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A systematic literature review to clarify the concept of vaccine hesitancy

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Vaccine hesitancy (VH) is considered a top-10 global health threat. The concept of VH has been described and applied inconsistently. This systematic review aims to clarify VH by analysing how it is operationalized. We searched PubMed, Embase and PsycINFO databases on 14 January 2022. We selected 422 studies containing operationalizations of VH for inclusion. One limitation is that studies of lower quality were not excluded. Our qualitative analysis reveals that VH is conceptualized as involving (1) cognitions or affect, (2) behaviour and (3) decision making. A wide variety of methods have been used to measure VH. Our findings indicate the varied and confusing use of the term VH, leading to an impracticable concept. We propose that VH should be defined as a state of indecisiveness regarding a vaccination decision.

In 2019, vaccine hesitancy (VH) was named by the World Health Organization (WHO) as one of the top-10 threats to global health, following a five-fold global increase in measles, a disease that can be prevented by vaccination[1,2]. The largest increase was reported in the WHO regions covering Europe and the Americas[2]. The impact of these measles outbreaks is substantial, with rises in morbidity, mortality and costs[3–5]. The increasing incidence of measles and other vaccine-preventable diseases has been attributed to a failure to reach adequate immunization coverage rates[2,6]. In the European region, VH has been identified as the main barrier to vaccination coverage[7,8]. This is in contrast to other regions, such as sub-Saharan Africa, where immunization coverage rates are challenged by a combination of barriers, including access and availability[9].

In the past decade, VH has become a key topic of research in various fields, following rises in vaccine-preventable diseases, the introduction of new vaccines, the spread of misinformation and lagging vaccination coverage[10]. Moreover, the COVID-19 pandemic has drawn further attention to the role of VH in limiting the uptake of vaccines and failure to achieve collective immunity[11–13]. This has led to the proliferation of scientific literature on VH in the public health, biomedical and social science research fields[10].

In 2012, the WHO established a strategic advisory group of experts (SAGE) working group with the mandate of defining VH and suggesting how to monitor and address it. The working group proposed a broad definition, describing a VH continuum from acceptance to refusal of vaccines or as a delay in acceptance or refusal despite the availability of the vaccines. The working group described VH as "A complex behavioural phenomenon specific to vaccines, context, time, and place and influenced by factors of complacency, convenience, and confidence"[14]. This broad definition emphasizes variability by describing that VH may vary between types of vaccines and different contexts, may change over time or between different geographical locations and is influenced by various determinants.

The concept of VH has been described and applied in various ways. When definitions are broad and lack clarity, this can lead to the emergence of different concepts with overlapping domains, with various concepts being used interchangeably by some and recognized as distinct entities by others[15]. Additionally, lack of conceptual clarity can lead to inadequate operationalization and cause confusion among researchers[15]. This is problematic because when studies use similar terminology with a different meaning, their results are incomparable across subgroups, locations or contexts. A clear conceptualization is needed to develop meaningful measures allowing comparison of results[16].

A lack of conceptual clarity is observed in the literature on VH, where VH is variously conceptualized as a psychological state and as different types of vaccination behaviour[17,18]. In addition, the terms 'vaccine confidence', 'low uptake' and 'low intention to vaccinate' are often equated with VH[19,20]. Confusion among researchers is then illustrated by inconsistencies in the applied definitions[21,22]. It has even been argued that VH is a catch-all category, aggregating many different concepts rather than being one measurable construct; and this is impeding progress in the research field[23].

A good concept definition consists of characteristics, attributes or features that are unique to that concept and distinguish it from other closely related concepts[15]. Given the importance of VH for predicting and influencing individual vaccination decisions, it is important to explore the uses of VH and propose an optimal operationalization, distinguishing VH from other closely related concepts. Such clarification could enable a universally adopted definition and aid further research in this area.

The purpose of this systematic review was to provide an overview of how VH is operationalized in the literature in terms of conceptualizations, subpopulations and measurements. Following an assessment of the various conceptualizations, we differentiated the common themes, related concepts, research fields and vaccine types. The scope and structure of this systematic review is visualized in Fig. 1. On the basis of an interpretation of these findings, we suggest a way forward by proposing a renewed definition for VH.

Results

Study selection and characteristics. The search strategy yielded 7,427 publications. After screening the titles and abstracts, 919

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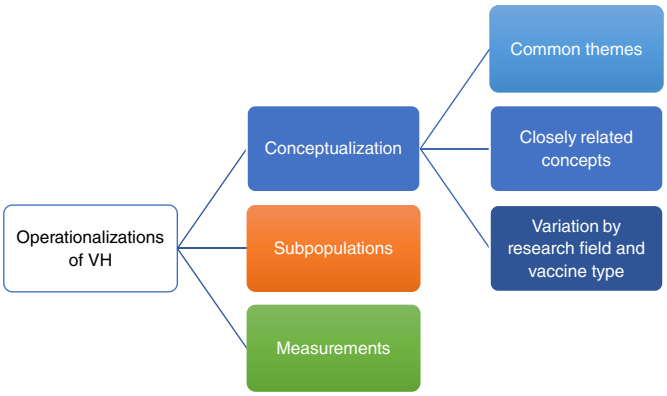

