



## INTRODUCTION

- Qualitative research can elucidate complex and sensitive topics in healthcare to provide insights into the patients' journey, experiences, and disease burden in ways that quantitative research is not able to
- By leveraging semi-structured discussions, qualitative research methods aid researchers to better understand the spectrum of disease impact on patients holistically, across multiple domains
- Healthcare organizations including the World Health Organization (WHO) have also endorsed the use of qualitative research in drug development, reimbursement, and payer decision-making<sup>1,2</sup>
- HTA agencies and payer decision-makers also refer to qualitative research findings to ensure their decisions remain patient-focused

## OBJECTIVES

- To identify and evaluate qualitative research methods used for evidence generation globally

## METHODS

- This literature review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist<sup>4</sup> paired with hand searching of literature (Figure 1)
- Manuscripts and conference abstracts published from 2017 to 2022 in PubMed and meeting the eligibility criteria were included
- Hand searching was also conducted to include relevant articles and grey literature (presentations, whitepapers, online reports, and articles) that met eligibility criteria
- The key search terms used (alone or in combination) included "qualitative research or study", "qualitative study", "observational study", "real world evidence", "qualitative interviews" etc.
- Inclusion criteria:** Primary qualitative/mixed research studies conducted in a patient population and in English language only;  
**Exclusion criteria:** Studies validating Patient Reported Outcome (PRO) questionnaires as an outcome

Figure 1 | PRISMA

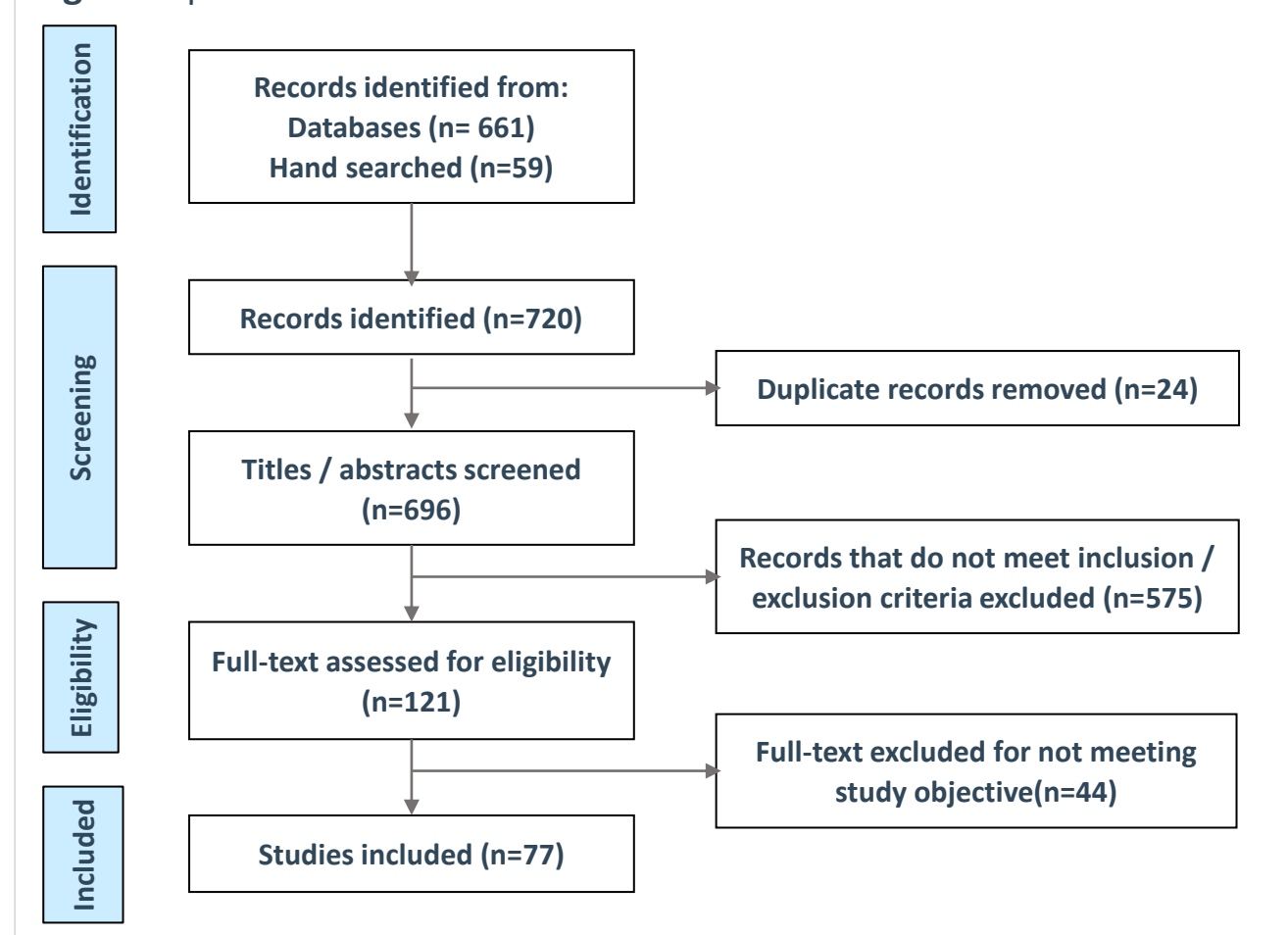
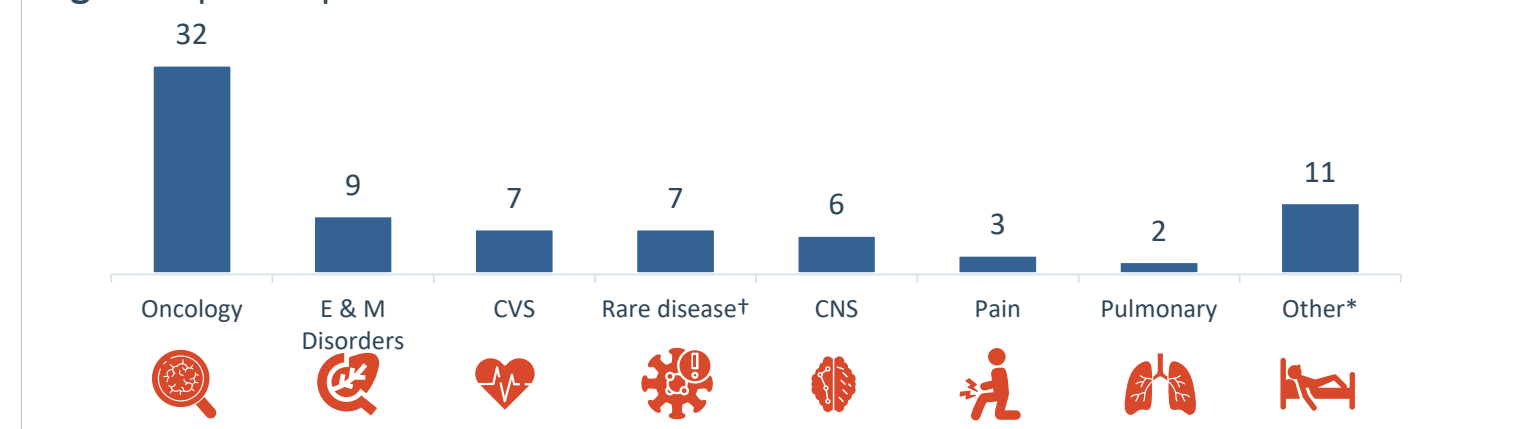


