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Brief communication

## The ethical challenges and opportunities of implementing engagement strategies in health research

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## ABSTRACT

**Purpose:** The American College of Epidemiology (ACE) held its 2019 Annual Meeting in Pasadena, California, September 7–10 with a theme of “Real-World Epidemiologic Evidence in Policy and Practice”. The ACE Ethics Committee hosted a symposium session at the annual meeting on the ethical challenges of stakeholder engagement in the health research setting. The purpose of this paper is to further examine the design and conduct of stakeholder engagement and reflect on the ethical challenges with the goal of offering best practices and identifying areas where future guidance, critical reflection and teaching may be needed.

**Methods:** Three speakers with diverse affiliations were selected to present on the opportunities and ethical challenges of stakeholder engagement in epidemiology and community health. Dr. K Coleman presented an “Overview of Stakeholder-Engaged Research Strategies” and “Engaging Stakeholders in Retrospective Observational Studies”; Dr. J Salerno presented on “An Ethical Perspective to Optimize Engagement Strategies”; and Ms. F Jones presented on the “Structure of Community-Partnered Participatory Research”.

**Results:** Three main insights were identified: (1) the need for a unifying framework of ethical principles for the implementation of stakeholder engagement, (2) an expanded set of research activities for stakeholders aligned with their engagement in epidemiology studies, and (3) strengths of a community-based partnership model of stakeholder engagement in community health, known as community-partnered participatory research (CPPR).

**Conclusions:** There is a need to broaden the dialogue and understanding of stakeholder engagement for researchers who are increasingly faced with the ethical challenges of implementing approaches and strategies to engage patients, communities, policy makers and the public as stakeholders. To address current challenges, we offered a unifying framework to guide best practices of stakeholder engagement by integrating the core ethical principles of research conduct involving human subjects with the guiding principles of patient engagement. We shared 2 model overviews of implementing stakeholder engagement: (1) a 4-staged model when implementing stakeholder engagement using an epidemiological study design, (2) a stakeholder engagement model rooted in authentic academic-community partnerships, known as community-partnered participatory research (CPPR) to address depression disparities. By critically reflecting on stakeholder engagement across disciplines and appraising the opportunities and ethical challenges of implementing stakeholder engagement in health research, we have provided insights on how to operationalize, conduct and implement stakeholder engagement and have contributed to moving this important field forward.

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## Introduction

Stakeholder engagement in health research, health system planning, and policy involves the use of diverse approaches by researchers, health system planners, and policy makers to integrate the perspectives, values, and lived experiences of affected individuals to enhance the understanding of a given health or community issue, and to use that new knowledge toward improving health research and action to benefit individuals and communities [1–3]. The potential impacts and benefits of engagement include: improved research quality and relevance, building community and individual capacity [4–6], providing an opportunity to those affected, the democratic right to contribute to health-related activities [7,8], enhanced mutual co-learning by stakeholders and researchers, increased stakeholder trust in research and researchers, and improved research uptake and adoption [9].

The growth of health researchers to utilize stakeholder engagement approaches has been driven by the establishment of a number of international bodies and funding agencies, including the U.S. Patient-Centred Outcomes Research Institute (PCORI) [10] and the Canadian Strategy for Patient-Oriented Research (SPOR) [11]. To achieve the goals of patient-engaged research (i.e., patient-oriented research), these organizations have outlined several key elements as guiding principles that health researchers ought to demonstrate in all aspects of their research. In the U.S., the PCORI guiding principles of patient engagement include reciprocal relationships, co-learning, partnerships, transparency, honesty, and trust [12]. In Canada, the SPOR guiding principles of patient engagement include inclusiveness, support, mutual respect, and co-build [13]. Although seemingly different and novel, patient-oriented research principles align with the principles of community-based participatory research (CBPR) which are rooted in active community-based partnerships, equity in decision-making by non-researchers, and community stakeholder's participation in all aspects of the research [6,11,14].

