

## **The Research Loop**

# **Transforming the Research Process with the Patient and Caregiver Voice**

## **About the Founder**



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### **Transforming the Research Process with the Patient and Caregiver Voice**

#### **Executive Summary**

The patient and caregiver voice in research is essential. Patients and caregivers have unique expertise from their lived experience in the healthcare system that can be used to improve research. Adding to international efforts to involve patients and caregivers in research, The Research Loop presents an innovative solution to traditional barriers that prevent patients and caregivers from having their voices heard.

The Research Loop is a web-based application hosted at [www.theresearchloop.com](http://www.theresearchloop.com) where patients and caregivers who have read published research articles can submit feedback to researchers. This feedback can help researchers identify better research priorities and enhance the quality of research including research design, analysis, and interpretation. The following paper outlines the linear research process and how current initiatives to involve patients and caregivers are still limited. The paper continues by exploring all the areas in the research process where patients and caregivers can have an effect and how The Research Loop's platform will facilitate elevating their voices to ensure they have maximum impact. It explores rationales for including patients and caregivers that go beyond the research process, including moral and funding justifications. Tenets for including patients and caregivers and the barriers to including them are addressed. Later, researchers' as well as patients' and caregivers' motivations for becoming involved in research are examined. And finally, the paper explains how The Research Loop aligns with current initiatives for patient and caregiver engagement, open access to research, and data sharing.

Throughout, the paper demonstrates that by giving patients and caregivers a platform to offer feedback to researchers, The Research Loop transforms the research process.

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## I. Introduction

The patient and caregiver voice in research is essential. Patients and caregivers have unique expertise from their lived experience in the healthcare system that can be used to transform research. However, patients and caregivers are rarely given the opportunity to contribute to research, their valuable voices are absent.

Patients and caregivers can improve research in a variety of ways starting with identifying better research priorities and improving relevancy research. Further, the patient and caregiver voice can enhance the quality of research by design, analysis, and interpretation. Once completed, patients and caregivers can assist with dissemination and implementation and add credibility to the research. Even with these growing initiatives, including the patient and caregiver voice remains limited.

While there are some initiatives around the world endeavoring to make the patient and caregiver voice a priority, they are limited. In the United States there is the Patient Centered Outcome Research Institute (PCORI).<sup>1</sup> In the United Kingdom, there is INVOLVE<sup>2</sup> and the James Lind Alliance (JLA).<sup>3</sup> In Canada there is the Strategy for Patient-Oriented Research (SPOR)<sup>4</sup> and Patients Canada.<sup>5</sup> The National Health and Medical Research Council (NHMRC) is part of Australia's efforts to involve patients and caregivers. The European Union has collaborated with the pharmaceutical industry to start the Innovative Medicines Initiative (IMI).<sup>6</sup> And Norway has pursued efforts to involve patients and caregivers as well.<sup>7</sup> The Research Loop recognizes the incredible work these organizations have already undertaken but also has identified where patients and caregivers are still left out.

The Research Loop is a web-based application developed that transforms the research process by adding the patient and caregiver voice in a new way. Through the website [www.theresearchloop.com](http://www.theresearchloop.com), patients and caregivers can submit feedback on published research articles which is then provided to the researchers. Researchers can choose to incorporate this feedback into their work and development of future projects. The Research Loop aims to improve research at all levels including priority setting, relevancy, quality, dissemination and completing the loop by filling the gap before new research begins. This innovative solution complements the initiatives above while empowering patients and caregivers as never before.

This paper will present the current need for The Research Loop. In the next section, the current linear research process is laid out, highlighting how the web-based application will transform this static trajectory with the patient and caregiver voice. Section III outlines how The Research Loop works. Section IV then discusses the traditional difficulties associated with finding and including patient and caregivers in the research process and how The Research Loop overcomes these obstacles to incorporate more voices. The importance of patient and caregiver involvement in priority setting is explored in Section V. The way in which patients and caregivers can impact quality, including design, data, analysis and interpretation are examined in Section VI. And in Section VII, the effect of including patients and caregivers can have on dissemination and implementation of research is discussed. Further justifications for including the patient and caregiver voice are explored in Section VIII, including that they add credibility to research, help increase public understanding of research, and moral arguments for their involvement.

Throughout Sections V-VIII, the case is made for how The Research Loop’s platform will allow patients and caregivers to have a role in every stage of research and thus transform the research process. Section IX addresses issues of research waste and research funding, providing another justification for including patients and caregivers. Section X discusses principles to consider when including the patient voice – including respecting their expertise and accepting their voices as part of a multidisciplinary team. Section XI reviews some further barriers that often interfere with including the patient and caregiver voice such as researchers not recognizing their value, institutional support, tokenistic efforts, and more and how The Research Loop can help address these issues. Research motivations are discussed in Section XII followed by patient and caregiver motivations in Section XIII. In Section XIV, initiatives including patient engagement, open access, and data sharing reviewed including how The Research Loop aligns with each.

In developing The Research Loop, all of these aspects were given careful consideration so that feedback provided by patients and caregivers could have the maximum impact on research. The Research Loop itself will be an evolving project seeking to push for ever more engagement of patients and caregivers in unique and meaningful ways.

## II. The Linear Research Process

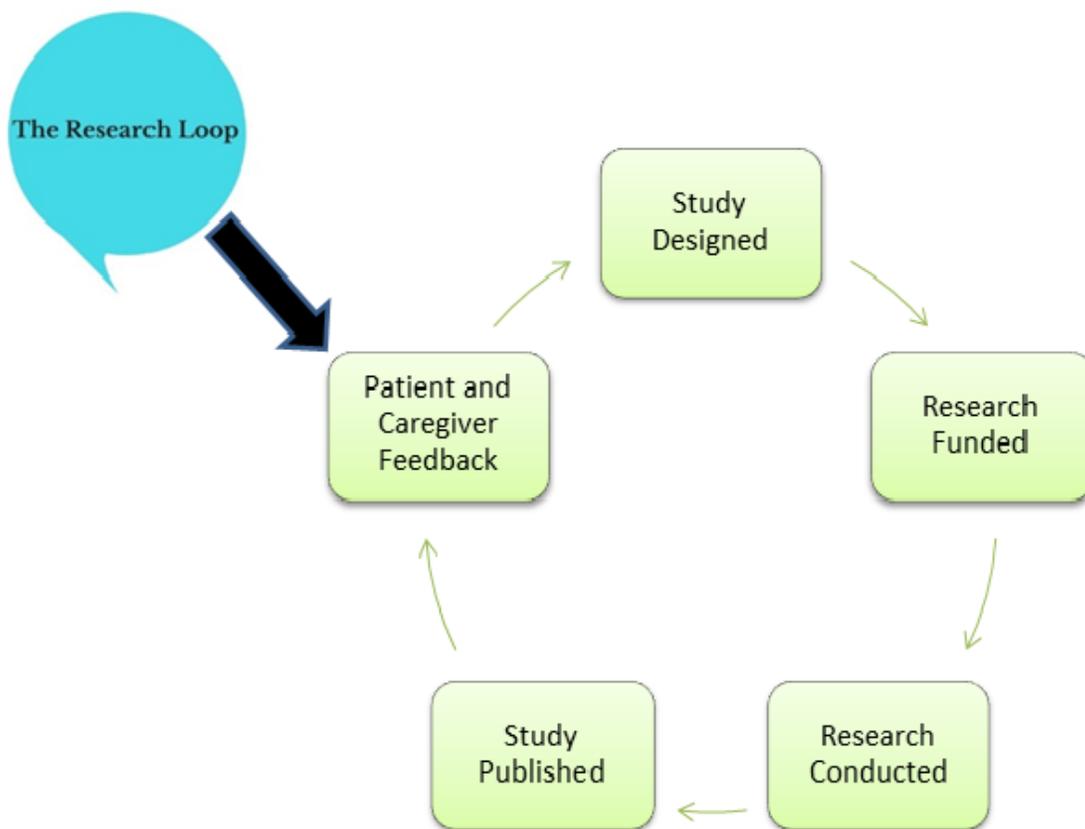
The research process is essentially linear with little opportunity for patients and caregivers to add their voice. Researchers often design their research study, seek funding, conduct the research, analyze the findings, and publish the study in isolation from populations their research will impact.<sup>8</sup> (See Fig. 1) Essentially, the research process follows a one dimensional trajectory lacking contact with the ultimate end-users – patients and caregivers.