Fig. 1 | Schematic illustration of the scope and structure of this systematic literature review. Aiming to give an overview of VH, we recognize three types of operationalizations: conceptualizations (blue), identification of subpopulations (orange) and measurements (green). Conceptualizations of VH are analysed at three levels: (1) common themes, (2) closely related concepts and (3) potential variation in conceptualization between research field and vaccine type. Each type of operationalization and its levels are discussed in separate sections.

publications were selected for full-text screening. A total of 420 publications met the inclusion criteria. Seven additional studies were found through citation searching, two of which met the inclusion criteria, adding up to a total of 422 studies. Some studies met the criteria of more than one category, with 36 studies categorized under VH conceptualizations, 63 under VH subpopulations and 373 under VH measurements. The search process is summarized in the PRISMA flow chart (Fig. 2)[24]. The characteristics of included studies are described in more detail in Supplementary Table 1.

The included studies cover a wide geographical distribution. The limited majority (54%) originated in high-income countries (HIC), mainly the United States, Canada, Italy, Australia and France. A smaller group (43%) originated in low- and middle-income countries (LMICs), primarily China, India and Turkey. The remaining studies (3%) originated in a combination of HIC and LMICs. The majority (60%) were published in 2021 and 2022.

The included studies approach VH in relation to various vaccine types: 51% pertaining to COVID-19, 29% to childhood, 4% to human papillomavirus, 4% to influenza and 2% to miscellaneous vaccines. Additionally, 11% of the studies concern vaccines in general. Various research fields are represented, including public health (43%), biomedical science (30%), paediatrics (15%) and social sciences (12%). Mixed methods appraisal tool (MMAT) scores were calculated for 88% of the included studies, while the others could not be assessed due to their study types. The majority (68%) scored 3 or higher, indicating that 60% of the quality criteria were met.

Vaccine hesitancy conceptualization. From the 36 studies on VH conceptualization, we extracted and analysed 304 excerpts. Supplementary Table 2 shows the extracted text excerpts for each study. Our thematic analysis revealed that 93 excerpts describe an overall characterization of VH. The majority of these (69%) describe the nature of VH as heterogenous[14,21,23,25–37], complex[14,18,20–23,25,26,29,33,35,38–43] or varied, depending on the type of vaccine and the context[14,18,20,21,23,27,28,30,33,35,37–44].

VH is conceptualized in 208 excerpts. The thematic analysis revealed three predominant conceptualizations in 165 (79%) excerpts: cognitions or affect, behaviour and decision making. These three conceptualizations overlap in the majority of the studies and excerpts. Illustrative excerpts of each conceptualization are presented in Table 1. The remaining 45 (22%) excerpts represent a fragmented group of conceptualizations, without emerging themes.

Vaccine hesitancy conceptualized as cognitions or affect. From all 36 studies[14,17,18,20–23,25–53], 98 excerpts were extracted as conceptualizing VH in terms of cognitions or affect, including questioning, emotions or beliefs regarding vaccination. For this conceptualization, we rank-ordered the most frequently used descriptions of VH, including having or expressing concerns[21,25–27,29,30,34–36,40,42,43,46,51,53], doubts[21,28,29,36,43] or questions[21,26,47] and being reluctant[23,27,29,32,36,38,45,49,53,54] or unsure[14,21,27,29,34]. Many authors describe VH as pertaining to beliefs[34,49], attitudes[21,26,37,43,51] or both[23,29,30,55]. Furthermore, vaccine-hesitant individuals are described as ambivalent to vaccination or perceiving ambiguity in vaccine-related risks[21,36,50,53].

Vaccine hesitancy conceptualized as behaviour. From 35 studies[14,17,18,20–23,25–52], 94 excerpts were extracted as conceptualizing VH as a behaviour. The majority of the excerpts describe VH in terms of various behaviours[14,18,20–23,25–27,29,31,32,34,35,37–41,44,45,51], as illustrated by the following example: "VH refers to a 'delay' in acceptance or 'refusal' of vaccines"[14]. Other excerpts describe VH as a range or continuum between the extreme ends of accepting all vaccines and refusing all vaccines[21,22,27–31,33,36,38,43]. In a minority of the excerpts, VH is described as a specific type of vaccination behaviour, including vaccinating as recommended (despite reluctance, concerns or feeling unsure)[26,46,47,49], refusing vaccines[28] or delaying vaccines and choosing an alternative schedule[50]. Some studies explicitly state that VH should not be described as a vaccination behaviour[17,18,36,40]. Within articles, there were inconsistencies in the behavioural descriptions of VH[18,22,26–29,31,38,41].

Vaccine hesitancy conceptualized as decision making. From 19 studies[18,21,23,26,27,30–32,36–38,40,42,44,45,50,52,53], 30 excerpts were extracted as conceptualizing VH in terms of vaccine decision-making. Some authors adopt the term VH when describing individuals who are undecided, indecisive or under consideration, and not yet having made a final vaccine decision[21,23,26,31,32,45,50]. Vaccine-hesitant individuals are described as being in various states of indecision[23,31,32,37] or as seeking more information to make 'the right decision' about vaccination[21,53]. Moreover, some authors describe VH as an approach to[38] or a transient stage in the process of vaccine decision-making itself[21,23,37].

