

Developing Design Guidelines for Precision Oncology Reports

Selim Kalaycı*

Department of Genetics and
Genomics and Icahn Institute for
Genomics and Multi-scale Biology,
Icahn School of Medicine at Mount Sinai

Çağatay Demiralp†

MIT CSAIL & Fitnesscity Labs

Zeynep H. Gümüş‡

Department of Genetics and
Genomics and Icahn Institute for
Genomics and Multi-scale Biology,
Icahn School of Medicine at Mount Sinai

ABSTRACT

Precision oncology tests that profile tumors to identify clinically actionable targets have rapidly entered clinical practice. Effective visual presentation of the results of these tests is crucial in accurate clinical decision-making. In current practice, these results are typically delivered to oncologists as static prints, who then incorporate them into their clinical decision-making process. However, due to a lack of guidelines for standardization, different vendors use different report formats. There is very little known on the effectiveness of these report formats or the criteria necessary to improve them. In this study, we have aimed to identify both the tasks and the needs of oncologists from precision oncology report design and then to improve the designs based on these findings. To this end, we report results from multiple interviews and a survey study (n=32) conducted with practicing oncologists. Based on these results, we compiled a set of design criteria for precision oncology reports and developed a prototype report design using these criteria, along with feedback from oncologists.

Keywords: Visual design, visual communication, precision medicine, oncology.

1 INTRODUCTION

Recent advances in next-generation sequencing (NGS) technologies [1] are improving our understanding of the role of inter-individual variability in the genomic lesions that drive disease predisposition or progression. Coupled with their low cost, genomic information from these technologies is increasingly being utilized in the clinic [2]. In fact, past several years have witnessed an emerging shift towards precision medicine approaches, which refer to treatments that are precisely tailored for each individual patient based on his or her unique genomic or epigenomic characteristics and lifestyle [3]–[5]. Since the mutational landscape of tumor cells plays an important role in the diagnosis, prognosis and treatment of multiple cancers, precision medicine approaches are especially well-suited for oncology practice. Under the remit of the Clinical Laboratory Improvement Amendments (CLIA) of 1988, genetic tests that are deemed to be analytically valid (e.g. accuracy and precision of gene mutation detection) by Centers for Medicare and Medicaid Services (CMS) can be adopted without any review of data regarding their clinical utility [6], and the utilization of test results to guide therapy resides entirely within the discretion of the treating physician. Consequently, gene panels that typically involve the targeted sequencing of 25 to 400 known cancer related genes are offered by both commercial vendors such as Caris (Figure 1—www.carislifesciences.com), Foundation Medicine (www.foundationmedicine.com), GeneDx (www.genedx.com) [7], [8] and medical centers. Among the commercial vendors, the

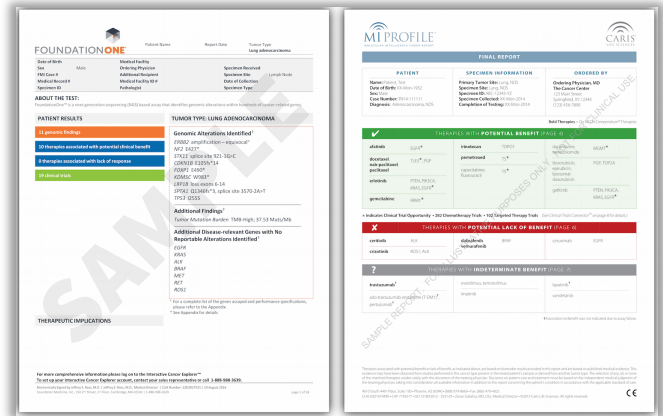


Figure 1: First page of sample reports from Foundation Medicine (left); Caris (right). See Supplementary Figure S1 and S2 respectively for full sample reports.

most frequently used panel is that from FoundationOne (Figure 1), which has produced more than 22,000 somatic tests in 2014 [9].

Results obtained from gene panel tests are typically delivered to clinicians as static print reports. So far there are no established standards, specifications or FDA guidelines. However, we can categorize the content commonly found in today's existing vendor reports into 5 main sections: patient/test identification, genetic alterations (mutations), therapeutic implications, test-related information, and appendix containing references and disclaimers (Table 1). Some vendor reports also provide one or more of the following: prognostic information, toxicity information, and pathologist interpretation of results. However, these are not necessarily included across different vendor reports. Since somatic genetic alterations form the basis of these tests, details provided on specific mutations drive most of the technical information presented in the reports.

The contents of the gene panel tests are critical as they alter treatment decisions in the clinic (i. e. hormone receptor targeting of hormone receptor positive breast tumors). However, challenges remain in communicating and interpreting these results. Several studies that investigate and report physicians' attitudes toward genetic testing and related concerns in the clinical care and practice of oncology suggest issues related with interpretation. In one of the earliest studies [10], only 29% of physicians reported that they felt qualified to provide genetic counselling to their patients, and nearly 75% of physicians thought that clear guidelines are not available for managing patients with positive test results. Similarly, more than 89% of physicians reported a need for guidelines. In a more recent study, Miller et al [11] conducted structured interviews with 17 physicians about genomic testing in oncology, and the results indicated a need for decision guidelines and education to assist physicians.

