Improving the impact of clinical documentation through patient-driven co-design: experiences with cancer pathology reports

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ABSTRACT

Objective With the unprecedented rise of patient access to clinical documentation through electronic health records, there is a need for health systems to understand best practices for redesigning clinical documentation to support patient needs. This study used an experience-based co-design approach to inform the redesign of cancer pathology reports to improve their patient-centeredness and impact on patient engagement.

Materials and methods Multiple methods for data collection and stakeholder engagement were used, including Delphi prioritisation with breast and colorectal cancer experts (n=78) and focus groups with patients with cancer (n=23) in the Seattle area. Iterative rounds of consensus generation and reflection were used to elicit themes and design recommendations for the development of patient-centred pathology reports on cancer care.

Results Although each cancer type had nuanced elements to consider, common design requirements emerged around two key themes: (1) clinical documentation language should be framed in a way that informs and engages patients, and (2) clinical documentation format should be leveraged to enhance readability and information flow. Study activities illuminated detailed recommendations to improve the patient-centeredness of pathology reports based on patients’ and clinicians’ lived experience.

Discussion The design requirements that emerged from this study provide a framework that can guide the rapid development of patient-centred pathology reports for all cancer types. Even further, health systems can replicate these methods to guide experience-based co-design of clinical documentation for contexts beyond cancer care.

Conclusion This work offers practice-based learnings that can more effectively guide health systems in their clinical documentation redesign efforts.

BACKGROUND

The past decade has seen unprecedented efforts to give patients access to their electronic health records (EHRs). In the USA, for example, health systems are rapidly increasing the depth and breadth of clinical documentation patients can access in response to national policies such as Meaningful Use and the Health Information Technology for Electronic and Clinical Health Act. This work is mirrored on an international scale; Sweden, for example, has worked to provide widespread patient access to their health records over the last decade, and similar initiatives have been documented for many Nordic, European and non-European countries. These efforts are rooted in the belief that increasing patient access to their clinical documentation will reduce information asymmetry and enhance patients’ ability to understand and engage in the care delivery process. However, most clinical documentation was not designed with patients as the target reader. Therefore, there is a need for health systems to consider approaches to

Summary

What is already known?

- Cancer pathology reports are critical tools for treatment decision-making, but are not patient-centred.
- Providing patients with more accessible communication tools can support their knowledge, engagement and satisfaction in care.
- Health information technology offers opportunities to translate medical documentation into patient-centred tools that support patient engagement.

What does this paper add?

- Common design recommendations, in particular related to language framing and format of information display, can facilitate rapid development and replication of patient-centred tools for cancer pathology interpretation.
- Engaging multidisciplinary stakeholders, including patients, in the design of innovative tools can enhance their ability to produce meaningful impacts on patients and health systems.
modify the presentation of clinical records to be more inclusive of patient perspectives.

Cancer pathology reports offer a valuable example for understanding potential approaches to the redesign of clinical documentation. Cancer pathology reports serve as an essential diagnostic tool and contribute to cancer treatment planning and decision-making throughout the cancer care continuum. In general, cancer pathology reports contain detailed clinical results, including a gross and microscopic description of the sample, an estimation of cancer stage and grade, and results of cancer-specific tests that may further describe genetic or immunohistochemistry characteristics of findings. Cancer pathology reports, though, are not designed for patients; therefore, they contain complex medical language and limited contextual clinical data, which hinder patient decision-making and overall satisfaction with care.12–14 Patients have historically only received a verbal summary of their pathology results from their providers, or a printed copy of their pathology results if requested. Yet as patient access to their electronic medical records rises, so does their use of pathology reports. A 2014 analysis of 6495 patients with cancer found that 37% of patients viewed their pathology reports within their patient portal, which further highlights the importance of ensuring clinical documentation is effectively designed to engage patients in their own health information.15

Recent years have also seen the rise of evidence-based methods for patient involvement in research design and the development of clinical practice guidelines16-18. In parallel, design science, and the use of user-centred design methods, have grown significantly, increasing the involvement of patients in the design of new patient-facing tools and technologies.19 These methods emphasise the need to engage target users throughout the design process (i.e., co-design) to improve usability, fit and ultimately care-related outcomes. In 2006, Bate and Robert introduced a method of experience-based co-design (EBCD), which targets the inclusion of patient stakeholders in all phases of health system improvement efforts and reframes the improvement design process around patients’ lived experience during the care delivery process.20 While each of these methods offers valuable recommendations to guide the co-design process, there is limited evidence on how well these methods apply in the context of co-redesign of clinical documentation within EHRs, which may have more constrained parameters for scope, resource and technical latitude.