Vaccine hesitancy and related concepts. VH is often described in relation to other concepts. We extracted 142 excerpts from 31 studies describing closely related concepts[14,18,20–23,25–27,29,30,32–36,38–48,50–53]. The three most common concepts are confidence or trust, complacency and convenience. Together, these are referred to as 'the 3 Cs'[14] and described in 69 of 142 (49%) excerpts. Most often, the 3 Cs are described as having a causal relationship with VH and as representing determinants[14,18,20,29,33,35,38,41,48,56].

From 25 studies, 46 excerpts were extracted as describing confidence[14,18,20–23,25–27,29,30,33–36,38,39,41–44,46–48,52]. 'Confidence' is defined as the trust that people have in the immunizations, the healthcare system itself, and the process leading to decisions on licensing or recommended schedules[14,27,35]. Few studies describe the (lack of) trust or confidence as a component of VH[23,34,52].

From 22 studies[14,18,20–23,25,26,29,30,33,35,38–41,43,44,47,48,50,52], 41 excerpts were extracted on the theme of complacency. 'Complacency' is the individual evaluation of the risks and benefits of vaccines and of the need to vaccinate[14,18,20,35]. The concept of complacency in relation to VH is described as the tendency to perceive the risks of vaccination as unknown or disproportionally high and the risks of the vaccine-preventable disease as low[44,50]. Vaccine-hesitant individuals are more committed to assessing vaccine risks and seeking ways to minimize them[23,40,47,50].

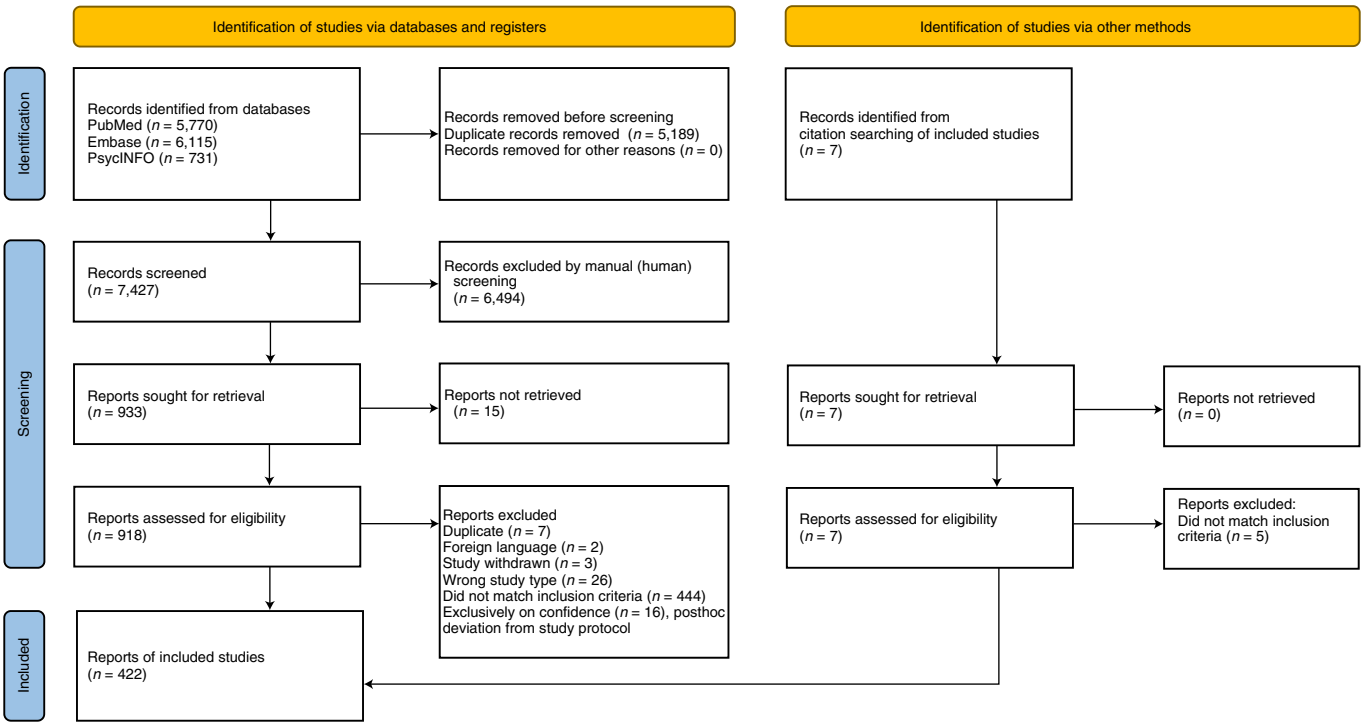

Fig. 2 | PRISMA flow diagram. Visualization of the process involving identification of records from databases, screening of records, assessing reports for eligibility, inclusion of eligible studies and exclusion of non-eligible reports with reasons for exclusion. The number of records or reports in each step of the process is shown in brackets.