Figure 1: The Linear Research Process



With initiatives to add the patient and caregiver voice to all aspects of research like those listed above, a few patients and caregivers may be asked to take part in these various stages. However, only even fewer will have the chance to be involved. Most patients and caregivers are only aware of research after it is completed; they can only respond to and provide feedback on published studies. Still, their responses to published research can have tremendous value for future research. The Research Loop recognizes the value of feedback and aims to transform the linear research process to a loop by adding the patient and caregiver voice. (See Fig. 2)

Figure 2: The Research Loop transforms the research process by adding the patient and caregiver voice.



Patients and caregivers can bring new life to findings that might remain unexplored after publication, which may impact future research as will be explored below. With patient and caregiver feedback, the research process becomes interactive rather than passive, self-perpetuating rather than stagnant while bridging the gap between researchers and the community.

### III. How It Works

The Research Loop is built to be a simple and intuitive solution to provide patients and caregivers an opportunity to add their voices to the research process. Anyone can come to the website, [www.theresearchloop.com](http://www.theresearchloop.com) and take a look at the varied resources and educational materials. For those who have read a published research article and want to give feedback, they simply fill out a short registration form to join. Once the registration is complete, they can enter the Offer Feedback to Researchers page where they are asked to fill out a form with their feedback. After submitting their feedback, it is reviewed to ensure it meets feedback guidelines and is then provided to researchers with an introduction letter explaining The Research Loop.

Patients and caregivers are prompted to offer feedback on their overall impression of the study, how the study has impacted their care or work, the study's design methods and conclusions, and future research ideas. They are also given the opportunity to comment more generally on the study. Patients and caregivers can enter any amount of feedback they wish to provide. The Research Loop encourages those giving feedback to use the educational materials to learn more about research in order to improve their feedback but believes that all levels of feedback are valuable.

An example of the introduction letter researchers will receive can be found in Appendix A. Example feedback on a research article can be found in Appendix B.

#### **IV. Involving Patients and Caregivers**

Patients and caregivers can have an impact on research but they need a platform to do so. Unfortunately, few patients and caregivers are given that platform and issues around outreach and practical barriers prevent many from having a voice in research. The Research Loop can help overcome these barriers for patients and caregivers and help researchers include their feedback in future research.

##### *a. Including New Voices*

One of the initial barriers to patient and caregiver involvement is helping researchers know who to ask to be involved. Some researchers turn to known patient or caregiver advocacy groups, others look to replicate colleagues' practices, and still others may invite patients and caregivers they know and have worked with before. While these are useful means to find patients and caregivers to participate in research, they are limited and may result in asking a small set or even the same set of individuals to take part. Since certain patients and caregivers might be known to an organization or the researcher, they are easily reachable and may be deemed dependable. However, including these individuals again and again risks excluding new voices with new perspectives and a wealth of knowledge that could impact projects. These individuals become "professional patients" and some even develop their own agendas.<sup>9</sup> While patients and caregivers who are often involved can be wonderful resources, researchers must realize that no one patient, caregiver, or organization speaks for all patients. Thus, asking as many different patients and caregivers is essential to truly understanding the patient and caregiver experience.

Similarly, some researchers may think that stakeholders, such as patient and caregiver organizations, can adequately represent patients and caregivers. Though some of these stakeholders may have patients or caregivers actively involved in their organizations, they do not necessarily represent patients or caregivers.<sup>10</sup> Rather, they may only represent the organization and the organization's agenda. Again, it is crucial that researchers recognize which voices they are asking to the table and try to make an effort to include patients and caregivers who speak for their experience and not just an organization.

By involving more patients and caregivers, researchers can help foster diversity in research as well. Many patient and caregiver communities and views are already underrepresented, which is only exacerbated by failing to look for new people to involve. These "hidden voices"<sup>11</sup>, those

not usually included, can bring new perspectives which can “increase the breadth of experience and skills brought to the project.”<sup>12</sup>

The Research Loop will endeavor to bring together a diverse set of patient and caregiver voices and their varied experiences and views. The platform will hope to overcome traditional challenges of “representation of patient participants of different regional, cultural, and social backgrounds”<sup>13</sup> and focus on diversity and inclusivity. As a result, the feedback patients and caregivers offer will enrich researchers’ understanding of the topics they are studying as well as the scope and implications of their work.

#### *b. Outreach*

Finding new patients and caregivers to become involved in research generally takes a dedicated outreach effort. Frequently though, the scope of outreach undertaken by researchers is limited. In a systematic review of patient engagement efforts, Domecq et al. found, “In general, most of the studies described convenience sampling as the method to identify patients (or representatives/surrogates) for engagement in research. Therefore, patients attending clinics or other patient care facilities were approached and asked to participate. Patients also volunteered in response to advertisements or Internet postings.”<sup>9</sup> These methods end up being limited to those who happen to see the advertisements or attend the clinics where the outreach is conducted and who meet the requirements to participate – thus circumscribing the number of patients and caregivers who might become involved.

Because many researchers already have the high burden of developing their research and recruiting study participants, the additional effort required to recruit patients and caregivers to be involved in the research process may be too great. Additionally, they may not have the resources or funds to conduct thorough outreach campaigns. As a result, outreach to new patients and caregivers may be short-changed and new voices are left unaware of projects they may be able to contribute to.

The Research Loop will have its own outreach efforts online and in patient and caregiver communities to let patients and caregivers know that there is a platform for them to have a voice. This will widen the number of people who are asked to be involved because they will not need to be near a certain clinic or institution to learn about The Research Loop. And because patients and caregivers will themselves come to The Research Loop, and their feedback will be provided to researchers, the onus on researchers to find new voices is greatly diminished, allowing them to focus on their work and the actual feedback provided.

#### *c. Practical Barriers*

Current patient and caregiver engagement efforts face practical barriers that also often exclude their voice from the research process. For instance, most of these efforts require that patients and caregivers be available in person to contribute – usually on a focus group, panel, or board with regular meetings.<sup>9</sup> This requirement restricts the set of patients and caregivers who can be involved to a geographic location.<sup>14</sup> Additionally, it means that patients and caregivers who are too unwell or have health issues that preclude them from traveling, those who have family or

work commitments, those with transportation obstacles or other issues are unable to attend and thus are left without a voice.

For individuals who are able to come to in-person meetings, facilitating patient and caregiver involvement comes with other unique barriers. The biggest of these barriers to consider is time. Patients' and caregivers' time is already limited. With work, families, and attending to their healthcare needs, the time commitment required to participate may prove too much.<sup>14</sup> Researchers then need to consider holding meetings outside business hours or on weekends, the length of each meeting, and how often they will be held.<sup>12,15-19</sup> Again, this can add a burden to an already stressed researcher and anxiety to patients and caregivers who want to offer their feedback. Unfortunately, it can also mean a frustrating level of attrition as patients and caregivers may not be able to sustain involvement.

In addition to time concerns, come more practical issues like providing food, child care, and parking to accommodate patient and caregiver needs.<sup>9,15</sup> And even with all these efforts, once set up, the meetings will need to be flexible to adjust to patients' and caregivers' needs, especially those that are unforeseen.<sup>20</sup> These all require researchers to invest additional time and resources – both of which may be limited.<sup>18,21</sup>

And finally, even if patient and caregivers are able to attend in-person meetings, many may feel uncomfortable in this formal setting.<sup>14</sup> Some individuals may be shy or worried their ideas will be rejected.<sup>22</sup> This may mean that other individuals dominate meetings while others are left unheard.<sup>22</sup>

Organizations like PCORI, INVOLVE, and SPOR and others are working to expand their efforts to include more patients and caregivers in research but their operations still highlight the issues above and why they are limited. The ability to participate with these organizations leaves many out. First, most require patients and caregivers to fill out lengthy applications to be involved, a substantial hurdle for many, and only a few are ultimately chosen to serve. These individuals then have to face the barriers of travel, time, and accommodation that cannot be overcome by many. For instance, in the past PCORI asked patients and caregivers to devote a substantial amount of time to reviewing grant applications in a short amount of time, travel across the country, sit through an excruciatingly long day of reviews with professional reviewers who have done this many times before, and pay for it in advance only to be reimbursed afterward. Patients and caregivers who could not afford a flight or food costs upfront were thus left out. Patients and caregivers who had travel limitations were left out. Patients and caregivers who did not have the time or energy for various reasons could not commit to the level of work asked of them. Once there, patients and caregivers needed accommodations that were often not planned for and were asked to speak in a situation where many were uncomfortable.