Researchers face the challenge of putting into practice these principles while accounting for the diverse and sometimes disparate perspectives of their multidisciplinary teams and the context of their projects. A growing body of literature has aimed to offer guidance on how to conduct and ensure meaningful stakeholder engagement by clarifying definitions [15], suggesting a mechanistic approach [16], and synthesizing the multitude of frameworks [17]. Less attention has been given to integrating ethical issues related to partnerships in health research [4]. We recognize that international research ethics frameworks (e.g., Belmont, Tri-Council Policy Statement) support the principles of patient and community engagement. We aim to demonstrate more explicitly the link between these principles to guide the best practices of implementing stakeholder engagement in health research (Fig. 1). Furthermore, we recognize that there is a need to increase the awareness and knowledge of successful partnership models of engagement for diverse audiences and population and public health disciplines (i.e., epidemiology).

The objectives of this paper are to fill the knowledge gap on the ethical challenges of stakeholder engagement and highlight oppor-

tunities and successful models of stakeholder-engaged research in epidemiology and community health. The American College of Epidemiology (ACE) Ethics Committee hosted a symposium session at the 2019 Annual Meeting in Pasadena, CA, September 7–10. Three topic areas were presented: engaging stakeholders in retrospective observational epidemiology studies (K.C.), an ethical perspective to optimize engagement strategies in health research and program planning (J.S.), and community-partnered participatory research, a model of engagement in community health research (F.J.). An overview of stakeholder-engaged research strategies was also presented (K.C.) This paper presents a summary and further discussion of the speakers' symposium presentations.

## Overview of stakeholder engagement

In this paper, we use a broad definition of stakeholder to include “an individual or group who is responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence” [2]. Notwithstanding, the extent to which any given stakeholder may be engaged may vary. The Spectrum of Engagement [18] framework depicts the level of engagement on a continuum marked by 2 boundaries. At the lower tier of engagement are approaches of input/consultation or informing, where health information has been developed externally to the individuals and communities who may be impacted, but they are being invited to provide input based on their lived experiences and unique perspectives. They are also provided with health-related information to further their understanding of the topic under consideration. Information may be disseminated using pamphlets, brochures, and websites in addition to meetings and discussion groups. At the higher tier of engagement are approaches of partnership/collaboration and empowerment, where decision-making on a health issue has been co-developed equally, with shared control over the process, and insofar as to place the final decision-making in the hands of the impacted individuals or communities. This shared decision-making can be accomplished using governance structures that meet on an ongoing basis such as a council, working group, an advisory committee or panel to ensure meaningful engagement [18–20]. Within these different levels, the roles and activities of stakeholders may involve defining research priorities, participation in the development of research proposals including the selection of data variables and the identification of patient-relevant outcomes, as well as in the interpretation of results and publishing in peer-reviewed academic journals, among other activities [21].

## Ethical challenges of stakeholder engagement

Some of the ethical challenges to stakeholder engagement are notable prior to initiating the research or health planning and policy activities. Do questions remain about whether there are ethical obligations at the pre-implementation (i.e., planning phase) of a project or research study that aims to engage either individuals or communities as stakeholders? Current guidance indicates a need for ethical sensitivity early-on [22] and throughout stakeholder engagement [23]. Ethical considerations are intended to be supportive and to mitigate negative consequences, such as: (1) allocating sufficient time; (2) avoiding tokenism; (3) communicating clearly; (4) allowing for immediate withdrawal; (5) promoting diversity and inclusion; (6) being clear about activities and whether they fulfill the definition of research or not; (7) working sensitively; (8) being conscious of confidentiality; and (9) valuing, acknowledging and rewarding stakeholders for their engagement [24]. Ethical considerations also include creating a meaningful learning environment such that each stage of work is informed as a result

*Abbreviations:* CPIC, Community Partners in Care; CPPR, Community-Partnered Participatory Research; IAP2, International Association for Public Participation; PCORI, Patient-Centred Outcomes Research Institute; SPOR, Strategy for Patient-Oriented Research; TCPS, Tri-Council Policy Statement; W4W, Witness for Wellness.