From 15 studies[14,18,20–22,25,29,33,35,38,39,41–43,48], 27 excerpts were extracted as describing the theme of convenience. 'Convenience' concerns not only physical availability and geographical accessibility of vaccines, but also the user-friendliness of and ability to understand immunization services[14,18,35,42]. In our analysis, we found that many authors refer to convenience by describing VH as the delaying or refusal of vaccines 'despite availability'[14,18,21–23,25,26,29,33,35,38,39,41]. This description acknowledges that availability of vaccines is related to vaccine uptake, while VH itself is not influenced by availability issues. However, one study adopts inconvenience and difficulty to access vaccines as dimensions of VH[42].

Variations between research fields and vaccine types. We identified the respective research field and vaccine type of each study in the qualitative analysis to explore related differences in descriptions of VH. We identified 19 public health studies[18,21,23,25–29,32,33,36–38,41,45,47,50,51,53], 6 paediatric studies[14,31,34,35,39,48], 8 social science studies[17,20,22,42,44,46,49,52] and 3 biomedical studies[30,40,43]. The primary difference observed was that conceptualizations of VH in terms of decision making emerged predominantly in the public health[18,21,23,32,38,50,54] and social science fields[42,44,52]. In studies conceptualizing VH in terms of cognitions or affect, the terms 'beliefs' and 'concerns' were used in all research fields, while 'reluctance', 'doubts' and 'questions' were used almost exclusively in the public health field. The conceptualization of VH as a behaviour occurred in all research fields.

VH was discussed in relation to vaccination in general[14,17,18,22,23,27–29,32,33,35,36,38,41–43,46,48,49] or specifically with regard to childhood vaccines[21,25,26,30,31,34,37,39,40,47,50,51,53], in 19 and 13 of the studies, respectively. The remaining 4 studies discussed VH in relation to COVID-19[44,45,52] and influenza[20]. Our analysis compared the studies on general vaccination and childhood vaccines but found no major differences in their respective conceptualizations.

Vaccine hesitancy subpopulations. Of the 422 included studies, 63 identified various VH subpopulations. We extracted text excerpts describing the classifications of these subpopulations and the authors' rationales for the distinctions. The analysis identified themes aligned with the three VH conceptualization categories. Fourteen studies grouped VH subpopulations on the basis of criteria from the conceptualization as cognitions or affect[21,23,57–68] and 3 studies grouped VH on the basis of the conceptualization of decision making[69–71]. VH subpopulations grouped solely on the basis of criteria from the behaviour conceptualization were not found. However, 19 studies grouped hesitant individuals on the basis of criteria from the conceptualizations of both cognitions or affect, and behaviour[26,47,72–88]. The remaining 27 studies did not identify subpopulations in terms of the three conceptualizations. Twelve studies identified subpopulations on the basis of degree of VH[51,89–99]. Although degree of VH does not directly contribute to understanding of the VH concept, the instruments used to quantify it and determine cut-off values for the subpopulations contain valuable information about the operationalizations. These instruments are discussed in the following section. In addition, a group of 10 studies distinguished a VH subpopulation by asking about willingness to be vaccinated but used different criteria to do so[100–109]. This method was mainly found in studies on COVID-19 vaccination, published in 2021. This demonstrates the emergence of a conceptual VH category that was not identified from the conceptual studies. The final 5 studies grouped subpopulations according to miscellaneous criteria[45,49,110–112]. An overview is provided Supplementary Table 3.

Measurements of vaccine hesitancy. Of the 422 studies included, 373 report a measurement of VH in individuals. An overview is provided in Supplementary Table 4, grouping the studies according to the instruments used. The most common, albeit highly heterogenous, method used in 210 (56%) studies is a brief VH assessment comprising 1–3 questions[64–66,68,71,74,75,84,85,88,90,96–98,100,102,103,105–109,111,113–298]. The questions, as well as the criteria or cut-off points used to define hesitancy, vary widely between the studies. The majority of questions used in this method cover operationalizations of VH that