In this work, we engaged multiple stakeholder groups to develop recommendations for improving the patient-centeredness of pathology reports, informed by EBCD methodology. Specifically, we sought to (1) identify design requirements for the development of patient-centred pathology reports that could supplement existing pathology reports, and (2) identify learnings related to the experience of engaging diverse stakeholders in the co-design process. This work builds off of prior demonstrations that simple modifications to existing pathology reports insufficiently increased their readability for patients, and the efficacy of developing supplemental patient-centred pathology reports for cancer care.21 22

Our goal was to expand this work and develop recommendations that could translate across cancer types, and inform broader efforts to engage patients in the co-design of patient-facing technologies.

METHODS

Our methodological approach was guided by action research framing for EBCD.20 23 Participatory action research methodology is characterised by iterative cycles of diagnosing, planning, acting and evaluating, and is advantageous for dynamic healthcare problems that involve multiple stakeholder perspectives.24 EBCD is an application of action research that stresses the importance of letting stakeholders’ lived experience guide the design process for health system improvements. Via cyclical and collaborative involvement of patient and clinical stakeholders throughout phases of capturing experiences, understanding experiences, improvement and reflective evaluation, EBCD facilitates the alignment of experiential and expert knowledge.23

Our work unfolded in four phases that align with goals for the EBCD process, as described in table 1. In accordance with existing best practices for participatory research and continuous engagement, we engaged multiple stakeholder groups in the design, conduct and interpretation of all study activities, including clinical experts (eg, oncology, pathology) and patients (experience with breast cancer, colorectal cancer or colorectal polyps).16 We focused on patients with—or at risk for—breast and colorectal cancers given: (1) these are among the most common cancers; and (2) the pathology results contain detailed clinical results, including a gross and microscopic description of the sample, an estimation of cancer stage and grade, and results of cancer-specific tests that may further describe genetic or immunohistochemistry characteristics of findings. Cancer pathology reports, though, are not designed for patients; therefore, they contain complex medical language and limited contextual clinical data, which hinder patient decision-making and overall satisfaction with care.12–14 Patients have historically only received a verbal summary of their pathology results from their providers, or a printed copy of their pathology results if requested. Yet as patient access to their electronic medical records rises, so does their use of pathology reports. A 2014 analysis of 6495 patients with cancer found that 37% of patients viewed their pathology reports within their patient portal, which further highlights the importance of ensuring clinical documentation is effectively designed to engage patients in their own health information.15

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own responses. In round 2, experts then re-ranked the pathology report concepts, using a fixed ranking method. There was an average of 6 weeks between rounds 1 and 2 for each panel (breast, colorectal) and a response rate of 58% on round 2. Surveys were administered electronically via Research Electronic Data Capture, an electronic data capture tool hosted at the University of Washington.27

Mean scores from panel participants were used to arrive at consensus for prioritised pathology report clinical elements. We examined a weighted score of pathology element rankings to construct an aggregate ranking score and identified thresholds at which pathology elements were de-prioritised. For both breast cancer and colorectal cancer expert panels, there was a naturally observable threshold at which pathology elements received no rankings of 2 or higher. These concepts and proposed language were further validated with the study’s patient advisors, who added additional considerations around patient preferences for pathology report language. The result of this first phase was a list of prioritised clinical concepts and identified thresholds at which pathology elements received no rankings of 2 or higher. These concepts and proposed language were further validated with the study’s patient advisors, who added additional considerations around patient preferences for pathology report language. The result of this first phase was a list of prioritised clinical concepts for each cancer type and associated recommendations for patient-friendly language to describe those concepts.

Phase 2: for the second phase of this work, we engaged with patients to better understand their experiences reviewing and interpreting cancer pathology reports. To start, we leveraged feedback from clinical experts and patient advisors to inform a semistructured discussion guide designed to elicit patient experiences with pathology reports for cancer diagnosis or polyp removal for cancer screening. In addition to broad concepts related to pathology report experiences, the discussion guide solicited targeted feedback on the patient-centeredness of pathology language for the core clinical concepts identified by our expert panel. Four focus groups were convened with patients (n=23) who had experience with colorectal cancer screening and diagnosis (two focus groups) or breast cancer screening and diagnosis (two focus groups), recruited from local cancer support groups as well as purposive sampling through study investigators’ clinical practices to increase diversity of patient treatment experiences. Since the goal of this phase was to understand patients’ lived experiences related to cancer pathology, focus group participants were not required to have viewed their pathology report; instead, the variety of their experiences (eg, receiving directly from providers, not receiving at all, accessing online) was explored.