Table 1 | Details of Included Studies

Descriptives of Included Studies	N=77 <sup>5-81</sup>
<b>Country [n(%)]</b>	
United States	18 (23%)
United Kingdom	9 (12%)
Canada	9 (12%)
Australia	7 (9%)
Sweden	6 (8%)
Norway	5 (6%)
<b>Sample size [mean(SD)]</b>	19 (±10)
<b>Population type [n(%)]*</b>	
Adults (≥18 years)	70 (91%)
Pediatric (≤13 years)	5 (6%)
Adolescents (14-17 years)	4 (5%)
Geriatric (≥60 years)	1 (1%)
<b>Study type [n(%)]</b>	
Only qualitative	67 (87%)
Mixed methods (qualitative and quantitative)	10 (13%)
<b>Studies conducted by Manufacturers<sup>§</sup></b>	8 (10%)

Note: Study types are not mutually exclusive; <sup>§</sup> Qualitative research studies specifically conducted by drug manufacturers included therapeutic areas (Tas) such as oncology, asthma, nasal polyp, and rare diseases such as Type 1 Usher syndrome (USH1), Stargardt disease, Congenital Athymia, and X-Linked Hypophosphatemia; all TAs found in the literature are summarized below

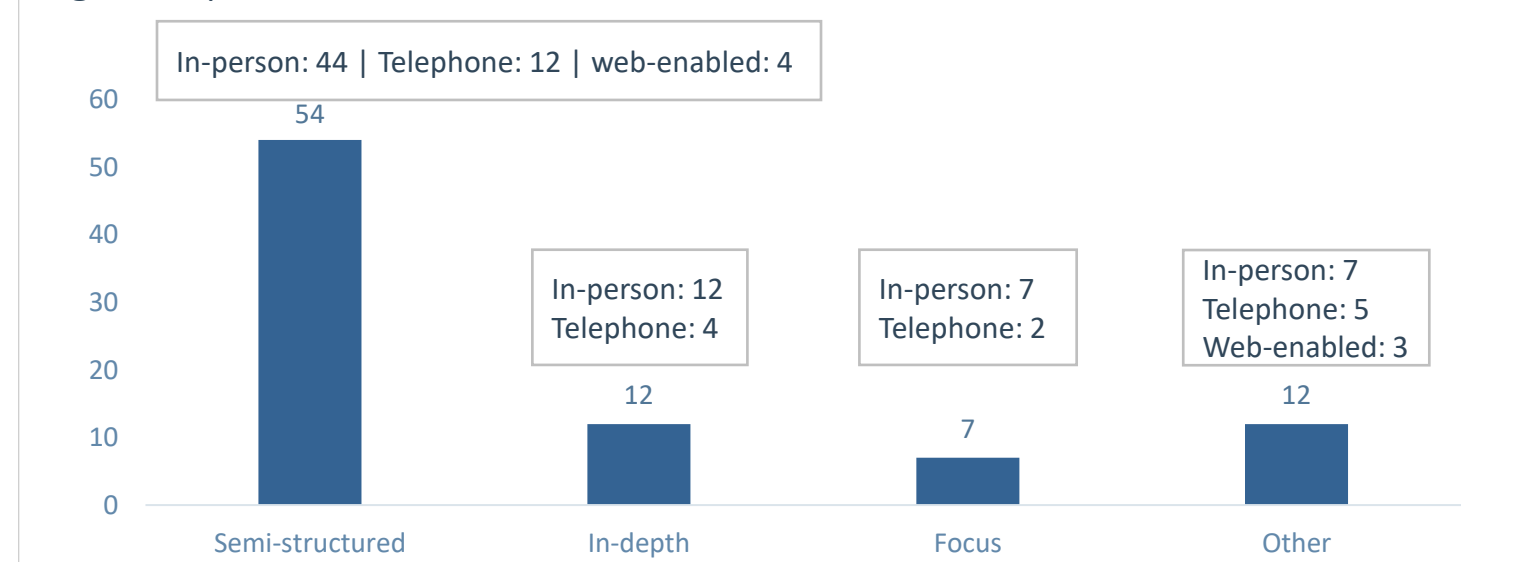
Figure 2 | Therapeutic Areas Evaluated in Included Studies



**Key Findings:** Oncology (42%)\* was the most evaluated TA across all studies. Patients with breast cancer, diabetes, rare diseases, and cancer survivors were commonly assessed. Qualitative research is carried out in a wide range of TAs and has been used effectively to demonstrate a wide variety of patient-centric metrics

References: <sup>7,9-10,16,18-19,22,24-25,27-28,30,35,40,42,45,47,50,52,54,56-57,59,64,72,73,74,76,78-79</sup>; Note: <sup>†</sup>Rare Disease: Authors categorized disease/condition affecting less than 200,000 people in the US as rare diseases in this study; Rare diseases included Type 1 Usher syndrome (USH1), Stargardt disease, Hemophilia, Acromegaly, Congenital Athymia, X-Linked Hypophosphatemia \*Others: Gastroenterology, neurology, musculoskeletal disorder, sleep disorder, neurovascular, gynecology, nephrology, and medical devices; please scan the QR code for abbreviations

Figure 3 | Data Collection Methods Utilized across Included Studies



**Key Findings:** The majority of interviews were semi-structured (62%)\* in nature and were conducted face-to-face either at healthcare facilities, interviewees' homes, or any place comfortable to the interviewees. Web-enabled interviews were seldom conducted using video enabling applications; other data collection modes included questionnaires, surveys and PROs to collect data from the respondents

References: <sup>15,7,11,14,16,19-30,32-33,37-43,45-47,49-51,53-57,60-64,66,68-74,78,80-81</sup>; Note: Type of data collection methods are reported as mentioned in the studies and not interpreted by the authors. \*A combination of data collection methods were used in some studies (e.g., in-person or by telephone)

## RESULTS

Table 2 | Use of Different Data Analysis Methods to Investigate Diverse Study Types/Topics