Table 1 | Illustrative excerpts containing a description of vaccine hesitancy

Conceptualization	Used terminology	Excerpt	Source
Cognitions or affect	Concerns	"These types of patients [hesitant] had *concerns* about necessity, safety, novelty, and age appropriateness of certain vaccines."	Deml et al.[26]
	Doubts	"Vaccine hesitant individuals may refuse some vaccines, but agree to others, delay vaccination or accept vaccination although *doubtful* about doing so."	Dubé et al.[28]
	Questions	"... this [VH] group, who are keen to have discussions in which their *questions* are answered satisfactorily…"	Leask et al.[47]
	Reluctance	"The majority of participants defined VH as a *reluctance* to receive recommended vaccination..."	Dubé et al.[29]
	Unsure	"… eligible [VH] parents were those who were '*unsure*' or 'did not want' to get their child vaccinated…"	Dubé et al.[27]
	Belief	"VH parents are a heterogeneous group who tend to have *beliefs* that fall between those of vaccine acceptors and rejecters..."	Opel et al.,[34]
	Attitude	"Many vaccine-hesitant individuals demonstrate nuanced *attitudes* towards immunization rather than dichotomous positive or negative attitudes."	Amin et al.[51]
	Ambivalent	"Some [hesitant] participants were *ambivalent* or reluctant to vaccinate their children..."	Sjogren et al.[53]
Behaviour	Vaccinate despite concerns	"... subgroup of patients [hesitant compliers] who vaccinate despite concerns."	Deml et al.[26]
	Refusal	"It [VH] was not consistently defined and several immunization managers interpreted it, explicitly or implicitly, as limited only to vaccine *refusal*."	Dube et al.[28]
	Alternative schedule	"Hesitancy was defined as not yet making a vaccine decision or choosing to vaccinate their children through an *alternative schedule*,…"	Blaisdell et al.[50]
	Accept, refuse or delay	"Such [VH] individuals may *accept* some vaccines but *refuse* or *delay* others."	Amin et al.[51]
	Continuum	"Hesitancy is thus set on a *continuum* between those that accept all vaccines with no doubts, to complete refusal with no doubts, with vaccine hesitancy the heterogenous group between these two extremes."	MacDonald et al.[14]
Decision making	Indecision	"The term VH should instead only be applied to those parents whose deliberations demonstrate something akin to *indecision*."	Bedford et al.[18]
	Degrees of indecision	"Vaccine hesitant individuals are a heterogeneous group who hold varying degrees of indecision"	Larson[32]
	Process	"We consider VH to be a kind of decision-making *process*."	Peretti-Watel[23]
	Right decision	"Most of these [VH] mothers said that they lacked knowledge to make the *right decision*."	Dube et al.[21]

The excerpts are grouped by the three main conceptualizations of vaccine hesitancy: (1) cognitions or affect, (2) behaviour and (3) decision making. The terminology used to describe vaccine hesitancy is shown in italics.

did not emerge from our conceptual analysis, including intention and willingness. A group of 124 studies assess VH by asking about vaccination intention. For example, one measurement asks "What would you do if a COVID-19 vaccine were available?". Respondents answering either "I would eventually get a vaccine, but wait a while first", "I would not get a vaccine" or "I'm not sure" are all classified as hesitant[169]. A group of 35 studies assess VH by asking about willingness, exemplified by the question: "Are you willing to receive the COVID-19 vaccination?". Respondents answering "yes, but I choose to delay timing of injection" are considered hesitant[100]. Furthermore, 23 studies assess VH by an explicit verbatim assessment of experienced hesitancy levels. This is exemplified by the question: "Overall, how hesitant about childhood vaccines would you consider yourself to be?". Respondents answering "not too hesitant", "not sure", "somewhat hesitant" or "very hesitant" are considered hesitant[136]. Finally, a minority of 14 studies assess VH with questions covering conceptualizations that did emerge from our conceptual analysis; for example, by asking about previous vaccination behaviour: "Have you ever hesitated, delayed, or refused getting a vaccination for your child or yourself due to reasons other than allergies and sickness?". Respondents answering "yes" to this question are considered hesitant[122]. The remaining 14 studies use miscellaneous questions to assess VH. Notably, the intention and willingness measures to assess VH are found mainly in studies published in 2021 on COVID-19 vaccination, while the other methods have been used throughout the covered period and in the context of different vaccines.

The second most common method, applied by 132 (35%) studies, is the use of a validated instrument. The most common instrument, used in 70 studies, is the parent attitudes about childhood vaccines (PACV) survey, introduced by Opel et al.[34]. The PACV consists of 15 questions about immunization behaviour, beliefs about vaccine safety and efficacy, attitudes toward vaccine mandates and exemptions, and trust[299], thereby operationalizing VH as both cognitions or affect, and behaviour. Trust (or confidence) is also included in this instrument. In our conceptual analysis, confidence emerged as a distinct concept, albeit closely related to VH. Clear cut-off points for hesitancy were formulated and applied in the vast majority of the studies using this instrument (shown in Supplementary Table 4). The PACV is variously used in its original form[34,91,299–338], or in adapted[339–355] or shorter versions[51,62,89,93,95,356–361].

Other studies use a variety of validated and broadly used instruments. The SAGE instrument is applied in 13 of the studies[41,362–373], with questions reflecting the different conceptualizations (cognitions or affect, behaviour and decision making) and related concepts including convenience, complacency and confidence[41]. The vaccine hesitancy scale (VHS), used in 39 studies[83,99,374–410], was derived from a subscale of the SAGE instrument, narrowed to conceptualize VH as cognitions or affect and include the related concept of confidence[69]. The studies using the SAGE instrument and VHS use varying outcomes or cut-off values (or no outcomes or cut-off values at all) to define hesitancy (shown in Supplementary Table 4). The Oxford COVID-19 vaccine hesitancy scale was recently designed exclusively for the assessment of VH for COVID-19 vaccination and subsequently applied in 5 studies[44,411–414]. Other instruments described in the context of VH but intended to assess other concepts include the 5C scale[22] of psychological antecedents of vaccine behaviour, the vaccine acceptance scale (which covers the domains cognitions and affects, confidence and legitimacy of government vaccine mandates[46]) and the multidimensional vaccine hesitancy scale covering perceptions regarding vaccines in general[42]. Instruments assessing confidence have also been applied to assess hesitancy[415].

