criticisms of the process (see Discussion), but feedback was generally interpreted as positive and encouraging of future work.

**4. Discussion**

This article described the VIM framework’s process, rationale, and initial application. Here, we reflect on its strengths, implications, and limitations, and outline future research directions for evaluating and refining the VIM framework.

The VIM framework was developed following an extensive review and analysis of literature on ‘managing values’ in science [9]. This process identified both philosophical and practical considerations relevant to structuring PPI in health economics modelling. The analysis concluded that any PPI process will remain subject to criticisms and the benefits of involving all team members in every decision are unlikely to outweigh the costs. Accordingly, the VIM framework encourages modelling teams to prioritize PPI in key modelling decisions and promotes a transparent and systematic process for doing so.

In practice, health economics modellers already set priorities for PPI. For example, Gibbs et al. [3] report prioritizing questions about unfamiliar cultural contexts and decisions about data sources and assumptions expected to greatly influence results. One of the strengths of the VIM framework is it provides a theoretical justification for implementing intuitive solutions like this. Moreover, the framework offers theory-informed guidance for how to prioritize decisions for PPI and what information to record throughout the modelling process. This includes whether decisions can be readily informed by uncontested science and/or well-established institutional guidelines, whether individual informants are required due to lack of systematic evidence, whether decisions pertain to ‘opaque’ model features that could influence user trust, and whether decisions are flexible from a scientific perspective and carry significant downstream social/ethical implications. By identifying these considerations, the VIM framework has provided the LEAP team with concrete guidance for structuring the PPI process and reporting it using the CHEERS (items 21 and 25) [1] and GRIPP2 checklist [47].

Key questions concern the evaluation of the VIM framework. While the current study provides only limited insight into these questions, it presents an opportunity to reflect on their importance and how they may be addressed in future research. Here, we briefly consider five distinct questions, which suggest different objectives and evaluation methods:

*Perceived value of proposed PPI procedure—* First, does the VIM framework propose the right procedure for PPI in health economics modelling generally? In this work, we built on the assumption that social procedures (e.g., scientific, legal, democratic) have intrinsic value, which can only be assessed subjectively by the individuals with an interest in the process. Features like perceived transparency, inclusiveness, fairness, accountability, deliberativeness, and legitimacy can all influence what value individuals ascribe to a procedure [42–46]. Informed by philosophical theory [9], the VIM framework was developed with the goal of enhancing these perceived features of the modelling process. However, we did not examine whether this goal was achieved. In the future, the potential exists to systematically assess the perceived value of the VIM framework—including compared to alternatives [4]—through formal surveys of patients and the public, decision-makers, and other members of the health economics community.

*Process benefits in the LEAP project—* Second, what impact did the VIM framework have on the modelling process in the LEAP project? When focusing on ‘process benefits’[8], one key question is whether the VIM framework led to PPI in the ‘right’ modelling decisions, irrespective of the content of participators’ input or its impact on the final model. Addressing this question requires judging what constitutes appropriate inclusion and exclusion of participators from modelling decisions— and future research is needed to shape these judgments. However, questions asked of participators at the end of this project provide some insight into their perspectives (Table 6). Importantly, none of the four participators felt their involvement in specific decisions was unnecessary or not appropriate. When asked if there were any modelling decisions they were not involved in where they felt their input would have been valuable, three out of four participators said no. However, one participator remarked that they were not fully aware of the relevant details and therefore could not answer the question. The same participator questioned whether the costs included in the model truly reflect the financial burden experienced by people living with asthma and suggested that “additional context from lived experience may have been beneficial”.

This critical feedback shows that not all participators felt they were adequately informed and included in the full scope of relevant decisions. This could be interpreted as a shortcoming of the VIM framework process, whereby modellers characterize decisions and the team lead determines which decisions will receive input via PPI. This process assigns considerable power and accountability to the team lead: although nothing in the VIM framework prevents asking participators which decisions they think they should be involved in, it is not a required step. Having modellers and participators co-identify decisions for PPI would further empower participators, but could also raise concerns. For example, participators might assume their role is limited to decisions with obvious connections to their lived experience, overlooking their legitimate contributions to seemingly ‘technical’ (but value-laden) decisions. Notably, we observed that participators were willing and able to contribute both types of decisions. Although not addressed here, numerous considerations deserve careful attention before adapting the VIM framework to encourage co-identification of decision-making strategies.