Focus groups lasted approximately 90 min and were audio recorded and transcribed. Team members trained in qualitative methods used Dedoose software to support qualitative coding and analysis.28 An inductive, open coding approach was used to develop salient themes about patients’ experiences and preferences for pathology report format and content.29 30 More specific feedback on proposed pathology report language and formatting was reviewed via content analysis to identify recommendations on which focus group participants reached consensus. When consensus was not reached or further language revisions were proposed by patients, the team leveraged the clinical and patient advisors to iteratively resolve discrepancies in patient feedback for cancer-specific recommendations. The output of this second phase included overarching themes that reflected patients’ experiences with pathology reports, and draft language for patient-centred pathology reports for breast and colorectal cancers.

| Phase | Activity type | Description | Stakeholders involved |
|-------|---------------|-------------|-----------------------|
| Phase 1: capture experiences | Expert panel, Delphi prioritisation | Identify and prioritise core clinical concepts to include for feedback in focus groups. Recommend draft language for patient-centred pathology reports. | Clinical experts (n=78), Researchers (n=3), Patient advisors (n=5) |
| Phase 2: understand experiences | Focus groups (n=4) | Understand patient experiences with pathology reports. Provide feedback on core concepts and draft language for patient-centred pathology reports. | Patients (n=23) |
| Phase 3: design improvements | Integration of phase 1–2 data, Identification of design requirements | Draft patient-centred language for pathology report core clinical concepts. Generate consensus and translate recommendations into design requirements across cancer types. | Clinical experts (n=6), Patient advisors (n=5), Researchers (n=3) |
| Phase 4: reflective evaluation | Reflective evaluation on co-design process | Iterative reflection on recommendations from expert panel and focus groups. Reflection on EBCD process. | Clinical experts (n=6), Patient advisors (n=5), Researchers (n=3) |

EBCD, experience-based co-design.
Phase 3: in phase 3, the themes and recommendations elicited from phases 1 and 2 were integrated and triangulated to inform design requirements for the development of patient-centred pathology reports for colorectal and breast cancer care. Through this, we developed template patient-centred pathology reports for multiple clinical scenarios associated with breast and colorectal cancer, which were iteratively reviewed with a representative core of clinical experts and patient advisors over a period of 8 months in terms of their clinical accuracy and patient-centeredness. Once templates were approved by our stakeholder groups, we compared templates to prior work on bladder cancer and prostate cancer to generate broad themes regarding language that could be used to express cancer pathology core concepts that are common across cancer types. The outputs of phase 3 include generalisable design requirements for the patient-centred presentation of cancer pathology findings that could support scalability to other types of cancer or forms of clinical documentation.

Phase 4: in our final phase, we reflected on the EBCD process with our clinical experts and patient advisors. We leveraged project documentation (eg, meeting minutes, project timelines and deliverables) to summarise how the co-design process unfolded for patient-centred pathology reports, documenting areas of divergence and conflict when able. We reviewed this summary of activities and outputs of each phase (1–3) with clinical experts and patient advisors, soliciting feedback on the barriers and facilitators to the co-design process from the perspective of each stakeholder group. Feedback from stakeholders was combined, integrated and documented as lessons learnt that could inform future EBCD work.

RESULTS

In phase 1, 78 clinical experts participated in the Delphi panel, representing breast cancer (45%) and colorectal cancer (55%) expertise. Panellists reflected multiple clinical specialties, including medical oncology (23.1%), surgical oncology (19.2%), radiation oncology (14.1%), pathology (15.4%), gastroenterology (16.6%) and cancer research (11.6%). Clinical experts prioritised five concepts related to breast cancer and five concepts related to colorectal cancer (see online supplemental material). Between 9 and 15 language phrasing options were identified for each concept, varying in length from a few words to several sentences, which informed focus group discussion in phase 2.