*Conflict of interests:* The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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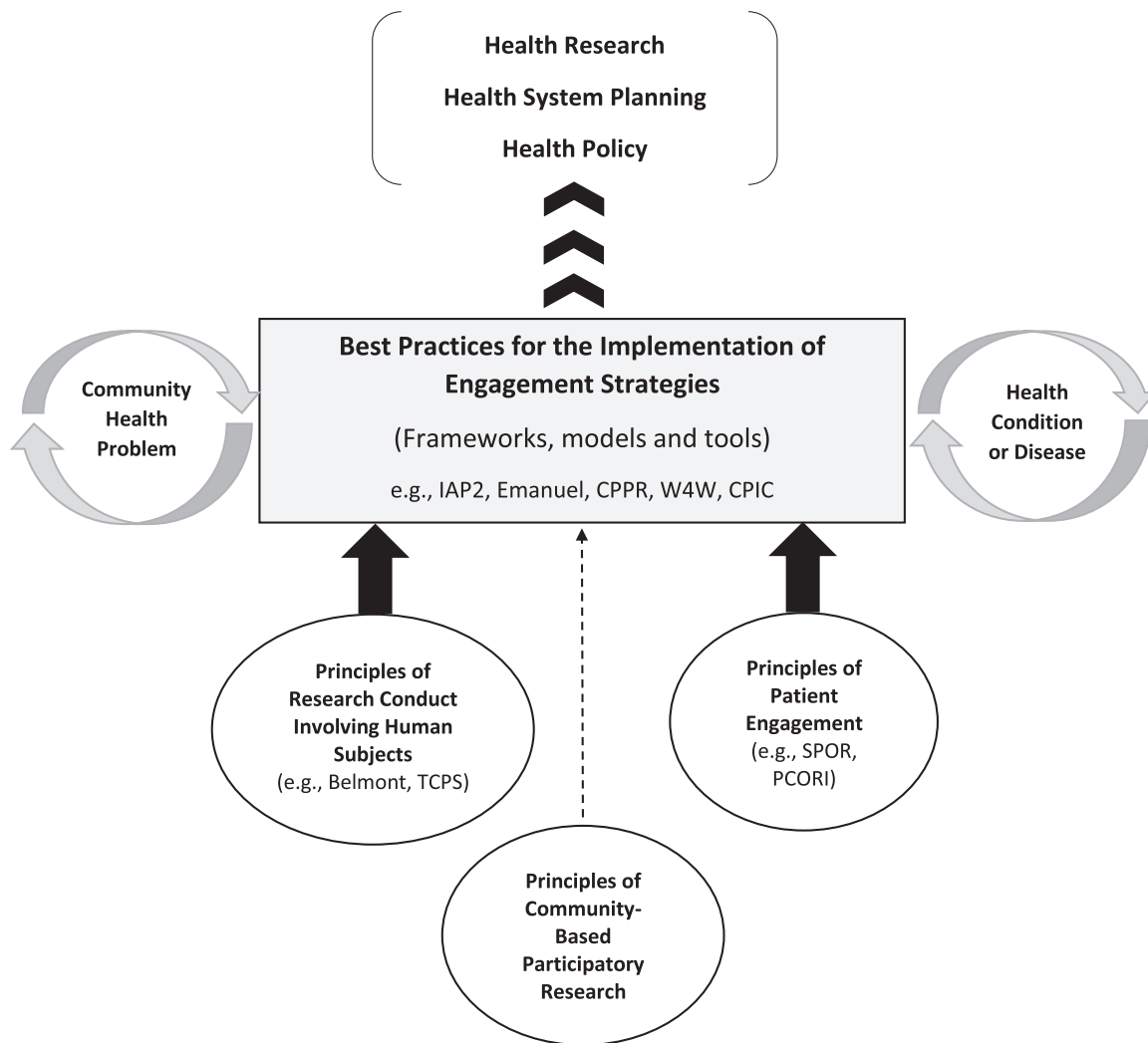


Fig. 1. Integrated framework of stakeholder engagement.

of integrated knowledge and where stakeholders' potential learning needs about the health system (i.e., access to health and social care), research methods, and processes are addressed [8]. The Emanuel Framework is a useful guide to address a number of these ethical challenges as it places the conduct of engagement alongside research conduct involving human subjects by using the principle of collaborative partnership as the starting point (e.g., how will the community benefit? how will responsibility be shared? how will respect be demonstrated? how will the benefits of research be shared to ensure fairness?) [23,25].