* email: selim.kalayci@mssm.edu

† email: cagatay@csail.mit.edu

‡ email: zeynep.gumus@mssm.edu

Table 1. Contents of a Typical Precision Oncology Report

Main Section	Sub-Sections	Details
Patient/Test Identification	- Patient Information - Specimen Information - Physician/Pathologist Information	- name, gender, id, etc. - specimen site, type, collection date, etc. - name, contact information, etc.
Genetic Alterations (Mutations)	- Detected gene alterations - Not detected gene alterations	- gene, type of mutation, interpretation - disease-relevant gene
Therapeutic Implications	- FDA Approved Therapies in patient's tumor type - FDA Approved Therapies in different tumor type - Clinical Trials	- drug name, interpretation - drug name, interpretation - title, phase, location, id, etc.
Test-related Information	- Gene List - Methodology	- list of all genes assayed in the test - specific technologies and procedures used to generate the test results
Appendix	- References - Disclaimers	- scientific works referred throughout the report - FDA status, legal/technical liabilities, etc.

In a larger study, Gray et al. [12] surveyed 160 clinically active oncologists at an academic cancer center to assess their current use of somatic testing, and their genomic confidence: 22% reported low confidence in their genomic knowledge. This study underscored a need for both evidence-based guidelines and enhanced genomics education efforts for physicians. In fact, genomic confidence was one of the strongest predictors of physicians' attitudes about and anticipated use of genetic testing. As is the case for the content, there are also no standards for the design and presentation of information in precision oncology reports. The layout, organization, design and representation of information at all levels vary widely across different vendors. In some instances, the results may indicate mutations in a large number of genes across multiple pathways, generating massive amounts of information [13]. For busy practicing oncologists, handling and interpreting such detailed and vast volumes of information presented in a nonstandard and impractical manner becomes a significant challenge. Thus, employing practical and effective reports is a crucial factor in the clinical adoption and utilization of precision oncology tests by oncologists.

To our knowledge, there are arguably no vendor-neutral/non-commercial research efforts aimed to improve and evaluate the effectiveness of precision oncology reports. On the other hand, multiple studies have focused on radiology reports. In [14], clinicians were asked to rank a variety of hypothetical radiology reports in order of preference. Reports presented in tables as opposed to traditional prose format were preferred and clinicians also preferred more detailed reports that included a clinical comment by the radiologist, for both normal and abnormal results. In a similar study [15], referring clinicians and radiologists indicated that structured reports provided better content and greater clarity than reports in simple text. In a study [16] that involved general practitioners (GP) who were asked to rank preferences for ultrasound reports with differing formats and levels of detail, the results again clearly suggested that GPs preferred detailed reports in a tabulated format.

Here, we investigated the challenges oncologists face in interpreting precision oncology reports and provided visualization solutions to some of these issues in a two-stage process, where we first identified design issues and requirements and then developed a design prototype. At every step of this process, we solicited feedback from the target audience, practicing oncologists.

2 DESIGN ISSUES AND EXPECTATIONS

In the first phase of our study, we aimed to understand the current status, needs and expectations of oncologists in terms of precision oncology report usage in their clinical practice. For this purpose, we conducted informal interviews with several oncologists at Mount Sinai Health System (New York, USA) regarding their

current experience, and expectations from the design of precision oncology reports. Based on these initial round of feedbacks, we prepared a draft survey questionnaire to get input from a wider community of oncologists. We revised the draft survey based on feedback from the same group to improve the relevance of the survey questions to the tasks of oncologists. After several rounds of revisions, we finalized the survey questionnaire.

2.1 Survey and Participants

We conducted the survey at a Hematology/Medical Oncology Grand Rounds meeting at Mount Sinai Health System in April 2016. After discussing the goals and scope of the project, the survey questionnaire was provided to all oncologists present at the meeting to fill voluntarily. The complete survey questionnaire can be found in Supplementary Table 1. In total, 32 oncologists responded to the survey.

Table 2 summarizes the demographics of the survey participants. The participants were almost exclusively made up of medical oncologists, majority of which were male (71%). Post-medical school years of experience exhibited a wide-range and were almost evenly distributed. The most commonly listed clinical foci among participating oncologists were blood cancer (42%), hematology (23%), and breast cancer (19%), where 31% of oncologists declared themselves to have multiple clinical foci.