In-person meetings are one way to involve patients and caregivers but they still leave many patients and caregivers excluded. Those who need transportation, those who cannot make the time commitment, those for whom accommodations cannot be made, and those who may not feel comfortable in group settings are often left out. The Research Loop can address these issues. As an online platform, patients and caregivers will be able to access the site anywhere in the world at any time. Patients and caregivers are not asked to make any time commitment and can access

the site when it is convenient for them. Thus it enables patients and caregivers who cannot attend in-person meetings to still have a voice in the research process.

Issues of accessibility and accommodation will necessarily need to be addressed on the site as it grows – especially for the visually impaired or those who have limited internet access (so as not to contribute to the ever widening digital divide). The Research Loop will look to address those issues but hopes to invite many more patients and caregivers to become involved in research than have ever been included before.

## **V. Priority Setting**

Good research starts with setting good priorities and decades of examples prove that patients and caregivers can help in that process. Research priorities are selected for a variety of reasons. Some institutions, funders, and even researchers may have their own biases and assumptions that influence what they believe is important to study. Other researchers may decide based solely on literature review, which is inevitably separated from reality. Researchers may also focus on areas that they think will get them more funding, a result of funding biases discussed above. For these and other reasons – including “commercial, political and academic interests” – there is often a mismatch between priorities set by researchers and what matters to patients and caregivers, a mismatch that can lead to research waste.<sup>23</sup> By including patients and caregivers though, better priorities can be pursued which may also improve relevancy.

### *a. Understanding What is Important to Patients and Caregivers*

“An efficient system of research,” according to Chalmers & Glasziou, “should address health problems of importance to populations and the interventions and outcomes considered important by patients and clinicians.”<sup>24</sup> Inviting patients and caregivers to discuss what priorities matter to them can call attention to incorrect assumptions.<sup>25</sup> They can also help refocus research toward areas that may have gone ignored but would greatly impact patients’ and caregivers’ lives. For instance, much research focuses on treatment to the exclusion of “burdens associated with living with the disease and coping with treatment.”<sup>16</sup> Furthermore, as Chalmers et al. write, “researchers often do not assess the effects of interventions in terms of functional, social, and emotional wellbeing, or adverse reactions and long-term outcomes,” and their clinical trials may have “little relevance in real-world settings.”<sup>23</sup> The result is a continued mismatch between patient and caregiver priorities.

Recognizing that quality of life can be as important as treatment is essential to developing research, particularly which research outcomes to pursue. By including patients and caregivers, researchers can reduce “some of the mismatches between research agendas and the needs of the users of research.”<sup>23</sup> Additionally patients and caregivers can help “identify a wider set of topics”<sup>12</sup>, suggest “ideas for new research areas”<sup>12</sup>, and address “a broader range of relevant research themes”<sup>26</sup>, while “helping to reshape and clarify the research.”<sup>12</sup>

A great example of the impact patients and caregivers can have on priority setting can be found in the work OMERACT (Outcome Measures in Rheumatology) underwent with “patient research partners” (PRPs). OMERACT consulted with patients on priority setting to discuss

meaningful outcome measures for rheumatology. Their PRPs identified fatigue as a priority, noting that “fatigue affects everyday life.”<sup>17</sup> While it was not part of the core outcome set before the consultation, once researchers recognized the impact it had, OMERACT decided fatigue was of such importance that it “now endorses fatigue as a necessary assessment in all [rheumatoid arthritis] trials.”<sup>17</sup>

Similar to the OMERACT example, Corner et al. conducted a study inviting cancer patients to take part in consultation groups on priorities in research. They found that patients identified “practical, social and emotional issues as a higher priority” than “biological and treatment related aspects.”<sup>22</sup> They felt that their study highlighted that “As the beneficiaries of discoveries and developments in cancer science, it cannot be assumed that [patient] views will automatically accord with those of the scientific community.” And furthermore, they concluded “patients with cancer, regardless of their personal situation have clear views as to the most important priorities for research investment. Their highest ranked concerns are not currently being addressed.”

Boote et al. wrote a reflective case study where researchers completely abandoned an idea after hearing from patients and caregivers.<sup>27</sup> The initial research idea was to have patients and caregivers as part of the NIHR Stroke Research Network help design a consent form. This form would then be compared to one similarly developed by researchers. The researcher pursuing this idea thought they had identified an important gap in the literature. Only after consulting patients and caregivers did they realize the idea, though it had approval from other researchers, would not actually provide the benefit intended.<sup>27</sup> As a result, Boote suggests that inviting patients and caregivers to discuss an idea can help “lessen the time that researchers spend developing research ideas of little interest to the public.”<sup>27</sup>

By giving patients and caregivers the opportunity to provide feedback, The Research Loop helps researchers see if their work is in line with priorities that matter to patients and caregivers. Patients and caregivers can simply relay whether the research was meaningful to them or not and why. This can give researchers a sense of whether they have chosen the right priorities or if they need to consider new directions. This may reduce research waste and affect implementation, both discussed below.

#### *b. James Lind Alliance*

The James Lind Alliance (JLA) is the leader in involving patients and caregivers in priority setting. Established in 2004 as part of the UK’s NIHR, the JLA recognizes,

“Research on the effects of treatments often overlooks the shared interests of patients, carers and clinicians. As a result, questions that they all consider important are not addressed and many areas of potentially important research are therefore neglected.”<sup>3</sup>

In this spirit, JLA has worked to establish Priority Setting Partnerships (PSPs) which bring together “clinicians, patients and carers to work together to identify and prioritise uncertainties about the effects of treatments that could be answered by research.”<sup>3</sup> These PSPs span many different diagnoses and produce lists of “Top 10” priorities for researchers to pursue. The

priorities chosen thus influence funding opportunities and, more importantly, the potential impact of research.

The Research Loop will work as an adjunct to endeavors like JLA, also recognizing the importance of including the patient and caregiver voice in setting priorities. While not all patients and caregivers can serve on a PSPS, their feedback can still be useful to researchers in the priority setting phase. Using the web-application, patients and caregivers submit feedback to help researchers identify focus areas, including areas that are under-researched or ignored. For example, a patient may read an article and reply to the researcher, “Why did you choose this topic? Did you consider looking at this area?” or simply, “I think this research is great and very important.” Even this simple feedback can offer researchers a wealth of information that can ask the researcher to retrospectively confirm their decisions which may improve future decisions or validate the researchers’ decisions, confirming their future endeavors.

### *c. Systematic Reviews in Priority Setting*

According to Moher et al., “Over 50% of studies are designed without reference to systematic reviews of existing evidence.”<sup>28</sup> In other words, researchers are unaware of work that may already be out there on a topic. Systematic reviews are important because, as Glasziou & Chalmers noted, “unidentified studies can help to inform decisions about whether further research is needed, which questions are unanswered, and how additional research can be designed to take account of the lessons from relevant previous research.”<sup>29</sup> Patients and caregivers can help with systematic reviews.

In Corner et al.'s study with cancer patients described above, the authors explain that “patients are well aware of the significant activity underway in research into new cancer treatments.”<sup>22</sup> So too are patients and caregivers across the healthcare spectrum. Patients and caregivers who are actively engaged in research may have read and studied much of the existing work on a topic and be a resource to researchers, informing them of what has already been done or what is not being done. This information can help researchers set better priorities and reduce waste.

Through the platform provided by The Research Loop, patients and caregivers can identify where the research they read falls in line with other research they have encountered. They might note in feedback that a similar study was done and ask the researcher if they knew about it or whether those research ideas would be considered in tandem in the future.

The Research Loop gives patients and caregivers a platform where they can provide feedback including comments relating to research that has already been conducted. For example, in one research study a researcher chose to outline new subtypes of a disorder. A patient with that disorder wrote back to the researcher asking why she did not validate or expand upon existing subtypes outlined in previous research. Once this feedback was provided to the researcher, the researcher noted that these ideas ran “somewhat parallel and that it might be “a good thing if all these findings would be bundled” in the future. In this case, the patient was able to provide a systematic review of the information out there to inform future endeavors the researcher may consider.