Additional ethical challenges arise as it relates to individual and community identification. Questions arise regarding who represents the community and how the community is defined, how integrated or credible are those representing the community, and how they are aligned with other community groups or organizations [3]. There are challenges in determining the nature of metrics to define the community or whether increasingly broad and diverse societal groups should be included [26]. During a global health crisis, such as the current COVID-19 pandemic, engaging with vulnerable and marginalized communities can provide insights into social and structural barriers, provide tailored solutions, and improve preventative efforts and compliance measures [27]. There is the potential for selection bias as those who self-select to participate may be more motivated and confident to participate [28] and biases introduced depending on who may be leading the

recruitment efforts [29]. The potential consequence is misrepresentation of the relevance and impact of the proposed work.

### Integration of stakeholder engagement into traditional research ethics

Like many research ethics guidance documents (e.g., Belmont, Helsinki), the core principles for research involving human subjects include respect for persons, beneficence, and justice, and their application to the conduct of research involving human subjects, including procedures of informed consent, assessment of risks and benefits, and the selection of participants [30–33]. Traditional biomedical ethics do not lend themselves easily to stakeholder engagement. The distinguishing feature is that stakeholders are intended to be members of the professional research team, whereas research participants are the subjects of the research being undertaken [12]. To begin to shed light on the ethical challenges encountered in the conduct of stakeholder engagement, we aligned the core research ethics principles to the principles of stakeholder engagement (i.e., PCORI and SPOR), with the hope to turn these critical reflections into best practices for the future. As shown in Table 1, we offer a unifying framework and outline practical applications to demonstrate the principles.

**Table 1**  
Integration of research ethics principles with the principles of engagement

Ethics principles	Engagement principles	Practical applications
Respect for persons	<ul style="list-style-type: none"> <li>■ Mutual respect*</li> <li>■ Reciprocal relationship†</li> <li>■ Transparency, honesty, and trust‡</li> </ul>	<ul style="list-style-type: none"> <li>■ Stakeholders' lived experiences, expertise and personal perspectives should be valued and a source of knowledge.</li> <li>■ Stakeholders ought to be given the opportunity to choose what shall or shall not happen to them and their communities.</li> <li>■ Meaningful engagement such that individuals and communities participate actively in open and honest communication when health decision-making is occurring and informing them of their contributions, not merely seeking approval.</li> <li>■ Respect for persons is upheld when stakeholders are treated as autonomous agents and when the roles, responsibilities and expectations for engagement and the rules for decision-making in the partnership are clearly outlined, and when individuals and communities are given the opportunity to participate or not, as well as end the partnership any time.</li> <li>■ Part of active participation and upholding the principle of respect for persons is to ensure that the engagement approach includes co-producing and co-developing the communication plan, the dissemination of knowledge, the messaging for intended audiences, and the scientific conduct.</li> </ul>
Beneficence	<ul style="list-style-type: none"> <li>■ Support*</li> <li>■ Co-build*</li> <li>■ Co-learning†</li> <li>■ Partnerships‡</li> </ul>	<ul style="list-style-type: none"> <li>■ Engagement should result in maximum possible benefits and minimal possible harms/risks. For example, building community capacity to create individual or community-centric solutions, valuing perspectives shared, providing financial compensation for time and transportation, demonstrating competencies in the areas of cultural sensitivity, diversity, project management, and avoidance of power imbalances and tokenism.</li> <li>■ Individuals and their communities should not be harmed, therefore pre-engagement community/needs assessment or priority setting may be required in new partnerships to better cultivate an environment of co-learning, meaningful partnerships, and an understanding of the perception of harm (as well as benefit) from the perspective of impacted individuals and communities.</li> <li>■ The bi-directional nature of capacity building to improve health is paramount to the principle of beneficence and stakeholders should be informed as to whether or not they will be receiving any direct benefits.</li> </ul>
Justice	<ul style="list-style-type: none"> <li>■ Inclusiveness*</li> <li>■ Co-build*</li> <li>■ Partnerships‡</li> </ul>	<ul style="list-style-type: none"> <li>■ This principle for engagement implies that the risks and benefits should be distributed fairly. The opportunity to participate in research, health system planning, and policy is a right - being "at the table" ensures that all partners who might benefit will have a fair chance to participate.</li> <li>■ Engagement approaches should strive to include diverse individual and community perspectives.</li> <li>■ Relevant perspectives are embraced at all stages and contributions are transparent and accounted for.</li> <li>■ Fairness in participation is upheld when barriers are removed (e.g., technology, location, costs) and there is flexibility in timeframes and priorities.</li> <li>■ Conflicts of interest are minimized as to who represents the community, who is "at the table", and whether or not contributions are unbiased and taken into account fairly.</li> </ul>