The remaining 31 (8%) studies use a variety of unique, self-developed methods to measure hesitancy. These are classified as 'miscellaneous'[25,50,52,69,73,92,94,416–439]. Examples include measurement of VH based on vaccination rates from medical records[418] and statistical procedures used to group participants according to their patterned responses to a questionnaire[92,439].

Discussion

Our systematic review reveals that VH is conceptualized in the literature as involving cognitions or affect, behaviour and decision making, representing three distinct but interacting entities. Closely related concepts include confidence or trust, perceptions of the need to vaccinate and of risk (complacency), and convenience. VH subpopulations are grouped according to a variety of criteria, with the majority originating in the three identified conceptualizations. Studies measuring VH have used a wide variety of instruments. The most commonly applied instruments include a brief assessment comprising 1–3 variable questions and the PACV for childhood vaccines. The instruments operationalize hesitancy using one or more of the three identified conceptualizations, but also introduce novel conceptualizations including intention and willingness. When synergizing the findings on different VH operationalizations, we found psychological and behavioural operationalizations, with the psychological operationalizations being cognitions or affect, and decision making.

Our findings illustrate the challenge of operationalizing VH, with studies adopting different conceptualizations, subpopulations and measurements. Dubé et al. acknowledged this challenge of operationalizing the VH concept due to its heterogeneity and the diversity in attitudes and behaviours[29]. Furthermore, our findings align with a recent study demonstrating the many interpretations of VH used across Europe[440]. These inconsistencies in terminology are even evidenced in the Merriam-Webster dictionary, where 'hesitancy' is defined as a quality or state of being that involves indecision or reluctance[441], aligning with VH conceptualized as decision making and cognitions or affect, while 'vaccine hesitancy' is defined as the reluctance or refusal to vaccinate[442], thereby also including a conceptualization of behaviour.

In the introduction, we describe interchangeable use of various terms with VH[19,20]. In our review, we also found numerous examples, including 'confidence'[443], 'low intention'[444] and 'unwillingness'[270]. We identify these concepts as related but not synonymous to VH. For instance, some authors note that confidence or trust are used interchangeably in relation to VH[19,22], suggesting equivalent meanings. Others describe an inverse relationship, meaning that lower levels of confidence are associated with higher levels of VH[19,33,54,56,445]. In line with this, VH is described as originating from a lack of confidence[446] and as a possible indicator of declining confidence[56].

Additionally, in our analysis of subgroups and measurements, we found that VH is frequently operationalized in terms of willingness and intention, which we did not find in our conceptual analysis of VH. Willingness and intention to vaccinate, similar to the 'vaccine confidence' concept, are inversely related concepts that are unequivocally linked to VH but are and should not be treated as synonymous. Using these terms interchangeably is not only inappropriate but also contributes to confusion and unclarity of the VH concept. This clarity is needed because unclear concepts give rise to differences in our understanding of its determinants, correlates and consequences, hindering efforts to study and address VH[15,23,440]. Furthermore, at an operational level, there may be a mismatch between a concept and its measures[15]. This is demonstrated in our review by the highly variable methods we found to measure VH, leading to incomparable results. Particularly during 2021, there has been a plethora of studies reporting VH measurements that, due to divergent definitions and methods, have been of questionable value. As a way forward, we base our reasoning for a renewed definition of VH on the three main identified conceptual categories—behaviour, cognitions or affect, and decision making—as these have proven most promising by their repeated representation in conceptual, subgroup and measurement studies

We argue that conceptualizing VH as vaccination behaviour is untenable, as mere behaviour is insufficiently discriminating between hesitant and non-hesitant individuals. For instance, people may accept vaccines with or without hesitation or reject vaccines with or without hesitation. As concepts are ideally defined by a unique set of features that distinguishes them from other closely related concepts[15], vaccination behaviour alone is not sufficient to define VH. Furthermore, vaccination behaviour is generally used as the indicator of (non-)acceptance of vaccination. Thus, to use this also to define another concept would create confusion. Authors have commented on the blurred distinction between VH and refusal of vaccines[25,39] and criticized behavioural operationalization for its failure to capture VH[17,18,23,25,40]. Although we agree that certain types of vaccination behaviour may be manifestations of VH, we argue that including behaviour in the definition and operationalization of VH is neither necessary nor sufficient.

Our analysis shows that VH is furthermore defined by two closely linked conceptualizations that we identify as psychological—cognitions or affect, and decision making. Larson et al. exemplify this stance, arguing that VH is by nature a state of indecision and reluctance[32]. We propose to reject types of vaccination behaviour as a viable conceptualization of VH; this logically results in the proposition that VH should be considered a psychological construct. This is in line with authors who have argued that VH is a psychological state rather than a behaviour[18,22,26,32,40], inspiring our current investigation of what exactly this vaccine-hesitant state entails. In the conceptualization cognitions or affect, VH is mainly described as 'doubts', 'concerns' and 'reluctance' regarding vaccination. Following our analysis, we interpreted these descriptions as different ways of how VH may be affected, experienced or expressed at an individual level, representing a layer surrounding the central element of VH. We therefore interpret cognitions and affect to go hand-in-hand, but not to be at the core of hesitancy. Moreover, we conclude that cognitions or affect are insufficiently distinctive to define VH.