## VI. Quality

Patients and caregivers can impact research quality throughout the research process. As discussed below, their feedback, submitted through The Research Loop can shape all areas of research including design, data, and analysis and interpretation. Feedback in all of these areas may also give research greater validity<sup>12,15,30,31</sup> and applicability.<sup>9</sup>

### *a. Design*

Research design can make or break a study's success. As Chalmers & Glasziou noted, a main driver of research waste is the "poor engagement of end users of research" in design.<sup>24</sup> They further pointed out that "New research is also too often wasteful because of inadequate attention to...important elements of study design"<sup>24</sup>

The voice of patients and caregivers can improve design in various ways. They can ensure that design focuses on identified priorities that are relevant to patients. They can make sure that research questions and outcomes are clear and point to inadequate descriptions.<sup>24,32,33</sup> They can assess a study's feasibility and barriers to recruitment.<sup>10,23,33</sup> They can help identify choice of methods for trials.<sup>33</sup> They can help develop research tools including rewriting documents in more accessible language.<sup>33</sup> And they can reveal any biases or assumptions researchers may have that could influence the research.

As discussed above, barriers to including patients and caregivers mean they are not able to be on the initial design team. Yet, their critical eye can retrospectively review the design of published research. With The Research Loop, patients and caregivers can offer feedback on the design choices made by researchers. This feedback can push researchers to evaluate why they made certain design choices and how that might have affected their results. The feedback can help researchers focus on priorities important to patients and caregivers and define better research questions. Additionally, patients and caregivers can suggest design improvements or new directions. In so doing, patients and caregivers can provide important input to shape future research studies.

### *b. Data*

Traditionally, patients and caregivers have not had access to data sets and thus have been all but excluded from this aspect of the research process. Occasionally, researchers have asked patients and caregivers to assist with data collection or allow them to be part of a research team. More often though, patients and caregivers are only seen as data points – a passive role that – rather than active collaborators in this stage.

Movements to compel researchers to share data with each other and with patients and caregivers are growing more and more each day. These efforts are in their infancy but have important backing from patient leaders who recognize the value patients and caregivers can add to research if data is available to them.

Even without fully published data sets, patients and caregivers can still take a minimal part in this part of the research process. For instance, patients and caregivers can identify where the presentation of data in a paper is unclear. According to Glasziou, “31% of all graphs published in the Journal of the American Medical Association in 1999 and 2000 could not be interpreted unambiguously because some features were not self-explanatory.”<sup>34</sup> While this statistic may have changed over the years, many patients and caregivers find research intellectually inaccessible precisely because the data is not intuitively presented. Involvement by patients and caregivers in this respect can result in “reporting [that is] more meaningful and understandable for participants and the community.”<sup>9</sup>

Patients and caregivers offering feedback through The Research Loop can similarly comment on tables and graphs and the data available. They can also comment on which statistical analysis methods the researcher chose and data points the researcher failed to include in their study. For instance, a study that misses important demographic or socioeconomic data that could inform their findings and provide context.<sup>14</sup> They can question what values the researcher deemed significant and ask the researcher to consider future studies that takes these views into account.

With this feedback in hand, researchers can consider what data they will collect in future studies, what methods for data collection and statistical tests they may use, and develop outputs and graphs that are more accessible and relevant to the public.

### *c. Analysis and Interpretation*

According to INVOLVE, the patient and caregiver voice in analysis and interpretation can “help to identify themes that researchers might miss, help in checking the validity of the conclusions from a public perspective, and highlight findings that are more relevant to the public.” In fact, Shippee et al. found, including patients and caregivers in analysis “resulted in an improved ability to contextualize conclusions..., added language and culture insight and highlighted [patients’ and caregivers’] priorities for a more focused analysis.”<sup>15</sup> More importantly, patients and caregivers can point to the “appropriateness of the analysis.”

As with design and data, The Research Loop offers patients and caregivers a forum to provide critical feedback on the analysis and interpretation presented in research studies. This may include highlighting areas where the analysis may not be focused and concise, or spotting inconsistencies in interpretation. Additionally, patients and caregivers might again identify researcher bias. Because researchers may be removed or isolated from the actual caregiver or patient experience, they may make certain assumptions that can lead to faulty interpretations. Those with firsthand knowledge of these topics may be the only ones able to help correct some assumptions. They may also be the best to explain and expand upon the implications of the research.<sup>35</sup>

Feedback on analysis and interpretation can influence researchers’ future studies by encouraging them to understand the patient and caregiver perspective for interpretation. It may also spark interest in aspects of the research not previously considered.

## VII. Dissemination and Implementation

The value of a research study cannot be realized until the results are disseminated and implemented. Yet dissemination of research is often inadequate and restricted.<sup>22</sup> Most patients and caregivers are unaware of research unless it is highlighted by media outlets or they specifically search for it. And even when found, research published in articles that are behind paywalls becomes inaccessible to the wider public. Thus, the public relies on media reports that may sensationalize findings or must put significant effort into seeking out research on their own.

Involving patients and caregivers in research can improve the dissemination of research studies to the public in several ways. First, patients and caregivers may know of more creative dissemination methods.<sup>15,33</sup> These methods might be more efficient<sup>15</sup> or leverage patient and caregiver-centered resources like social media, patient and caregiver networks<sup>12</sup>, accessible and trusted newsletters and media<sup>12</sup>, and patient and caregiver forums. Second, if patients and caregivers were involved in other aspects of the study such as analysis and interpretation, the findings may be easier to understand and thus dissemination becomes more meaningful as the information is clearer for all audiences.<sup>9,12</sup> And third, patients and caregivers themselves can communicate the findings, thus no longer needing interpretation from media or researchers who are disconnected from patient and caregiver communities.<sup>14</sup>

As Shippee noted, “adequate dissemination has proven to be helpful for future implementation, and making results known within several strata may facilitate obtaining resources and funding for implementation.”<sup>15</sup> With this, as part of dissemination efforts patients and caregivers can be part of dissemination by “lobby[ing] to ensure that changes are made and research is more widely applied.”<sup>10</sup>

Implementation can only be effective if the end-users of the research have both access to the research and can interpret and apply the findings. Researchers may also note that patients and caregivers themselves, as end-users, will be the ones implementing the findings individually or with other healthcare providers. Involving them in the research process at various stages will facilitate and possibly accelerate implementation as the research may have more meaning, may be more relevant, or may be more easily understood.<sup>16,26,36</sup> It may also allow patients and caregivers to point out where there may be difficulties with implementation and help researchers adjust accordingly.<sup>37</sup>

The Research Loop can be a useful tool for researchers to understand how their studies are disseminated and implemented. The Research Loop feedback form asks patients and caregivers to self-report where they encountered the research and how it affects them. This information may help researchers find areas where dissemination efforts are working and where they can improve. It can also indicate how the findings might be implemented or where there are issues with implementation and translation of the findings into practice.

In its current form, The Research Loop cannot disseminate research directly but does point patients and caregivers to resources where they can search for articles that might interest them. The site will also use social media and other patient and caregiver forums to disseminate research from time to time as appropriate.

Additionally, The Research Loop will join efforts to push for open access to all research and will facilitate open access to the extent possible. The Research Loop believes the feedback provided through the site can impact open access by proving to researchers and institutions the value of the patient and caregiver voice when patients and caregivers have the opportunity to read research that is not locked behind paywalls.

## **VIII. Other Justifications**

There are a plethora of justifications for including patients and caregivers in research beyond improving research quality, dissemination, and implementation. These justifications include increasing the credibility of research, increasing public understanding of research, and moral arguments for including the patient and caregiver voice.

### *a. Credibility*

Including the patient and caregiver voice in research can enhance the research's credibility, which imbues a sense of legitimacy and authority in the research as well.<sup>9,11,12,36</sup> This credibility and authority ultimately has the effect of increasing public confidence in the research<sup>22,26</sup> and perhaps even increase the uptake and application of the findings.<sup>11</sup>

Feedback from The Research Loop can lend credibility to researchers' work outright by confirming aspects of the study, giving researchers a sense of authority as they propose new projects. It can also lend credibility to researchers who take the information to learn from errors in past studies and apply it to future studies and in so doing increase public confidence in any new findings.

### *b. Increased Understanding of Research*

Inviting patients and caregivers to become involved in research has the effect of enhancing public understanding of research.<sup>11,33</sup> Being part of the research process and learning how each stage is developed and conducted can give patients and caregivers insight into a field that they have been traditionally excluded from.

The Research Loop expects to be a source of education for patients and caregivers to help them understand research and thus be able to more actively engage with research. Several educational materials will be posted on the site along with links to resources where patients and caregivers can learn more.