Twenty-three patients participated in the focus groups of phase 2. On average, patient ages ranged from 37 to 74, with a mean of 56 years of age. Overall, 82% of patients were women (consistent with the recruitment emphasis on breast cancer), and 9% of patients were non-white. During focus group discussions, patients described significant challenges understanding their pathology reports, and they reiterated the urgent and emotional nature of cancer treatment decision-making. The standard pathology report added burden and complexity to an already overwhelming patient experience, and—in many cases—this report limited their involvement in and satisfaction with the treatment decision-making process.

Let me understand what it is, and make decisions based on full knowledge, not going, you know, months later going if I had only known that I might have made a different decision. (Breast cancer participant)

The integration of expert panel data (ie, prioritised clinical concepts and recommended descriptions of concepts) and focus groups data (ie, experiences interpreting clinical concepts for individual decision-making, feedback on concept descriptions and format) produced a wealth of rich feedback around how to make pathology reports more patient-centred (phase 3). Although there were highly nuanced discussions among stakeholders within each cancer type, the majority of recommendations for pathology report formatting and language were consistent across cancers. The following are key learnings and design requirements integrated from study activities in phases 1–3, related to (1) language and (2) format.

Design learnings: frame language in a way that informs and engages patients

The language used to describe complex medical terms and concepts had a critical impact on patient comprehension and use of pathology reports. Patients emphasised the need for patient-centred pathology report language to be comprehensive, clear and framed towards a lay audience. Patients expressed that they did not want to be shielded from medical language, as that could further the communication divide between patients and clinical team members. Patients therefore recommended keeping medical language present in patient-centred pathology reports to help familiarise patients with the terminology their clinical teams might use, but accompany each medical term with a clear explanation of its meaning. Providing explanatory clarifications was particularly important for pathology terms that used directional language, such as ‘positive’ or ‘negative,’ as those could be easily misinterpreted by patients given their use in non-medical contexts. Patients also highlighted that explanations should not be oversimplified, as this might be “a disservice to the patient who wants to know more” (Participant with polyp).

Just say what it is then explain what it means. (Participant with breast cancer)

I always appreciate when people don’t talk down to me, when they give me real information. (Participant with breast cancer)

When translating medical terms and concepts into patient-friendly language, patients cautioned against phrasing or terminology that might be inflammatory to a patient receiving a new cancer diagnosis. Patients advised maintaining an agnostic tone and clearly conveying when...
findings are uncertain or more information is needed. Participants also described the importance of including enough information to help patients grasp the broader context around their findings (ie, ‘what does this mean for my cancer’). Understanding their tumour size or location was the common example patients discussed that demonstrated how the lack of broader context hindered their ability to fully understand pathology report findings.

I think you just need to define what each stage is, and what the prognosis associated with that is. [...] Then you can look at that to say ‘Okay, I’m there, and this is what’s probably going to happen.’ (Participant with breast cancer)

Providing the full context of medical concepts would help patients better manage expectations and connect their pathology report findings to the implications for their decision-making. Yet, patients also recognised that it may not always be possible to provide implications without a clinical interpretation and conversation. In these scenarios, patients recommended providing clarity around where pathology report findings may be uncertain.

I may or may not understand the implications and I’m probably going to think either the absolute worst or the absolute best. (Participant with colorectal cancer)

Feedback from the focus group participants led to the identification of multiple recommendations related to patient-centred pathology report language that translated across cancer types (table 2).

Table 2  Language requirements for patient-centred pathology reports

| Clinical element    | Key requirement for patient-centred translation |
|---------------------|-----------------------------------------------|
| General             | ► Keep tone agnostic and/or neutral            |
|                     | ► Include, but define, pathology terminology  |
| Diagnosis           | ► Describe the type, size and location of cancer |
|                     | ► Provide additional explanation to help place size and location in broader context of patient anatomy |
| Stage               | ► Explain the ranges and directionality of stages available |
|                     | ► Provide details on what clinical elements contribute to staging |
| Grade               | ► Explain the ranges and directionality of grades available |
|                     | ► Provide details on how grade connects to cancer aggressiveness |
| Surgical margin status | ► Clarify directionality of ‘positive’ and ‘negative’ margin status |
|                     | ► Provide implications to guide discussions with their provider |
| Ancillary studies   | ► Connect ancillary studies to treatment decision-making |
|                     | ► Clarify when there is uncertainty about the role of ancillary studies in decision-making for an individual diagnosis |

Following the focus groups, the study team engaged in iterative reviews with clinical and patient advisors to reach consensus on specific language that could be used across cancer types and determine how analogies would be incorporated into patient-centred pathology report language.