PCORI = Patient-Centred Outcomes Research Institute; SPOR = Strategy for Patient-Oriented Research.

\* SPOR principles.

† PCORI principles.

### Respect for persons

As shown in Table 1, respect for persons includes the virtuous traits of relationship building, equality, reciprocity, co-building, valuing knowledge, transparency, trust, and mutual respect. This principle would engage stakeholders at the higher tiered levels on the spectrum of engagement to participate collaboratively and actively. The voluntary nature of engagement in itself affirms auton-

omy and does not preclude the requirement of researchers to apply the underlying research ethics principles to demonstrate meaningful engagement: duty to clearly communicate the process of engagement to stakeholders, develop relationships/partnerships that are built on trust and respect, and inform stakeholders of the risks and benefits of their engagement activities [34].

From the perspective of Institutional Review Boards (IRBs), the need for informed consent depends on the engagement approach

and reflects the evolution of engagement. When the interest is in obtaining anonymous feedback from stakeholders through a satisfaction survey or a questionnaire on how to optimize the engagement processes, these approaches do not require informed consent due to the anonymous nature of the input provided. There are several additional examples of activities where formalized informed consent is not required including [35]: (1) asking stakeholders to join an advisory group and provide feedback; (2) inviting stakeholders to co-present at meetings or conferences; and (3) inviting stakeholders to contribute to manuscript writing, grant review, summaries or briefs, tailoring language in documents for their peers and other audiences, and other forms of document review and development, especially for optimizing knowledge translation [35]. The momentum to make research more relevant and accelerate the research to practice pipeline with significant investments from funding agencies and accountable policies has increasingly led for a need to demonstrate how stakeholders' engagement has improved health outcomes and the delivery of health care [7]. This expectation has placed informed consent at the forefront of engagement plans in order to evaluate the process and impact of engagement and report on demographics, metrics, and other performance indicators. Similarly, when we are interested in collecting and storing data of a personal nature from our stakeholders and its analysis as an added component to the advisory roles and activities that tend not to require IRB approval, this in turn, elevates the engagement plan and risks to data privacy and confidentiality and to requiring IRB review and the need to obtain informed consent.

### Benevolence

Traditionally, the principle of benevolence requires that researchers protect their research subjects and, in doing so, perform an assessment of the risks versus benefits according to their planned research proposal. In turn, potential research subjects can assess for themselves the trade-off of the risks and benefits and determine what is acceptable to them and whether they would like to participate [30]. The benevolence principle conveys a researcher-driven top-down approach of paternalism. It is far from an engagement model that describes the equal partnership, trust, and relationship building between researchers and stakeholders when using participatory methods. However, the spectrum of engagement does not preclude a didactic engagement approach. Despite a growing literature on the risks and benefits of engagement [4,36], some IRBs take into consideration whether there will be a direct benefit to stakeholders that extends beyond the proximal benefits of engagement, such as empowerment outcomes. This approach is consistent with our application of the principle of benevolence, as shown in Table 1. To the extent that engagement approaches may be outlined a priori to include strengthening community capacities such as by advancing programs and services to those who are partnering in the research or improving access to resources and supports that may benefit individuals and communities, the principle of benevolence will be a challenge to demonstrate if the project or research study is only seen as benefiting researchers or academia.