### *c. Moral Arguments*

Moral arguments for including patients and caregivers in research include ideas of accountability, democracy, fairness and justice, and equity. The Research Loop believes patients and caregivers have a right to be involved in research and to hold researchers and institutions accountable for any public funds used for research as discussed in the next sections.

### i. Democratic Right

The World Health Organization's Declaration of Alma-Ata states that "people have the right and the duty to participate individually and collectively in the planning and implementation of their healthcare."<sup>38</sup> This may be reasonably expanded to the research that affects their healthcare.

In fact, this concept is central to INVOLVE's philosophy of patient and caregiver engagement. INVOLVE states that "Public involvement in research is founded on the core ethical principle that people who are affected by research should have a right to have a say in what and how research is undertaken."<sup>36</sup> They further describe such involvement as "an intrinsic part of citizenship."<sup>12</sup>

Ideas of fairness and justice further support this notion that patients and caregivers have a right to be involved in research.<sup>35,39</sup> As Dr. Andreas Laupacis said, "Fairness and justice would say these people have got the disease ... surely they should have a bit of a say."<sup>21</sup> As SPOR succinctly states, "It is our health...It is our system..."<sup>19</sup>

### ii. Accountability, Transparency, and Stewardship of Public Funds

One of the most persuasive moral arguments for involving patients and caregivers in research is accountability and transparency, particularly of research funded by the public.<sup>14,33</sup> More specifically, the idea that "the public, as taxpayers, have the right to be actively involved in any publicly funded research that may impact on their health or the services that they receive."<sup>27</sup> As Oliver et al. writes, this is one of the main reasons for researchers to involve patients and caregivers. They argue that "More transparent governance of public resources is part of public accountability and participatory democracy."<sup>40</sup>

Researchers must be held accountable for the funds they receive from tax payers and they must as well as funds from non-profit organizations as those funds come from monies entrusted to non-profit organizations by the public.<sup>33,41</sup> Researchers must justify the funding they receive is being well spent and be held accountable as stewards of these funds.

Patients and caregivers both have a right to participate in research and a duty to hold accountable researchers. However, many of them not been able to exercise that right or fulfill their duties because they are not given the opportunity to participate in research. By presenting a new way to include the patient and caregiver voice, The Research Loop can help with the realization of that right for all individuals and can continue to scrutinize the use of funds disbursed to researchers.

## **IX. Research Waste and Funding**

Funding may be the greatest incentive to involve patients and caregivers in research. Research funding becomes more competitive by the year while at the same time research funds and grant monies become scarcer. Including the patient and caregiver voice can give researchers an edge as they seek funding for their studies, if not only because some institutions require that patients and caregivers be included. Including the patient and caregiver voice can decrease research waste and demonstrate that a project will be a sound investment.

### *a. Research Waste*

In an era where research funding is limited, researchers will want to prove that the research they conduct is not wasteful. Billions of dollars are spent around the world on research and development<sup>1</sup>, yet much of that spending goes to waste. In 2009, Chalmers & Glasziou estimated that 85% of research investment was wasted.<sup>24</sup> This waste, they claimed, was a product of three main factors – choosing the wrong questions for research, doing studies that are unnecessary or poorly designed, and biased or unusable reports of research.<sup>24</sup> In 2014, Chalmers and colleagues expanded on this idea stating, “waste results when the needs of users of research evidence are ignored.”<sup>23</sup>

By involving patients and caregivers, the end users of research, the threat of waste may be moderated. Patients and caregivers can help researchers set better priorities and shape research that is more relevant and of a higher quality, among other benefits. As presented in the preceding sections, The Research Loop facilitates adding the patient and caregiver voice in research, therein helping researchers reduce the risk of waste.

### *b. Financial Incentives*

Securing funding by showing that research waste might be avoided is one financial incentive to include patients and caregivers among many. Another incentive can be that involving the patient and caregiver voice is a requirement for funding. In fact, many funders now require that the patient and caregiver voice be included in research. This is, in part, a direct result of policy changes at national levels. Policy makers who established institutions like INVOLVE, PCORI and others realized the value of the patient and caregiver voice and thus pushed for initiatives to ensure their voices were included. Following suit, other funders realized the benefits that came from including patients and caregivers and started to require their involvement as well.

Researchers also must prove that they and their work are a good investment. All funders want evidence that their investment will prove productive and even profitable, which requires researchers to demonstrate something meaningful comes from their studies and that they have reduced waste in the process.<sup>42</sup> In their paper, *Increasing value and reducing waste in research, design, conduct, and analysis*, Ioannidis et al. wrote, “Funders are eager to ensure that they get a good return on their investments; inadequate research diminishes the fiscal investment that they have made.”<sup>8</sup> Involving patients and caregivers not only reduces waste but may improve cost efficiency, which will demonstrate to funders that they made sound investments.<sup>12</sup>

In addition to decreasing waste and increasing cost efficiency, alignment with patient and caregivers priorities is of great importance to secure funding. As Corner and colleagues note “...the legitimacy and sustainability of investment decisions made by research funding bodies will increasingly depend on how well they reflect the underlying values of the public.”<sup>22</sup>

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<sup>1</sup> It can be estimated based on GDP and percent of spending on all research (not just health research) (2.788173%) that total spending on research in 2015 in the United States equals over \$500 billion. In the United States alone, the National Institute of Health Budget in 2016 was \$31.3 billion ([https://www.iriweb.org/sites/default/files/2016GlobalR%26DFundingForecast\\_2.pdf](https://www.iriweb.org/sites/default/files/2016GlobalR%26DFundingForecast_2.pdf)).

Researchers can show their work reflects patient and caregiver values by including them at several stages in the research process. According to INVOLVE, a researcher who includes patients and caregivers in the design stage can “demonstrate to funders and commissioners that the topic is important and relevant to the end users of research.”<sup>12</sup> Consequently, as The Consumer and Community Health Research Network in Australia points out, “Harnessing consumer experience and needs...[might] increase the likelihood of success in attracting research funding” because “the research results are more likely to respond to a prevailing problem and to be utilized in the real world.”<sup>18</sup> In other words, including patients and caregivers in research at the design stage can prove that the research is a good investment.

The Research Loop allows patients and caregivers to provide feedback on every stage of research. As will be presented in the sections below, this feedback can have a significant impact on research and, if properly utilized by researchers, it can be leveraged to show how their work is relevant and worthy of funding.

### *c. Funding Biases*

Many have noted that research funding is currently biased toward certain types of research that does not match the needs of the public and this distorted funding can lead to research waste.<sup>28</sup> Moher and colleagues specifically note issues of publication bias – “a reward system based on quantity of publications and journal impact factor rather than on research quality.”<sup>28</sup> Yet there may be many reasons for this bias, including as Tallon et al. describe, “vested researcher interests; professional dominance of research (ie, medical and surgical professions directing research funding; publication bias...; and a lack of consumer involvement in research (ie, consumers not consulted about priorities).”<sup>31</sup>

Together, these result in biased research agendas that are not likely to focus on important priorities. To assess their research agenda, researchers should consider inviting patients and caregivers to apply a critical lens to reveal any deep-seated agenda bias the researcher, research institutions, or their funders may not realize exists. In so doing, patients and caregivers can help researchers develop a better research agenda which will impact funding. As more researchers take this route, they may help change how funding is allocated.

Iain Chalmers, in his foundational publication on including patients in research stated “Greater lay involvement in setting the research agenda would almost certainly lead to greater open mindedness about which questions are worth addressing, which forms of healthcare merits assessment, and which treatment outcomes matter. It should also help to counter the perverse incentives that lead researchers to do trivial and sometimes frankly unnecessary research...”<sup>35</sup>

The Research Loop will help researchers add the patient and caregiver voice to their work which may help them secure funding for future projects, reduce waste, and repair biased funding schemes. This simple tool will provide researchers with feedback that, as discussed above, can increase participation of patients and caregivers, help set better priorities, make research more relevant, improve quality (including design, data, and analysis and interpretation), augment dissemination and implementation, enhance credibility, support educational efforts to help the

public better understand research, and much more. In total, the impact of The Research Loop can help transform the research process.

## **X. How to Include the Patient and Caregiver Voice**

Researchers should work with patients and caregivers, not simply for them. Patients and caregivers should be considered experts, actively participating as consultants and collaborators as part of a multidisciplinary team at all stages of the research process. The Research Loop allows patients and caregivers to become part of a team by providing feedback through the site.