Design learnings: leverage formatting to enhance readability and information flow

Beyond the language used to describe pathology report findings, focus group participants discussed the important role of report formatting to support patient comprehension and use. Patients provided several intuitive recommendations, such as using simple sentence structures and avoiding large blocks of text. However, focus group discussions included broader input on how patients may access and use pathology report information over the course of their treatment. Patients described that the initial receipt of their pathology reports may be marked by high emotions, and during that phase, a simple summary or ‘bottom line’ is most helpful. As one patient said,

When [the pathology report] comes in I want to know the answer. (Participant with polyp)

Yet as patients become acclimated to their diagnosis, they are more likely to seek more detailed information.

Peel back the onion skin to get the layer that you want. (Participant with colorectal cancer)

There may be points in their treatment where patients need to revisit their pathology findings to understand...
the next steps in their treatment, or identify questions to support decision-making. The level of information detail that patients want will therefore wax and wane throughout their treatment. Thus, patients recommended leveraging layout, such as the use of a ‘call-and-response’ format, to help direct patients to key information quickly.

Like where, when I was diagnosed and kind of deciding treatment, I’m deep-diving. Then there’s times where it’s just building anxiety and I’m kind of trying to not do that as much. (Participant with colorectal cancer)

I want to be able to quickly find the information so that I can draft my questions. (Participant with colorectal cancer)

Patients also acknowledged that each patient may have a different preference for information density and information-seeking behaviour around their diagnosis. Patients recommended maintaining a balance by using links to external resources (eg, ‘guided research’) to offer the option for patients to explore some topics in more detail. Lastly, patients suggested managing the flow of information within the patient-centred pathology report by starting with broader concepts and moving to more nuanced findings as the report progressed. Feedback from the focus group participants led to the identification of multiple recommendations related to patient-centred pathology report formatting, as described in Table 3.

Formatting recommendations from patients generally aligned with feedback from clinical advisors, yet there was a discrepancy between their recommendations around the volume of content that should be included in the patient-centred pathology reports. Clinical experts recommended only including pathology report findings that were relevant to that individual patient’s diagnosis, to avoid overburdening patients with additional concepts that may not impact decision-making. Patients advocated for the inclusion of all prioritised findings, including negative findings. Patients articulated that having an awareness of negative findings contributes to their understanding of the broader context of their treatment pathway. Several patients brought up examples of interactions with other patients regarding test results which they were unsure whether they were obtained for themselves. This led to a perception of missed opportunities for their care.

If you just said ‘you have,’ and I didn’t know what other things I did not have. (Participant with breast cancer)

The concept of knowing what you don’t have is helpful. (Participant with breast cancer)

The study team reached consensus on the inclusion of negative findings to support patient engagement in their care. Figure 1 summarises design requirements from phase 3 in an example patient-centred pathology report for breast cancer.

Finally, phase 4 produced lessons learnt about the EBCD process itself. By taking an EBCD approach, we were able to let the lived experiences of patients and clinical experts serve as the anchor for the design process. Feedback from our clinical experts and patient advisors highlights the challenge of managing competing recommendations from different stakeholder groups. A key facilitator that emerged from our process was the use of ‘consensus checks’ at each stage of the design process (see Figure 2). By engaging in routine consensus checks, this allowed for the perspectives of stakeholders to generate some discordance, as needed, but ensured that the design process did not move forward to its next phase without establishing consensus. Understanding this discordance was critical to designing a tool that would address the barriers patients and their clinical teams currently face; however, establishing consensus more regularly helped to avoid more significant barriers in later stages of design. Learnings from our stakeholders clarified the importance of reaching consensus from stakeholders at multiple, pivotal points in the design process.