This interpretation does not mean that the identified cognitions or affect are irrelevant to VH. On the contrary, they may prove crucial in shaping VH. However, to arrive at a clear definition of VH, cognitions and affects should be treated as clearly defined entities as well. Only by unravelling and distinguishing them can the exact nature of their relationship with VH be clarified in further research.

In the conceptualization decision making, VH was described as being 'undecided', 'indecisive', 'in consideration' or 'not yet making a vaccine decision'. All these descriptions include an element of indecision, and this provides a unique and distinctive feature for VH. Additionally, we found that this conceptualization is predominantly discussed in studies in the public health field. This is rather logical, as one would expect this field of research to take a more pragmatic approach, examining the presence of VH at a stage where people have been offered a vaccine or to anticipate public sentiments around willingness to accept a vaccine when it is offered. This probably triggers a decision-making process where VH can emerge and manifest. On the basis of these findings, we argue that VH is a psychological state of being undecided, indecisive or not yet making a decision regarding vaccination.

The study selection was conducted independently by different members of our research team. However, one possible limitation is that we did not attempt to exclude studies of lower quality, as we wanted to maintain a robust selection of studies to enable a broad overview of the relevant literature. Our MMAT assessment, however, indicates that the majority of the studies are of medium quality. A second limitation is that a considerable number of the included conceptual studies (17 of the 36)[14,18,20–23,25,26,29,35,38–44] quoted the VH definition introduced by the SAGE working group, which may have led to an amplification of the SAGE definition. This may indicate that this definition is well recognized, but potentially overshadows less recognized conceptual definitions of VH. We chose to include all quoted definitions and found that many studies used more than one. We did not look further into conflicting definitions within the articles, but doing so could yield interesting insights.

In conclusion, we propose a definition of VH as a psychological state of indecisiveness that people may experience when making a decision regarding vaccination. We acknowledge that experiencing concerns, doubts or reluctance regarding vaccination may play a vital role in shaping VH. However, we argue that these factors have the highest potential to advance scientific knowledge when treated as relevant constructs integral to shaping VH, rather than treating them as synonymous to VH. Operationalizing VH by measuring or distinguishing subpopulations should ideally be directed at this state of indecision. To avoid confusion, it is important to separate VH from vaccination behaviour, which is already a well-defined concept. This proposal of a renewed definition of a concept that has been used for a decade could be perceived as 'putting old wine in new bottles'. However, we feel that due to the large amount of highly varied literature, and given the importance of VH research in predicting, explaining and influencing immunization behaviour, it is necessary to take a snapshot of the status quo. The conclusion of this review is that VH is, for now, an impracticable concept, due to the confusing use of multiple, varied operationalizations. To aid further research, the VH concept must be clearly conceptualized and adapted from its broad and inclusive form to a pragmatic and refined alternative. Working on such an alternative, the field should first reach consensus on the definition and then measure VH accordingly. This approach allows for a much-needed comparison between studies to improve our understanding of VH determinants, correlates and consequences on an individual and societal level. Our way forward is to simplify and clarify the operationalization of VH by returning to its root core of indecisiveness.

Methods

This systematic review was registered on 11 November 2020 in the PROSPERO database (CRD42020211046). The record and study protocol are available at https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=211046.

Search. Relevant publications were searched using the PubMed, Embase and PsycINFO databases to ensure coverage of all relevant research areas in the medical, public health and social science fields. The CINAHL database was also considered, but a pilot search revealed that its unique contributions were limited.

An experienced research librarian used the following keywords to develop a search strategy (Supplementary Methods): 'vaccination', 'immunization', 'vaccination refusal', 'vaccination avoidance', 'vaccination hesitation', 'vaccine hesitancy', 'vaccine uptake', 'vaccination behaviour', 'vaccination attitude', 'vaccine confidence', 'vaccine acceptance' and 'vaccine barriers'. The limitations included a publication date of between 2010 and the date of the search (14 January 2022). Conference abstracts were excluded from the search of the Embase database.

Eligibility criteria. The included studies were all published in peer-reviewed journals and written in English. All study types were eligible, except editorials and commentaries, as we sought to include original studies. Studies on animal vaccines were excluded.

The purpose of this review was to clarify the VH concept by analysing how it is operationalized. We recognized operationalizations at two main levels: conceptual and empirical. This resulted in three main groups: (1) studies describing or defining the VH concept and studies applying the concept by (2) identifying VH subpopulations and (3) measuring VH in individuals. This approach allowed comparison between conceptual and empirical operationalizations of VH.

Study selection. In the first selection round, two members of the research team used RAYYAN software to independently assess the titles and abstracts. Studies were selected when the title or abstract contained the term 'vaccine hesitancy'. Studies were also selected if the title or abstract indicated that the full text contained further information on VH conceptualization, subpopulations or measurements. Papers without an abstract were selected for full-text screening. After double-screening, the results were de-blinded to allow the researchers to discuss their conflicting judgements until consensus was reached.