### *a. With not For*

A fundamental concept of including patients and caregivers is orienting researchers to understand that “Instead of undertaking research on or about patients, research is undertaken jointly with them.”<sup>37</sup> In other words, research should be “carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for. them.”<sup>43</sup> Most research is beneficently undertaken by researchers *for* patients and caregivers. However, as discussed above by inviting patients and caregivers to work *with* researchers, better research priorities can be selected, higher quality research can be undertaken, and a greater impact made by the completed project.

### *b. As Experts*

As part of a team, researchers must first recognize the expertise patients and caregivers have through their lived experiences within the health system and as individuals with diverse backgrounds including various forms of education (both formal and informal) and work-related experience. Given this diversity, all forms of knowledge must be respected and valued, qualifying patients and caregivers as, in the least, experiential experts. This however “requires a recognition that knowledge is produced in arenas other than academia.”<sup>37</sup>

In the past such “Experience-based experts have...been excluded from knowledge sharing and decision making because their knowledge has been seen as inferior to certified expertise.”<sup>41</sup> Many researchers and institutions continue to question whether patients and caregivers without the same certifications as researchers can truly offer much to research. But as Shippee et al. noted, patients’ and caregivers’ “abilities should not be undervalued: challenges such as serious mental illness or lack of resources in developing countries have not prevented [them] from understanding research foundations, giving feedback and strengthening research.”<sup>15</sup>

Chalmers reminds us that “No one – and certainly not researchers – can claim a monopoly of relevant wisdom in discussions about what deserves attention in health research. Lay people can draw on kinds of knowledge and perspectives that differ from those of professional researchers.”<sup>35</sup> Thus, when involving patients and caregivers in research, Evans points out “Service users should have equal status with other research team members for the expertise they bring; all team members’ views should receive equal consideration.”<sup>33</sup>

The Research Loop recognizes the power of patient and caregiver expertise and works to elevate their voices to transform the research process. While researchers will ultimately decide whether

to accept the feedback offered by patients and caregivers, The Research Loop echoes INVOLVE in urging researchers to remember: “Members of the public might have personal knowledge and experience of your research topic or be able to provide a more general perspective. Even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition.”<sup>12</sup> Accordingly, The Research Loop hopes that researchers will also recognize the expertise of patients and caregivers and include their voice in the research process.

*c. As active participants*

In the past, patients and caregivers have merely been “passive subjects” of research<sup>22</sup>, essentially only as data points.<sup>9</sup> However, there is increasing recognition that they should be “active partners” in research.<sup>10,39</sup> Such active participation recognizes the value of the patient and caregiver voice, including their expertise as consultants and collaborators and acknowledges that involvement of patients and caregivers should not be tokenistic (as further discussed below). It also encourages patients and caregivers to propel research forward.

The Research Loop ensures that patients and caregivers can be active participants. Section IV demonstrated how patients and caregivers are often left out of the research process all together given the obstacles that in-person meetings pose. The Research Loop solves many of these issues so that patients and caregivers are given a voice that can truly impact research at all stages.

*d. As consultants and collaborators*

Patients and caregivers may be asked to participate at varying levels of involvement and engagement – from passive participants in research, to consultants, to collaborators. Consulting and collaboration allow patients and caregivers to bring their expertise to the table to influence various stages of research. Ideally, patients and caregivers should be collaborators with researchers, making decisions together. Short of that, having patients and caregivers act as consultants whose input researchers look to when making decisions is of great importance.<sup>44</sup>

The Research Loop allows patients and caregivers to act as consultants. As The Research Loop develops, there is promise in developing relationships between researchers and patients and caregivers that might lead to more collaborative partnerships. Currently, by providing feedback, patients and caregivers can offer their expertise as active participants on a research team.

*e. As part of multidisciplinary team*

Given patients’ and caregivers’ expertise, their input can be viewed as part of engagement on a multidisciplinary team. As Natland et al. point out, including patients and caregivers in the research process takes them “From being an object of research, the patient can now become a co-researcher in a team that jointly formulates the goals and methods of the research project.”<sup>37</sup> An approach that they say “emphasizes interdisciplinary, collaboration and a given context.”<sup>37</sup> This kind of collaboration is increasingly encouraged. In fact, to increase value and reduce waste, Chalmers et al. say it is important to encourage researchers “to work across traditional academic

boundaries can lead to creative sharing of ideas...” and recognize the importance of multidisciplinary teams.<sup>23</sup>

Patients and caregivers using The Research Loop platform can be seen as adjuncts to a research team. The feedback they offer will hopefully drive researchers to see beyond those “traditional academic boundaries” by introducing them to new viewpoints. This expert feedback can help shape future research just like feedback any co-researcher developing a study.

*f. At all stages of the research process*

Patients and caregivers should be involved in all stages of research including priority setting, research design, data collection, analysis, interpretation, dissemination and implementation to have the greatest impact.<sup>33</sup> Many emphasize the importance of involving patients and caregivers at the earliest stages of research development. In that way, patients and caregivers can perhaps have the greatest impact. However, as INVOLVE states, “it’s not too late to involve people” at any stage of research<sup>12</sup> and, as demonstrated above, patients and caregivers can provide valuable input at all stages.<sup>45</sup>

The Research Loop gives patients and caregivers the opportunity to impact all stages of research by providing a platform to let them comment on all aspects of research. Patients and caregivers are specifically asked to provide input on design, analysis, and impact. Additionally, through educational materials posted on the site, patients and caregivers can learn more about research and other efforts to involve patients and caregivers in research. These resources can help increase the ability for patients and caregivers to understand and comment on all aspects of research.

Not only does The Research Loop allow patients and caregivers to offer feedback for all stages of research, The Research Loop presents this information at the earliest stage of research – before future projects are conducted. The feedback, as discussed above, can impact the very first stage of priority setting. Ultimately The Research Loop fills the gap between the end of a research study and the beginning of the next, transforming the linear research process into a perpetuating research loop.

## **XI. Barriers to Including the Patient and Caregiver Voice**

While including the patient and caregiver voice presents many opportunities to improve research, barriers to their engagement must be addressed. As discussed previously, patients encounter the barrier to being active participants – an issue The Research Loop directly addresses. Yet further barriers exist of which researchers must be aware.

*a. Recognizing Value*

Though presented in this paper and many others, researchers may still not see the value of involving patients and caregivers above. To help researchers understand how patient and caregiver feedback can be useful may require continued educational efforts and training for

researchers. The Research Loop will offer educational materials to support researchers in recognizing the value of the patient and caregiver voice in many ways.

*b. Respect*

i. Respect expertise

As laid out in Section X, patients and caregivers have valuable expertise to offer researchers. It is then disappointing that this expertise is not always recognized. Unfortunately, “Many researchers remain dismissive of suggestions that patients, carers, and clinicians should help to prioritise research...”<sup>24</sup>

The Research Loop will attempt to help researchers recognize the value of the patient and caregiver voice – both through education and the actual provision of feedback. Educational efforts will focus on presenting to researchers how patients and caregivers can transform research. In fact, this very paper can be used as educational material as it presents arguments for involving patients and caregivers.

Researchers who receive feedback from The Research Loop may develop more respect for the patient and caregiver voice. Hopefully these researchers will then use their experiences to impress upon their colleagues the importance of the patient and caregiver voice.

ii. Respect emotions

Some researchers question including patients and caregivers, thinking that these individuals may be too emotional. However, researchers should realize that emotions can in fact provide important feedback. As Uhm noted, “Emotion and anecdote can be ‘the motivation to discuss, and to engage with, material and fellow citizens.’”<sup>41</sup> As such, emotions should be seen as an asset.

Researchers might also be reminded, that research is very personal to these patients and caregivers. These studies may directly affect their lives. Thus, researchers should approach feedback from patients and caregivers with compassion and understanding.

The Research Loop, at least in its initial stages, will attempt to screen feedback to ensure that it does not violate feedback guidelines but will not censor feedback that may come across as “unprofessional.” Feedback guidelines lay out what feedback is inappropriate and how patients and caregivers can write constructive feedback that is more beneficial to researchers. But to the extent that the guidelines are followed, The Research Loop will allow feedback that is emotional. This includes feedback that may make researchers uncomfortable.

While researchers will be more receptive of feedback that is perceived as positive or constructive, there is still value in patients and caregivers simply stating, “this research is awful.” Such feedback may be imbued with emotion but if accepted, can be used as any other feedback to inform future research. Though not specific, such a statement may encourage researchers to review the work they conducted with a more critical eye and re-evaluate future endeavors to

assess whether their topics are relevant, if the research is flawed, and where improvements can be made.