*Impact on the LEAP model—* Third, how did the VIM framework affect the final model? An important limitation of this article is that it excludes model results, due to scope and space constraints. However, we described several changes to the model that resulted from PPI, including the addition of sensitivity analyses, the exclusion of a potentially misleading variable (salbutamol dispensations), and the expansion of model outcomes (Table 4). This adds to the growing body of literature that demonstrates that PPI triggers changes to health economics models [2–5]. A difficult question is whether these changes make the models ‘better’. There is no gold standard to answer this question, which must be assessed subjectively by model developers, decision-makers, and citizens with an interest in model results. In our view, PPI in ‘Pivotal’ decisions identified through the VIM framework resulted in *prima facie* improvements to the final model, perhaps the most compelling of which is the exclusion of salbutamol dispensations as an outcome of interest. The LEAP team agreed that, given participators’ insights into why salbutamol dispensations may be insensitive to changes in asthma symptoms, this outcome was arguably irrelevant to the decision problem and its inclusion could be criticized by others down the road. One limitation of the present study is that we did not ask others to evaluate the changes to the model that resulted from PPI. Crucial areas for future research include broader, in-depth, systematic analysis of how decision-makers and other public groups value changes to health economics models driven by PPI, including PPI structured by the VIM framework.

*Impact on participators—* Fourth, what impact did the VIM framework have on the participators involved in LEAP? Focusing on this question, at least two distinct outcomes should be considered. The first is participators’ *perceptions of the model:* for example, did the PPI process structured by the VIM framework influence participators' trust in the model or views of how it should be used? The second is participators’ *personal experiences:* for example, how did the process affect participators’ sense of empowerment, burden, satisfaction, etc.? We aimed to generate preliminary insights by asking participators questions about the LEAP model (Table 6) and administering the Patient Engagement in Research Scale (PEIRS) (see Supp. Mat. 3). However, in-depth, systematic evaluation of these outcomes was out of scope, which is an important limitation. Further research is needed to better understand how to collaborate effectively with participators in modelling and improve their perceptions of the final model. Although feedback received from participators was generally positive, one participator was relatively critical of the process (see Table 1, Supp. Mat. 3). Follow-up with this participator (a co-author) suggests future work should strengthen communication between modellers and participators. In their words: "While I trusted the modelling team’s intentions and appreciated the inclusive environment, I sometimes found it difficult to tell whether my input had a meaningful impact on certain decisions. This uncertainty, along with my limited expertise in technical modelling and moments where I felt unsure about my contributions during meetings, may have influenced my lower scores on the PEIRS. Greater clarity on how decisions were made and how feedback was integrated could have helped me feel more confident and valued in the process." In the future, it may be beneficial to schedule routine follow-up meetings between participators and the facilitator, rather than make them available upon request. Despite this constructive criticism, feedback generally suggested that our process was successful in upholding best practices for participatory research. This includes fostering relationships based on mutual trust and respect and ensuring that meetings and facilitation materials are accessible to all [47,48].

*Impact on decision-making—* Finally, an important question is whether downstream policy decisions based on the LEAP model will be influenced by the implementation of PPI following the VIM framework. We did not address this question, which is an important area for future research as LEAP model results become available. Formal qualitative research, including interviews with policymakers, would be valuable.

In addition to raising key evaluation questions, implementing the VIM framework pointed to areas for improvement at the conceptual and practical levels. For one, team members found it challenging to identify ‘Pivotal’ decisions as defined by the VIM framework, as ultimately every modelling decision could potentially be classified this way. A closely related criticism of the concept of a ‘Pivotal’ decision (raised by a reviewer of this article) is that the impact of a modelling decision cannot be known in advance. In the future, the VIM framework may be refined to better guide modellers through these challenges in characterizing modelling decisions. This may require more carefully distinguishing between decisions where a significant impact on model results can be anticipated with high confidence and decisions where the impact will not be known until the model is run. It may also require the addition of other decision ‘types’. As shown in Table 6, many decisions in the current project were not marked as belonging to any of the four decision ‘types’ defined by the VIM framework. There is room for conceptual development to characterize decisions that do not clearly fit the descriptions currently highlighted by the VIM framework.