In the second selection round, the full texts were screened. The first 30% of studies were double-screened to establish a uniform method. Studies were screened on whether they met the criteria for one or more of the three categories (conceptualization, subpopulations and measurements). The category of 'conceptualization' included studies that describe, discuss or explore the VH concept or propose a novel VH measurement instrument. Studies falling into only the second category (subpopulations) were excluded if they merely distinguished between hesitant and non-hesitant groups, since a dichotomous grouping does not contribute to understanding of VH. The references from the included full-text articles were screened to find additional studies matching the selection criteria.

We deviated posthoc from our preregistered study protocol by adjusting the study selection criteria as follows. Initially, we also included studies containing the term 'vaccine confidence' (that is, with no mention or operationalization of vaccine hesitancy) as indicated in our study protocol. During the process, we realized that this deviated from our primary aim to clarify the VH concept by differentiating its related concepts. Therefore, we adapted the protocol and excluded 16 studies that were exclusively on vaccine confidence from our analysis

Data collection. The study characteristics were extracted from each of the full-text articles. Data were extracted by one researcher and verified by a second member of the research team. The variables included the first author, year of publication, research field of the first author, type of study, type of participants, number of participants, type of vaccination and country in which the study was conducted (with corresponding economic status)[44,47]. For the studies that do not include data collection, the country of origin was determined using the affiliation of the first author.

From the studies on VH conceptualization, text excerpts that define or describe VH or describe the relationship of VH to other concepts were extracted. These excerpts were further analysed in the qualitative analysis. From studies that describe different VH subpopulations, information about the categorization of these various subgroups was extracted, including the rationale for the distinguished subpopulations. From studies that describe VH measurements, the instrument(s) and criteria used to define VH were extracted.

Synthesis of results. The text excerpts extracted from the studies conceptualizing VH were thematically coded using ATLAS.ti software. Three research team members developed a coding book of themes and subthemes after independent coding of 30% of the studies. Thereafter, one researcher continued the coding process for the remaining studies. Any emerging new codes were discussed with the other research team members. The results were analysed qualitatively, and the predominant themes were identified by the three team members. When possible, results were grouped by research field and vaccine type to allow for comparison.

The data extracted from the studies describing VH subpopulations were summarized in a table and grouped according to the common themes identified. The data extracted from the studies describing a VH measurement were summarized in a table and grouped according to the instrument or method used. Where multiple measurement instruments are used in one study, the tool used to determine hesitancy was selected as the main instrument.

Quality assessment. The quality of each study was assessed using the MMAT[44,48]. This tool contains appraisal guidelines for different study types, covering the majority of the included studies. An overall score was calculated (1–5) on the

basis of additional communication about the MMAT 2018 version, with higher scores indicating higher quality levels[449]. The first 20% of studies were assessed independently by two members of the research team to ensure consistency. Thereafter, one member of the research team continued the assessment.

Reporting summary. Further information on research design is available in the Nature Research Reporting Summary linked to this article.

Data availability

All data generated or analysed during this study are included in this article and its Supplementary Information. This systematic review is registered in PROSPERO (CRD42020211046).

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Author contributions

D.B.-V., J.L.A.H., O.V. and M.E.J.L.H. designed the project and analysed the data. D.B.-V., J.L.A.H., L.V., O.V. and M.E.J.L.H. interpreted the data. The manuscript, figures and tables were drafted by D.B.-V. and edited by J.L.A.H., L.V., O.V. and M.E.J.L.H.

Competing interests

The authors declare no competing interests.

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Study description	Systematic and qualitative literature review aiming to clarify the VH concept by analyzing how it is operationalized and suggest a way forward
Research sample	We recognized operationalizations at two main levels; conceptual and empirical. This resulted in three main groups; 1) studies describing or defining the VH concept and studies applying the concept by 2) identifying VH subpopulations and 3) measuring VH in individuals. Therefore, studies were included when a conceptualization, subpopulation or measurement of VH was described. The category conceptualization included studies with the purpose to describe, discuss or explore the VH concept or design a novel VH measurement instrument. The included studies in these three groups give a representative overview of the VH concept in the literature.
Sampling strategy	Relevant publications were searched using the PubMed, Embase and PsycINFO databases to ensure coverage of all relevant research areas within the medical, public health and social sciences.
Data collection	Study characteristics were extracted from included articles using a data extraction template. From the studies including VH conceptualizations, text excerpts were extracted that contained a definition and/or description of what VH, or a VH synonym, is or is not, or a description of the relation of VH to other concepts. These excerpts were further analyzed in a qualitative analysis using ATLAS.ti software. For studies that described different VH subpopulations, information about the identification of the various subgroups was extracted to a talbe, including the rationale behind distinguished subpopulations. From studies that described VH measurements, the instrument(s) and the criteria used to define VH were extracted to a table. The researchers were not blinded during data collection. The purpose of this review was to clarify the VH concept by analyzing how it is operationalized and suggest a way forward; no hypotheses had been established beforehand.
Timing	Studies were included when published between 2010 and the search date, January 14 2022.
Data exclusions	Papers were included when published in a peer reviewed journal and written in English. All study types were eligible except editorials and commentaries, since we aimed to include original studies. Additionally, studies on animal vaccines were excluded.
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