Several challenges to patient engagement have been reported, such as feelings of tokenism, lack of preparation, time pressures, group conflicts, and workload burden [37], which in turn may threaten retention, partnership sustainability, and psychological harm. The ethical challenges for stakeholder engagement related to threats to privacy and confidentiality and the potential for harm also depend on the engagement plan. The aim to create increasing relevant research through patient engagement strategies has shifted focus from using single-bodied governance structures, such as a group of peers or patients with a particular health condition, to highly complex governance structures with multi-stakeholder advisory boards. The privacy threats include the individual and

community identification at the time of participation during which the personal, professional, and history of individuals or communities may be revealed more broadly, with implications for potential harm. IRB review of the engagement plan would be paramount to circumvent engagement plans where individuals information may be treated as 'data' as well as provides a framework for upholding internationally recognized research ethics principles: ensuring respect for privacy, informing individuals of their right to withdraw themselves and their information at any time, communicates risks and benefits, and outlines the plan for the collection and use of personal information as part of the informed consent process. IRBs should be consulted during the development of engagement plans to ensure the fewest negative impacts on individuals and communities.

### Justice

For participatory approaches, the principle of justice is an ethical consideration at the time of community or individual identification. It determines what groups may stand to benefit and who is left behind. It also places the spectrum of engagement in an ethical dialogue to the extent that there is *procedural justice*, and the partnership will truly co-create and co-develop knowledge for capacity building and advance health policy to benefit individuals and communities [38]. Aligned with the principle of justice is the guiding principle of inclusiveness (Table 1), such that a broad and diverse group of individuals can partner and that barriers to participation are removed, for instance, by conducting a needs assessment or pre-consultation work with impacted communities and individuals to foster their involvement [39]. There is an obligation to represent better individuals and communities who are in greatest need due to health inequities resulting from social and economic circumstances. Engaging increasingly vulnerable and diverse populations ensures a future where a dialogue with the local IRB of the proposed engagement plans will, at the very least, be part of ethical practice, where applicable (e.g., University).

### Stakeholder engagement in epidemiological studies

Stakeholder engagement is being used across different research methodologies [40] and disciplines [41]. Tailoring and adapting the engagement approach is required to optimize its application to increasingly specialized fields or stages of research. Stakeholder engagement in epidemiological studies is one such example. Below, we provide an overview of a 4-staged engagement model for use in epidemiological research and describe the sequence of activities to consider at each of the 4 stages. Engagement in the *planning phase* includes selecting variables; determining inclusion/exclusion criteria; defining study population characteristics; considering in-scope and out-of-scope parameters; developing and refining study questions; determining relevant outcomes; generating hypotheses; and creating the analysis plan. Engagement in the *implementation phase* includes validating data; understanding clinical or community data sources and their respective processes for collecting data; and refining variables and the analytic plan. Engagement in the *interpretation phase* includes contextualizing the study findings; critically appraising study findings for relevance (statistical and clinical); determining implications of findings and study conclusions; developing recommendations where relevant; publishing; and crafting messages/briefing notes to promote knowledge translation to appropriate audiences. Engagement in the *dissemination phase* includes developing communication plans and materials; planning knowledge translation meetings/events; implementing dissemination plans; reporting; and evaluation.

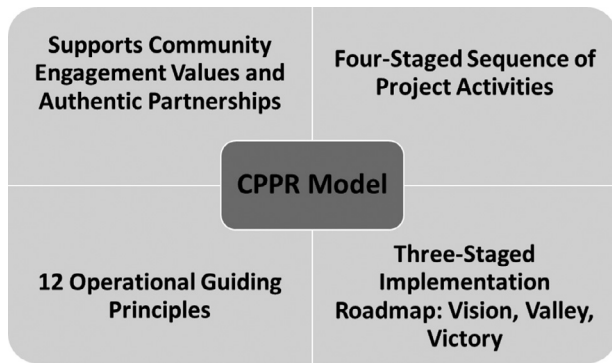


Fig. 2. Overview of CPPR model. CPPR = Community-Partnered Participatory Research.

### Community-partnered participatory research model

Participatory research approaches actively involve community stakeholders throughout the research process. It is defined as a “systematic inquiry, with the collaboration of those affected by the issue being studied, for purposes of education and taking action or effecting changes.” [8] Paradigms that are not based on partnerships have several features challenged by contemporary models, for instance, when health-related activities and timelines have been pre-determined in the absence of community realities. New community engagement models have shifted toward engagement approaches rooted in building partnerships, sustainable capacity and trust; promoting co-ownership; honoring shared agendas, plans and methods; and reporting back to funders and stakeholders. This type of approach to community engagement in research is called the Community-Partnered Participatory Research (CPPR) model [41].