Another issue that was not addressed here is how to select individuals to participate in the modelling process. Participator characteristics are expected to influence the results of PPI in modelling and concerns surround the possibility of over- and under-representing specific public groups and sets of values in the process. Although this problem is emphasized in the literature that informed the VIM framework, the framework itself does not aim to solve it. Rather, it rests on the simplifying assumption that some level of PPI in modelling is better than none. In this study, all four participators involved for the duration of the project were members of the LAH CPC with lived experience of asthma and they do not represent all members of the general public. Notably, all four participators agreed with modellers’ original proposal to use scaling factors obtained from an external source that estimates a ~50% increase in wildfire in Western USA from 2001–2010 to 2050–2059 [29]. This choice reflects, at least in part, shared values around model ‘signalling’ effects [45] and raises the question of whether other transdisciplinary participators would provide the same or different direction to model development. For example, EW pointed out that members of communities who are investigating strategies to control wildfire might want to model a scenario in which wildfire activity actually decreases in the future—an outcome that is optimistic, but not impossible, and whose representation would signal to model users that reducing wildfire is itself a relevant goal [45]. As norms develop surrounding the selection of participators in modelling, the VIM framework should be adapted to reflect them.

Last, the resource implications of implementing the VIM framework should be considered. In this project, the PPI process was supported by numerous personnel, including four researchers at the professor or senior scientist level and four Masters-level trainees. The four participators received compensation dictated by the Legacy for Airway Health (LAH) Community Partner Community (CPC), which at time of writing is CDN $40 per hour. While detailed reporting of resource use is outside the scope of this article, PPI clearly carries significant financial costs. Further research should clarify PPI’s benefits, helping funders weigh them against costs.

Grounded in philosophical theory, the VIM framework aims to help identify and deliberate about value-laden modelling decisions, regardless of the particular model or participators involved. This high-level focus creates the potential to adapt the framework to contexts beyond the LEAP project. As the LEAP project continues, ongoing refinement and evaluation of the VIM framework will help determine the value of broader adaptation.

**References**

1. Husereau D, Drummond M, Augustovski F, De Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. PharmacoEconomics. 2022;40:601–9.

2. Bunka M, Ghanbarian S, Riches L, Landry G, Edwards L, Hoens AM, et al. Collaborating with Patient Partners to Model Clinical Care Pathways in Major Depressive Disorder: The Benefits of Mixing Evidence and Lived Experience. PharmacoEconomics. 2022;40:971–7.

3. Gibbs NK, Angus C, Dixon S, Parry C, Meier P. Stakeholder Engagement in the Development of Public Health Economic Models: An Application to Modelling of Minimum Unit Pricing of Alcohol in South Africa. Applied Health Economics and Health Policy. 2023;1–9.

4. Staniszewska S, Hill EM, Grant R, Grove P, Porter J, Shiri T, et al. Developing a framework for public involvement in mathematical and economic modelling: bringing new dynamism to vaccination policy recommendations. The Patient-Patient-Centered Outcomes Research. 2021;14:435–45.

5. Xie RZ, Malik E deFur, Linthicum MT, Bright JL. Putting stakeholder engagement at the center of health economic modeling for health technology assessment in the United States. Pharmacoeconomics. 2021;39:631–8.

6. Harvard S, Winsberg E. Patient and Public Involvement in Health Economics Modelling Raises the Need for Normative Guidance. PharmacoEconomics. 2023;41:733–40.

7. Staniszewska S, Jakab I, Low E, Mossman J, Posner P, Husereau D, et al. Commentary: Advocating for patient and public involvement and engagement in health economic evaluation. Research Involvement and Engagement. 2023;9:45.

8. Harvard S, Werker GR. Health Economists on Involving Patients in Modeling: Potential Benefits, Harms, and Variables of Interest. PharmacoEconomics. 2021;39:823–33.

9. Harvard S, Winsberg EB. ‘Managing values’ in health economics modelling: Philosophical and practical considerations. Social Science & Medicine. 2024;358:117256.

10. Adibi A, Turvey SE, Lee TY, Sears MR, Becker AB, Mandhane PJ, et al. Development of a conceptual model of childhood asthma to inform asthma prevention policies. BMJ Open Respiratory Research. 2021;8.