### iii. Respect level of ability

Patients and caregivers come to research with differing levels of ability – including educational, mental, or physical ability. As noted above, those with what some researchers deem as “lesser” levels of ability have typically been excluded from research or their feedback devalued. Researchers may think that it is too difficult or impractical to include these individuals. However others have demonstrated that engagement is feasible even “in populations and communities with high prevalence of social inequities (intellectual disparities, poverty, unemployment and illiteracy) traditionally considered difficult to reach”<sup>9</sup> Many may in fact be surprised to learn how patients and caregivers can impact research regardless of level of ability.

Professor Dame Sally Davies, the Chief Medical Director at the National Institute for Health Research in the U.K. affirmed this idea, stating, “No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost efficient as well.”<sup>12</sup>

The Research Loop believes that all patients and caregivers can add to research and thus aims to be accessible to all individuals regardless of ability level. The solution is developed so that patients and caregivers can offer simple feedback, such as “this is a great paper” to more detailed discussions of each aspect of the research. With education, The Research Loop hopes patients and caregivers will be able to give more detailed feedback. Yet even if patients and caregivers cannot offer detailed feedback, The Research Loop recognizes the value of their voice and that it should not be excluded from the research process.

### c. *Cultural shift/Institutional support*

Adding the patient and caregiver voice to research will take a cultural shift and institutional support. In the past years, with the push from organizations and funders, that shift has started and more and more institutions do support patients and caregivers. Still, many are resistant to the idea and question the utility of adding the patient and caregiver voice.<sup>18,39,40</sup>

Jinks et al. suggest from their study that ensuring the patient and caregiver voice is included it takes, “Strong and genuine academic leadership” and a “Clear organizational commitment”.<sup>30</sup> However, for that commitment to fully develop, institutions may need to see the actual benefit that comes from patient and caregiver involvement<sup>48</sup> – a bit of a catch-22. The Research Loop can help make the case to institutions that the patient and caregiver voice is in fact valuable and thus encourage institutional backing. Additionally, educational materials and resources will be posted on the site to help researchers make the case to their institutions about the benefit of involving patients and caregivers.

#### *d. Tokenism*

Unfortunately researchers' efforts to involve patients and caregivers can at time be tokenistic. In other words, they do not invite patients and caregivers to be active partners but merely to a fill a role, often to check them off as a requirement of funding. This however defeats the purpose and spirit of true patient and caregiver involvement. As ISPOR points out, "When undertaken in the right spirit, [patient and caregiver involvement] can bring important new insights and in many ways can be regarded as the ultimate "reality check" on the project in hand, which should repay its (relatively small) cost many times over in increased efficiency and can even prove critical to the success of the project. However, if it is skimped or undertaken in a spirit of tokenism the reverse will often be the result."<sup>25</sup>

The Research Loop cannot fully address the issue of tokenism. That responsibility lies in researchers' control. Researchers should recognize, though, the value of the feedback by patients and caregivers, accept it in the altruistic spirit it is offered. Their feedback should be respected if for no other reason than they have devoted a significant amount of their time and energy hoping that by offering their input they will in some way impact not only research but the lives of those who will benefit from the end result of research.

#### *e. Patient and Caregiver Support*

Part of involving patients and caregivers in research is providing them with support. Education about research in general is one aspect of support. Some patients and caregivers who are newer to research may be unsure they have anything to add.<sup>18,21</sup> Encouraging patients and caregivers to speak and empowering them with the tools to make them feel comfortable adding their voice to the conversation is essential.

Some patients and caregivers may experience burnout by "repetitive consultation fatigue" especially "where they have seen no benefits from their earlier efforts to contribute."<sup>40</sup> Patients and caregivers volunteer for many efforts – including research, fundraising, non-profit organizations. If they feel they were not heard or their ideas not put to use, they may become disappointed and less likely to contribute in the future.

The Research Loop wants to encourage patients and caregivers to continue giving to research. By offering a simple web-based application, The Research Loop may lighten the onus on patients and caregivers who want to be involved in research but experience "consultation fatigue." And the supportive educational materials will continue to provide patients and caregivers with support to be active participants over time.

## **XII. Researcher Motivations**

In addition to the tangible benefits that come from including patients and caregivers including funding and quality of research, researchers may find other motivations to include patients and caregivers in their studies. For instance, many researchers find personal enrichment. Many articles have highlighted researchers' motivations. In particular, they have reported researchers' found including patients and caregivers:

- “rewarding, enjoyable and made their work more meaningful and valuable”<sup>46</sup>
- “gave them confidence and reassurance they were going in the right direction”<sup>46</sup>
- “reminded [them], merely by the presences of patients or carers, of the ultimate purpose of their own work and so be motivated further.”<sup>40</sup>
- Led to “personal satisfaction and encouragement”<sup>30</sup>
- “had given them the confidence to keep going with a study when recruitment was slower than anticipated. The researchers also reported that patient or community representatives had reassured them of the importance of the trial.”<sup>14</sup>

The Director Translational Informatics and External Innovation at Johnson & Johnson, Anthony Rowe stated it best in a report by the European Federation of Pharmaceutical Industries and Associations Innovative Medicines Initiative:

“By working with a [Patient Input Platform], you realise this data comes from patients living with a condition that causes daily hardship. That this data requires them to take days off work to provide. That it’s given in the hope that other coming after them will have better therapies. The hope that parents will not have to sit up all night watching their children struggling to breathe. That spreadsheet is no longer just a table of numbers but something much more important.”<sup>47</sup>

### **XIII. Patient and Caregiver Motivations**

Like researchers, patients and caregivers have various motivations for getting involved with research. As mentioned above, many patients and caregivers give their time altruistically. But patients and caregivers also find it meaningful<sup>48</sup> and want to influence research for themselves, their family, or their community.<sup>40</sup> Some also find it empowering and can be good for their personal development.<sup>12,26,36,37,40</sup> Certain patients and caregivers who have had good healthcare experiences may want to give back, others who have had poor experiences want things to change, and some just want to have their story heard.<sup>10,12,26,40</sup> Additionally, there are patients and caregivers who become involved because they think it’s important to push for accountability and be involved as citizens.

Even though patients and caregivers want to get involve, as discussed above, they do not often get a chance. The Research Loop will empower patients and caregivers through education and facilitate their altruism in sharing their expertise.

### **XIV. Alignment with Other Initiatives**

#### *a. Patient Engagement Organizations and Patient-Centeredness*

The Research Loop aligns and supports several other initiatives in health policy around research. As an innovative solution, The Research Loop will enhance the efforts of organizations previously mentioned such as INVOLVE, JLA, NHMRC, PCORI, SPOR, and others focused on involving patients and caregivers in research. These organizations seek to include patients and caregivers at all stages of research. As of yet, these organizations do not have a way to remotely

include patients and caregivers outside the traditional, linear research process. The Research Loop closes the gap these organizations leave and in so doing, hopes to enhance their efforts.

### *b. Open Access*

Currently, most research is locked behind paywalls. Articles and journal subscriptions are too expensive – leaving most patients and caregivers without access to research. However, more and more patients and caregivers are demanding that research be open access. They rightfully assert that because a lot of research is funded by taxpayer money or contributions to charitable organizations, the public has a right to the research produced. Furthermore, they make the reasonable argument that research is less useful if it cannot be read by everyone, particularly end-users.

The Research Loop cannot provide patients or caregivers with access to research articles. The site lists resources pointing patients and caregivers to places to find research articles. However, The Research Loop will support aims to push for open access to all research and expects to add to those efforts. If researchers, institutions, and funders realize the impact the patient and caregiver voice can have in research, they will want to have more patient and caregiver feedback. To have more feedback, they will need to make the research more available. Thus, the feedback offered through The Research Loop can be the proof these individuals and entities need to support open access.

### *c. Data sharing*

As discussed previously, recent movements have pushed for researchers to release data and make it publicly available to all. These measures are largely resisted by the research industry for various reasons. However, patients and caregivers make a compelling argument that releasing the data is almost a moral imperative, noting that the data is in fact about and from patients and caregivers and thus they have a right to that data. They also argue that releasing the data will increase transparency so any errors may be discovered, producing more accountability and greater accuracy. In finding errors, researchers may be able to identify where research failed and improve future research. Furthermore, patients and caregivers argue that sharing data will spur research efforts, leading to more innovation and discoveries rather than letting data languish in isolated repositories.