Data Analysis Method	Number of Studies (N)	Details of Data Analysis Methods Used	Study Types/Topics (% number of studies)*
Thematic Analysis <sup>5-39</sup>	35	<ul style="list-style-type: none"> <li>Inductive, deductive or abductive approaches to thematic analysis</li> <li>Constant comparison methods captured recurrent themes</li> <li>Braun and Clarke's six-phase framework commonly used for analyzing data which involves data familiarization, generating codes, searching for themes, reviewing, defining, and reporting them</li> </ul>	
Content Analysis <sup>40-52</sup>	13	<ul style="list-style-type: none"> <li>Comparison, categorization, condensation and structuring of meaning through narratives</li> <li>Enables opportunity to evaluate Institute of Medicine's 6 domains of quality framework</li> <li>Method involves introducing variables in the materials for capturing patterns and contradictions</li> </ul>	
Phenomenology <sup>53-60</sup>	8	<ul style="list-style-type: none"> <li>Giorgi's phenomenological analytic methodology, Ricoeur's phenomenological-hermeneutic approach, Colaizzi's method, van Manen's method, and interpretative phenomenological analysis were reported in the studies</li> <li>Method of choice to understand the meaning of experience associated with a phenomenon, suited for under-researched groups</li> </ul>	
Framework Analysis <sup>51,61-64</sup>	5	<ul style="list-style-type: none"> <li>Familiarization with data, theme identification, indexing, charting of emerging themes, and synthesizing data to conceptualize thematic categories</li> </ul>	
Grounded Theory <sup>65-68</sup>	4	<ul style="list-style-type: none"> <li>Interviews were based on topic guides</li> <li>Constructivist, emergent or Charmaz's approach were used to analyze the data</li> </ul>	
Systematic Text Condensation <sup>69-71</sup>	3	<ul style="list-style-type: none"> <li>Inspired by systematic text condensation in four steps according to Malterud, which involves chaos to themes, from themes to codes, code to meaning and finally condensation to description and concepts</li> <li>Includes obtaining an overall impression of the interviews, creating preliminary meaning units, sorting into subthemes and condensing into main themes</li> </ul>	

Note: Other data analysis methods included interpretive description<sup>72-74</sup> (n=3), inductive approach<sup>75</sup> (n=1), inductive and iterative analysis<sup>76</sup> (n=1), narrative analysis<sup>77</sup> (n=1) \*Pie charts for study types are not comprehensive and include other study topics for e.g., patients' feedback on a treatment program/regimen, and public health initiatives

Figure 4 | Reported Reasons for Conducting Qualitative Research



Note: Not a comprehensive list of reasons for conducting qualitative research reported in the studies

Table 3 | Regulatory and Payer Perspective on Including Qualitative Research in Decision Making

Country	FDA and HTA Guidance on Including Qualitative Research in Decision Making
USA	US FDA developed a 4-series guidance document for patient-focused drug development to address collection, and submission of patient experience data for regulatory decision making <sup>82-85</sup>
GBR	NICE health technology evaluation manual (PMG36) recognizes qualitative evidence synthesis to explore values, preferences, acceptability, feasibility, and equity implications in the decision-making process <sup>86</sup>
DEU	IQWiG has guidelines on qualitative research methods and syntheses in development of health information for decision making <sup>87</sup>
ESP	Qualitative research methodological guidelines are included in RedETS HTA guidelines and the Patient Involvement Strategy <sup>88</sup>
CAN	CADTH guidelines for qualitative research and evidence synthesis are in a rapid review process <sup>89</sup>

Note: HTA bodies across France and Italy did not have specific guidelines or recommendations for inclusion of qualitative research to include patient voice in the decision-making process. Further research is recommended to characterize the use of qualitative to aid manufacturers prepare for HTA submissions International bodies including WHO and EUPATI have recommendations and guidance for patient involvement in HTA processes<sup>1-2</sup>

## DISCUSSION & CONCLUSION

### Critical to Capture Patients' Voices Using Qualitative Research

- Qualitative methodologies are one of the most appropriate and patient-centric approaches to discovering and capturing humanistic experiences and viewpoints directly from the research participants (i.e., patients in this instance)
- Researchers use creative data collection methods and leverage various methodologies to test their hypotheses using qualitative research
- As a result of the unprompted data collection approach, qualitative research captures open-ended responses, thereby discovering unexplored aspects of patients' disease burden compared to a closed-ended, quantitative assessment of patients' unmet needs
- Manufacturers also utilize this versatile and credible research method to understand disease burden, impact on quality of life, and patient perspective on clinical trial endpoints across many disease areas, especially in rare diseases and oncology

### Synthesis of Qualitative Research Approaches

- Researchers utilized a variety of study designs, coding rules, analytical processes, and reporting guidelines to demonstrate the rigor of qualitative research methods and ensure the scientific validity/reliability of the study findings

### Role of Qualitative Research in HTA and Reimbursement Decision Making

- Payer organizations include qualitative research in their evaluations and reimbursement coverage decision-making process due to its ability to collect patient input, identify the unmet needs/patient challenges, and determine necessity for a new treatment
- Further research is required in developing standard processes for incorporating qualitative patient research in HTA and/or payer assessments

# Abbreviations

CADTH: Canadian Agency for Drugs and Technologies in Health

CNS: Central Nervous system

CVS: Cardiovascular System

E & M Disorders: Endocrinology and Metabolic Disorders

EUPATI: European Patients' Academy on Therapies

FDA: U.S. Food & Drug Administration

HTA: Health Technology Assessment

IQWiG: Institute for Quality and Efficiency in HealthCare

NICE: National Institute for Health and Care Excellence

TA: Therapeutic area

WHO: World Health Organization

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