11. Lee TY, Petkau J, Johnson KM, Turvey SE, Adibi A, Subbarao P, et al. Development and Validation of an Asthma Policy Model for Canada: Lifetime Exposures and Asthma outcomes Projection (LEAP). medRxiv. 2024;2024–03.

12. Lee TY, Petkau J, Saatchi A, Marra F, Turvey SE, Lishman H, et al. Impact analysis of infant antibiotic exposure on the burden of asthma: a simulation modeling study. Frontiers in Allergy. 2024;5:1491985.

13. Harvard S. Making Decision Models Fit for Purpose: The Importance of Ensuring Stakeholder Involvement. PharmacoEconomics. 2024;s40273-023-01348–6.

14. Harvard S, Werker GR, Silva DS. Social, ethical, and other value judgments in health economics modelling. Social Science & Medicine. 2020;253:112975.

15. Abelson J, Wagner F, DeJean D, Boesveld S, Gauvin F-P, Bean S, et al. Public and patient involvement in health technology assessment: a framework for action. International journal of technology assessment in health care. 2016;32:256–64.

16. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. The Milbank Quarterly. 2012;90:311–46.

17. Canada’s Drug Agency. Narrative Review of Patient Involvement in Organizational Governance [Internet]. Ottawa: Canada’s Drug Agency; 2018 [cited 2025 Apr 30]. Available from: https://www.cda-amc.ca/narrative-review-patient-involvement-organizational-governance

18. Freebairn L, Atkinson J-A, Kelly PM, McDonnell G, Rychetnik L. Decision makers’ experience of participatory dynamic simulation modelling: methods for public health policy. BMC medical informatics and decision making. 2018;18:1–14.

19. Aitken M, Tully MP, Porteous C, Denegri S, Cunningham-Burley S, Banner N, et al. Consensus Statement on Public Involvement and Engagement with Data Intensive Health Research. Int J Popul Data Sci. 2019;4:586.

20. Harvard S, Winsberg E. The epistemic risk in representation. Kennedy Institute of Ethics Journal. 2022;32:1–31.

21. Harvard S, Winsberg E, Symons J, Adibi A. Value judgments in a COVID-19 vaccination model: a case study in the need for public involvement in health-oriented modelling. Social Science & Medicine. 2021;286:114323.

22. Winsberg E; Harvard S. Scientific Models and Decision Making. Cambridge University Press; 2024. Available from: https://www.cambridge.org/core/elements/abs/scientific-models-and-decision-making/B7AC2159C941E7D0A08D9981FC8822F1

23. Parker WS. Model evaluation: An adequacy-for-purpose view. Philosophy of Science. 2020;87:457–77.

24. Mayo DG, Spanos A. Severe testing as a basic concept in a Neyman–Pearson philosophy of induction. The British Journal for the Philosophy of Science. 2006;

25. Sanderson BM, Fisher RA. A fiery wake-up call for climate science. Nat Clim Chang. 2020;10:175–7.

26. Hanan EJ, Kennedy MC, Ren J, Johnson MC, Smith AMS. Missing Climate Feedbacks in Fire Models: Limitations and Uncertainties in Fuel Loadings and the Role of Decomposition in Fine Fuel Accumulation. J Adv Model Earth Syst. 2022;14:e2021MS002818.

27. Winsberg E. Values and uncertainties in the predictions of global climate models. Kennedy Institute of Ethics Journal. 2012;22:111–37.

28. Winsberg E. Philosophy and climate science. Cambridge University Press; 2018.

29. Paul N, Yao J, McLean KE, Stieb DM, Henderson SB. The Canadian Optimized Statistical Smoke Exposure Model (CanOSSEM): A machine learning approach to estimate national daily fine particulate matter (PM2.5) exposure. Science of The Total Environment. 2022;850:157956.

30. Readme raqdps en - MSC Open Data / Données ouvertes du SMC [Internet]. Ottawa: Environment and Climate Change Canada [cited 2025 Apr 30]. Available from: https://eccc-msc.github.io/open-data/msc-data/nwp\_raqdps/readme\_raqdps\_en/

31. Xie Y, Lin M, Decharme B, Delire C, Horowitz LW, Lawrence DM, et al. Tripling of western US particulate pollution from wildfires in a warming climate. Proc Natl Acad Sci USA. 2022;119:e2111372119.