The Research Loop will support data sharing as it supports open access. By releasing data, patients and caregivers can take a bigger role in research, as collaborators and perhaps even initiators of research. Additionally, greater transparency will produce better research in line with the goals of The Research Loop which aims to improve all research.

## **XV. Limitations**

There are a few limitations to The Research Loop that will be addressed as it grows.

### *a. Building Relationships*

First, most believe that an important part of these partnerships between researchers and patients and caregivers is to establish relationships. This can foster trust between the parties and perhaps encourage researchers to be more open to the patient and caregiver voice.

While in its current iteration, The Research Loop will provide feedback from patients and caregivers to researchers with only a brief introduction to the idea (see Appendix A), in the future there may be a chance to build relationships between those giving and receiving feedback. Initially though the feedback will be deidentified to the extent possible to minimize privacy risks to patients and caregivers who may disclose sensitive health information. If researchers want to contact patients and caregivers after they receive feedback, The Research Loop will try to facilitate a connection if the patient or caregiver is willing. As The Research Loop progresses, there will be more opportunity to see how such connections can grow.

### *b. One-sided communication*

Because The Research Loop is meant to be a simple solution for researchers to involve patients and caregivers in their work, no commitment is asked of researchers at this time. This will lead to a rather one-sided process as researchers will not be required to provide a response or comments to the feedback they receive. The Research Loop will send out a link if researchers wish to provide comments and will use that information to improve the site and provision of feedback. The Research Loop can of course also be contacted via email at any time if researchers have questions.

### *c. Training*

As discussed above in several places, patients and caregivers will come to The Research Loop with varying degrees of training and knowledge of the research process. The Research Loop will continue to provide educational materials and links to resources but cannot provide training on specific research projects.

## **XVI. Conclusion**

The Research Loop was born of the idea that patients and caregivers who read research have valuable feedback to offer researchers – feedback that can impact all stages of research from priority setting, to research design and analysis, to dissemination and implementation. Patients and caregivers do not often have the opportunity to be involved research as most initiatives require them to be available in person or substantial barriers prevent them from being able to contribute. Many may only know of research once it is published and then are left without a means to give their input. The Research Loop enables patients and caregivers from all over the world, at any ability level to submit feedback on research they have read. The web-based application overcomes traditional obstacles of inclusion and allows patients and caregivers to be involved in research in a new way thereby transforming the linear research process into a dynamic research loop.

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## **Appendix A**

### **Example Introduction Letter to Researchers**

Dear [Researcher],

I am writing to introduce you to The Research Loop, a new way to give patients and caregivers a voice in the research process. The Research Loop is a website that allows patients to enter feedback on research articles. That feedback is then given back to you, the researcher, in the hopes that it will impact future research projects. Attached you will find feedback on your article entitled [Title].

As a former merit reviewer for the Patient Centered Outcomes Research Institute, former researcher at the Judgment, Decision, and Intuition Lab at the University of Colorado at Boulder, and patient advocate who has worked in the area of health law and policy, I developed The Research Loop to fill a gap in the research process and give patients and caregivers a new way to become involved in the research process.

The Research Loop recognizes that patient and caregivers can offer valuable insight given their lived experience in health care. Their expertise can help you identify priorities for research, improve the quality of research including design, analysis, and interpretation, and provide context and meaning to the work you do. Often patients and caregivers want to give feedback on research but do not have the opportunity because they are not aware of a project until after the research is completed and published. The Research Loop gives them that opportunity.

In addition to impacting your work, The Research Loop aims to build a bridge between researchers and patients and caregivers. The site contains multiple educational materials to help patients and caregivers understand research and encourage them to become more engaged in the research process. As The Research Loop grows, we hope to foster connections for collaboration between these communities across the world.

The Research Loop is not a website that publishes research and feedback is not published directly on the site. Any feedback that is submitted through the site is screened to ensure that it meets our guidelines before being passed on. And while you are under no obligation, you are invited to let us know if the feedback affected your work by emailing me at [erin@theresearchloop.com](mailto:erin@theresearchloop.com).

If you have any questions, please do not hesitate to contact me.

Sincerely,

Erin M. Gilmer  
Founder, The Research Loop  
[erin@theresearchloop.com](mailto:erin@theresearchloop.com)

## **Appendix B Example Feedback**

[note: This is an open access paper that can be found at:  
<https://academic.oup.com/jamia/article-lookup/doi/10.1093/jamia/ocw169>]

### **Feedback for Dr. Zikmund-Fisher**

Below you will find feedback offered by a patient through The Research Loop website about an article you authored. We hope that this feedback will be useful to you as you consider future projects. If you have any questions or would like to let us know how this feedback impacted your work, please email me at [erin@theresearchloop.com](mailto:erin@theresearchloop.com).

#### **Article Citation**

Zikmund-Fisher, B.J., Scherer, A.M., Witteman, H.O., Solomon, J.B., Exe, N.L., Tarini, B.A., and Fagerlin, A. (2016). Graphics help patients distinguish between urgent and non-urgent deviations in laboratory test results. *Journal of the American Medical Informatics Association*, 24(3), 520-528.

#### **Date the person read this article (may be best estimate)**

5/23/2017

#### **This person identifies as a:**

Patient, Patient Advocate

#### **This person is from:**

United States

#### **The reason person was interested in this study:**

They were interested in the design and/or findings of this study

They were interested in the implications this research had for their care or the care of others they know

#### **Overall impression of the study:**

I really like this study. As a patient, I know how hard it is to interpret test results from my doctor. Having a colored line I think would be the most helpful to me.

#### **Feedback on the study's design:**

I was glad to see that you had many people to sample from in this project so that you could get diverse views. I was wondering however if you would consider in future projects working with specific patient populations? For instance, I would assume that cancer patients or patients with type 1 diabetes might have more experience with these areas and thus be able to provide feedback from their experience.

I did not like that you did not have a way for people to select that they might check online or ask a friend about results before reaching out to their doctor. I think many people will check online or ask a friend as an action that falls between doing nothing (and perhaps a

lower urgency) and doing something (seeking out care). Since these patients are already online, one could assume that they might use online resources to put their findings in context.

**Feedback on the study’s findings or conclusions:**

I thought these findings were exactly what I would expect from the general public – that a colored line would be more helpful than a table. In the discussion you talked about how hard it may be to determine the range and might select default display ranges. I think though that the tables already do this by indicating if a result is “Within Normal Limits” (WNL). Perhaps you do not need to set endpoints as much as make sure there are clear markers for what is WNL.

**Ideas for future research:**

As I said above, I think it would be important to do a version of this study for patients who more frequently go to appointments – patients with chronic illness or with specific diseases like cancer.

**How the person thinks the findings might impact patients or patient care:**

I have seen this issue talked about with doctors and patients before – that the numbers and tables are hard to read and interpret. I think this will really help patients. However, it may be overwhelming if there are graphs like this for each result. Often I get maybe 20 results at a time and if I had to look at 20 graphs I might get confused or visually overwhelmed.

**How the person thinks the findings might impact healthcare policy:**

I think doctors and patients should push for this kind of information to be standard in all patient portals. I also think in general there should be better patient education of what lab results may mean – perhaps better resources for finding information online.

**General questions or feedback:**

I was struck at the beginning of this article when you said that patients may “overreact to slightly elevated or reduced values.” I think this is a very stigmatizing statement. Patients and caregivers do not “overreact” they simply react. There has been a narrative in medicine for a long time that patients are incapable of determining what results mean. In fact, I have found myself having to interpret the results on my own many times and pointing out problems to my doctors that they miss. An article by Francesca Pillemer in PLoS ONE in 2016 talks about the potential releasing these results has to improve patient safety. In my own experience, I know that my doctors may miss test results that may seem WNL but for me are abnormally high or low. To say that I am “overreacting” is to dismiss my level of engagement and knowledge about my own care.

To that end, because I track my own results, I often compare my current results to past results. As EHRs are used more, they may keep track of these differences and make comparisons as well. How would a graph work that both shows where I am in comparison to WNL and in comparison to my own results? It seems like a simple line graph may not work for that.

I have seen a lot of tracking apps and I think the site Patients Like Me has experimented with graphing results. Have you worked with them or others to develop these ideas further. I worry, just like EHRs, the type of graphs produced if different organizations create their own will mean patients have to learn new graphs each time we get results from a different doctor. We need a way to make this standard.