**DISCUSSION**

Through an in-depth, stakeholder-driven design process rooted in EBCD methods, our team was able to develop design recommendations for patient-centred
pathology reports that would supplement breast and colorectal pathology reports. Our design process included initial work to understand patients’ and clinicians’ experiences applying pathology report information in practice. This informed selection of the elements within pathology reports that are most salient to treatment decision-making. Iteration of different language and formatting options prioritised readability, comprehension and consistency across cancer types. Lastly, we reflected on the role of consensus-building in the EBCD process itself. Each phase of development incorporates the perspectives of patient, clinician and pathology expert stakeholders. This work builds on the team’s prior exploration of patient-centred design for prostate and bladder cancers, and highlights that—despite nuanced considerations within each cancer type—there are common design recommendations.21 31

The design recommendations that emerged from this work align with existing guidance on enhancing the readability of pathology reports, including the need to leverage headings and language density to optimise readability for users.32 Attention to language and format can improve readability and patient-centeredness of how pathology findings are presented. Heading formats such as call and response, for example, allow patients to rapidly identify higher priority report elements and break the content of the report up into information that can be processed more easily.22 33 However these recommendations extend these learnings to the context of the patient user, and provide a framework that can guide the systematic and rapid development of patient-centred tools to support other types of pathology and laboratory results.32 33 Prior work demonstrates the value of using a design framework to support the consistent design of pathology reporting tools and increase interoperability of pathology information across technology platforms users may interact with.24 This work further extends the value of the design framework to enhance the patient-centeredness of pathology reports across health systems and diverse technologies.

Echoed throughout our methods was the benefit of continuously engaging stakeholders so as to optimise

Figure 1  Sample PCPR section with annotated design requirements.
Figure 2  Framework for stakeholder engagement in the design of patient-centred pathology reports.
the user-centeredness and acceptability of design learnings to target audiences. One example of the value of our EBCD approach is further highlighted by the incorporation of clinical meaning alongside several of the featured pathology elements, so as to generate common language between patients and providers. This design recommendation reinforces the collaboration between patients and their care providers, and aligns with the objectives of the Health Information and Management Systems Society Patient Engagement Framework.9,35 Furthermore, this stakeholder-centred co-design process can yield greater patient engagement in changes and innovation at the health system level. There are regulatory levers driving greater patient engagement in EHRs that are oriented to the technology, but lack guidance for development of the content. Greater attention to the content derived from health information documents within EHRs can serve as one avenue for enhanced patient engagement. The end result could be a democratisation of knowledge and the potential for downstream benefits including reduced costs and improved patient satisfaction.7

There are some important limitations to acknowledge with this work. First, this study took place in one geographical area within the USA, and may not reflect the experiences and perspectives of patients and cancer care teams in other settings within and outside of the USA, and how other settings leverage technology, such as patient portals, in different ways. Not all health settings use patient portals (and other patient-facing technologies) in the same way, which may limit the generalisability of these learnings. Second, the clinical experts and patients we recruited do not fully represent the racial, ethnic and language diversity of the US population broadly, so more work needs to be done to understand the perspectives of more marginalised and historically under-represented groups. Finally, this work reflects experiences for two common cancer types: breast and colorectal. Although this work builds off and corroborates prior work in prostate and bladder cancer, there is value in continuing to understand how these recommendations apply to other cancer types.

CONCLUSION

In this study, we sought to develop design recommendations to translate cancer pathology reports into patient-centred tools that support patient knowledge and decision-making for breast and colorectal cancer care. Clinical documentation such as cancer pathology reports would benefit from a process of redesign that translates them into patient-centred tools, and health systems need guidance on methods to approach this. Our work demonstrated the value of taking an EBCD approach to engaging patients and clinical experts in the redesign of cancer pathology reports, and identified key design recommendations that can apply to clinical documentation more broadly. As health systems continue to increase patient access to clinical documentation, it is imperative that these health information documents are reframed to enhance the patient experience and goals for patient engagement in care delivery.

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Contributors JLG presented the study concept, in accordance with this study’s participatory approach, all authors were involved in study activities that provided study data. JLG, EJA and JRL performed data analyses. CWK, MRK, EUP, SHJ, AIM, JLG and EJA performed results interpretation. EJA wrote the manuscript in consultation with JLG, and received input from all authors.

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Appendix Material: Clinical concepts prioritized by expert panels for breast and colorectal cancers

| Breast cancer concepts                  | Colorectal Cancer concepts                         |
|----------------------------------------|---------------------------------------------------|
| • Estrogen / Progesterone receptor status | • Cancer type                                     |
| • Her2Neu receptor status              | • Depth of invasion                               |
| • Surgical margin status               | • Lymphovascular invasion                         |
| • Tumor grade                          | • Tumor differentiation                           |
| • Multifocality                        | • Surgical margin status                          |