32. Liu Y, Liu Y, Fu J, Yang C-E, Dong X, Tian H, et al. Projection of future wildfire emissions in western USA under climate change: contributions from changes in wildfire, fuel loading and fuel moisture. Int J Wildland Fire. 2021;31:1–13.

33. Yao J, Eyamie J, Henderson SB. Evaluation of a spatially resolved forest fire smoke model for population-based epidemiologic exposure assessment. Journal of exposure science & environmental epidemiology. 2016;26:233–40.

34. Kang I, McCreery A, Azimi P, Gramigna A, Baca G, Hayes W, et al. Impacts of residential indoor air quality and environmental risk factors on adult asthma-related health outcomes in Chicago, IL. Journal of Exposure Science & Environmental Epidemiology. 2023;33:358–67.

35. Li Z, Xu X, Thompson LA, Gross HE, Shenkman EA, DeWalt DA, et al. Longitudinal effect of ambient air pollution and pollen exposure on asthma control: the Patient-Reported Outcomes Measurement Information System (PROMIS) pediatric asthma study. Academic Pediatrics. 2019;19:615–23.

36. Agache I, Canelo‐Aybar C, Annesi‐Maesano I, Cecchi L, Rigau D, Rodríguez‐Tanta LY, et al. The impact of outdoor pollution and extreme temperatures on asthma‐related outcomes: A systematic review for the EAACI guidelines on environmental science for allergic diseases and asthma. Allergy. 2024;79:1725–60.

37. Khreis H, Kelly C, Tate J, Parslow R, Lucas K, Nieuwenhuijsen M. Exposure to traffic-related air pollution and risk of development of childhood asthma: a systematic review and meta-analysis. Environment international. 2017;100:1–31.

38. Lee S, Tian D, He R, Cragg JJ, Carlsten C, Giang A, et al. Ambient air pollution exposure and adult asthma incidence: a systematic review and meta-analysis. The Lancet Planetary Health. 2024;8:e1065–78.

39. Shin S, Bai L, Burnett RT, Kwong JC, Hystad P, van Donkelaar A, et al. Air Pollution as a Risk Factor for Incident Chronic Obstructive Pulmonary Disease and Asthma. A 15-Year Population-based Cohort Study. Am J Respir Crit Care Med. 2021;203:1138–48.

40. Liu S, Jørgensen JT, Ljungman P, Pershagen G, Bellander T, Leander K, et al. Long-term exposure to low-level air pollution and incidence of asthma: the ELAPSE project. Eur Respir J. 2021;57:2003099.

41. Hamilton CB, Hoens AM, McKinnon AM, McQuitty S, English K, Hawke LD, et al. Shortening and validation of the Patient Engagement In Research Scale (PEIRS) for measuring meaningful patient and family caregiver engagement. Health Expectations. 2021;24:863–79.

42. Rawls J. A theory of justice. Rev. ed. Cambridge, Mass: Belknap Press of Harvard University Press; 1999.

43. Habermas J, Lenhardt C, Habermas J. Moral consciousness and communicative action. 2. print. Cambridge, Mass: MIT Press; 1991.

44. O'Neill O. A question of trust. Cambridge: Cambridge Univ. Press; 2010.

45. Fung A. Varieties of Participation in Complex Governance. Public Administration Review. 2006;66:66–75.

46. Daniels N, Sabin JE. Accountability for reasonableness: an update. BMJ. 2008;337:a1850–a1850.

47. Community-based participatory research: A guide to ethical principles and practice (2nd edition) [Internet]. Bristol: NCCPE. [cited 2025 Aug 22]. Available from: https://www.publicengagement.ac.uk/resources/guide/community-based-participatory-research-guide-ethical-principles-and-practice-2nd

48. The NIHR Imperial BRC Patient Experience Research Centre (PERC). A Rough Guide to Public Involvement. [Internet]. London: National Institute for Health Research (NIHR); 2021 [cited 2023 Mar 11]. Available from: https://www.imperial.ac.uk/media/imperial-college/medicine/perc/PERCs-Rough-Guide-to-Public-Involvement---Dec-2021.pdf