We present an overview of the key elements of the CPPR model as one example of a well-developed approach to community engagement (Fig. 2). First, the CPPR model furthers the community engagement approach to value authentic and equal community-academic partnerships and power-sharing in all phases of research while building capacity in diverse communities. CPPR values an assets-based approach; engages communities as equal research partners in all stages; ensures collaborative ownership and locus of control; provides opportunities for shared leadership and resource equity; disseminates findings to benefit communities; assists with sustainability; builds new work together; and builds community capacity and resiliency while respecting scientific rigor [42]. Second, the CPPR model outlines a step-by-step approach to the implementation activities of community engagement including: (1) identify health/community issue and academic capacity; (2) create a coalition of stakeholders; (3) conduct community engagement and assess readiness; (4) establish working groups and leadership council to develop, implement and evaluate action plans [41]. Third, additional direction to implementing the CPPR model is provided across CPPR’s 12 operational guiding principles that describe potential challenges and offer several solutions and resources [43]. Fourth, the CPPR model outlines a 3-staged implementation roadmap to partnered research referred to as the 3 V’s: *vision* (i.e., develop project strategies and goals), *valley* (i.e., project implementation and activities) and *victory* (i.e., project completion and knowledge dissemination) [44].

A real-world example of this partnership model is in mental health. The Witness for Wellness (W4W) project focusing on the translation of depression care in racial and ethnic minority communities used a combination of engagement approaches that were deemed meaningful to the community and co-produced by the academic-community partnership. Using the CPPR model,

the engagement activities and impacts included developing a partnership agreement, operationalizing of the guiding principles, widespread community engagement, establishing an overarching council, mixed methods evaluation and analysis, hosting of conference, development of action plans and working groups, and the co-creation of W4W logo and website [45]. This work laid the foundation for the evaluation of Community Partners in Care (CPIC), a group-level randomized trial that compared the effectiveness of community engagement and planning (i.e., CPPR approach) to implement depression quality improvement programs across diverse sectors, compared to resources for services (i.e., non-CPPR approach), for which beneficial effects on several health and social determinants of health were shown. [46]

### Conclusions

There are a number of practical challenges that arise when engaging individuals and communities in health research, health system planning, and health policy, which are driven in part by a constant determination of researchers and health professionals to engage individuals and communities in innovative ways to increase relevancy and quality of health research and decision-making. We have tried to move toward an integrated approach to stakeholder engagement by drawing on examples in epidemiology and community health and reviewing relevant frameworks and models. By aligning the core research ethics principles to patient engagement’s guiding principles, we offered a unifying framework that demonstrates how these principles are complementary and accounts for the meaningful, respectful, and fair engagement of stakeholders. The CPPR is one model that we suggest that provides several solutions to ensure that engagement strategies are executed and implemented soundly in research while upholding the widely shared principles of engagement. While the conduct of engagement may appear straightforward, planning for engagement and implementing stakeholder engagement approaches where individuals and communities are not only providing input or acting in an advisory role but are instead being engaged meaningfully as equal partners is challenging and is often in tension with the constraints of grant funding timelines, fiscal reporting and fast-paced environments. Regardless of where on the spectrum of engagement by which researchers or other health professionals in government or non-profit organizations engage with communities and their representatives to advance population health using engagement strategies, the multiple contexts of engagement (e.g., types of stakeholders, setting, goals, approaches) give rise to ethical issues. We recognize that current realities may require new ways of negotiating roles, expectations and activities with stakeholders especially as today’s public health measures limit face-to-face meetings and interactions. An important area not addressed in this paper is engagement within the context of a health care setting, although many of the same ethical principles of engagement apply. To truly engage individuals and communities as partners requires a multifaceted lens by which the ethical principles of respect for persons, beneficence and justice are evaluated in a new light and the ethical principles of engagement guide, raise awareness, clarify, and promote moral actions throughout research phases and across all involved health and professional disciplines.

### Author contribution

All authors contributed to the conceptualization of the paper, writing of the original draft, and reviewing and editing the final draft of the paper.

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