Table 2. Demographics of Oncologist Survey (N = 32)

Demography	Respondents
Gender	(n = 31)
Male	22
Female	9
Years since medical school	(n = 32)
0 - 5	5
6 - 10	8
11 - 15	2
16 - 20	2
21 - 25	3
26 - 30	4
31 - 35	4
36 - 40	4
Type of Physician (multiple answers allowed)	(n = 31)
Surgical Oncologist	1
Medical Oncologist	31
Radiation Oncologist	0

Table 3. Design Goals for Precision Oncology Reports

Design Goal	Explanation
DG-1: Present Genetic alteration (Biomarker) information in the best possible way	This is the most important information for oncologists (Fig. S3.4), and also the most time-consuming component during interpretation (Fig. S3.5). Thus, relevant information should be presented in a concise, non-confusing manner. Also, the whole component (especially the actionable items) should be made prominent in the overall layout of the report.
DG-2: Distinguish clinically-relevant information from non-relevant technical information	Verbosity of technical information is the most troublesome aspect of reading these reports (Fig. S3.6). Oncologists expressed that they end up sifting through a lot of data to access information that is clinically important. Thus, the overall layout should keep essential (clinically relevant) information together before non-essential (e.g. standard disclaimers, technology-related explanation, etc.) information.
DG-3: Actionable summary results should be easily discoverable	Ease of locating actionable summary and critical information is among the most troublesome aspects of reports (Fig. S3.6). Actionable summary result information should be kept together, centralized, and emphasized with design elements.
DG-4: Presentation of information should be natural and easy-to-follow for oncologists	Organization and presentation of technical information should be in accordance with the customs and experiences of oncologists. Also, design elements used with an aim to help structure/organize information should not interfere with the interpretation activities of oncologists.
DG-5: As much as possible, the design should be consistent/compatible with existing vendor reports	Unless there is good reasoning not to do so, commonly used and well-performing design aspects of existing vendor reports can be reused. This, to a certain degree, helps with the desired standardization expectations (Fig. S3.8) of oncologists.
DG-6: When applicable, employ proper visual summary/representation of data	To address the verbosity aspect of technical information in existing reports (Fig. S3.6) and oncologists' expectations of summarized data (Fig. S3.8), proper visual design elements should be incorporated. Utilization of these visual elements should not be in contradiction with the objectives of previous design goals.

2.2 Results

Here, we provide a summary of our survey results. A complete analysis can be found in Supplementary Figure S3.

Genetic alterations are the most important information. Oncologists who participated in the survey stated that the most important information they look for in a tumor profiling report is genetic alterations (84%, Figure S3.4.). Therapy information and clinical trial information were also selected by 69% and 66% respectively (multiple selections were allowed).

Finding actionable genetic alterations is the most time-consuming task. By a wide margin, the most time-consuming component of interpreting such a report was stated as finding actionable genetic alteration information (57%, Figure S3.5) followed by clinical trials information (29%) and information about therapies (21%).

Verbosity and clutter limit the effectiveness of the reports. In general, oncologists stated that they preferred more concise reports; and that the most troublesome aspect of reading these reports was the verbosity of technical information (59%, Figure S3.6). Ease of locating actionable summary (45%) and ease of locating critical information (34%) were also identified as issues, which to a certain degree supports our previous observation.

Layout and visual encoding are the most critical elements of a vendor report. By a wide margin, oncologists selected the layout and presentation of information (61%, Figure S3.7) as the most problematic feature of a vendor report that makes it harder to interpret its content (next: more technical details, 32%), emphasizing the importance of our overall study. Furthermore, none of the participants stated that they were satisfied with current reports (Figure S3.8) when asked regarding the effectiveness of the reports. Furthermore, 58% of oncologists suggested standardizing the design of vendor reports. Finally, 50% suggested adding visualizations to summarize various data and to improve the effectiveness of oncology reports. Even though the percentage of those suggesting visual summarization of data may not look substantially high, it is quite noteworthy to observe such

a demand from a diverse demography of clinicians who are highly accustomed to dealing with extensive textual information.

3 REPORT DESIGN

Based on our findings from the survey study, and additional more in-depth feedback from interviews with several oncologists, we identified six main criteria for precision oncology report design, as listed in Table 3.

3.1 Design Process

Conforming to the design goals in Table 3, we designed several report prototypes in an iterative process. Briefly, we used different visual encoding and styling (e.g. shapes, colors, scaling, etc.) options to present information in a concise and clear format. In addition, we utilized multiple design elements (e.g. bold/larger font, shading, etc.) to highlight important information. Furthermore, we employed contrasting design elements (e.g. varying colors and shapes, etc.) to arrange the large-volume of information in an easily distinguishable manner. At each iteration, we had in-depth consultations with two oncologists and revised the designs accordingly. Among multiple prototypes that came out of this process, the one with the highest consensus is shown in Figure 2. Accordingly, the rest of the discussions regarding the report prototype (RP) refer to this specific design.

3.2 Design Choices

The main choices we made in the RP are summarized as follows. First, due to the conventional usage and expectations of clinicians (DG-4), the test/patient identification information was kept at the top of the page. We then designed a Results Summary section at the top left-half of the page to address DG-3. In this section, we used a table format and incorporated basic visual elements (DG-6) to summarize the information. To address DG-1, we designed a Genomic Alterations section at the top right-half of the page. This section lists all the detected genetic alterations as well as disease-

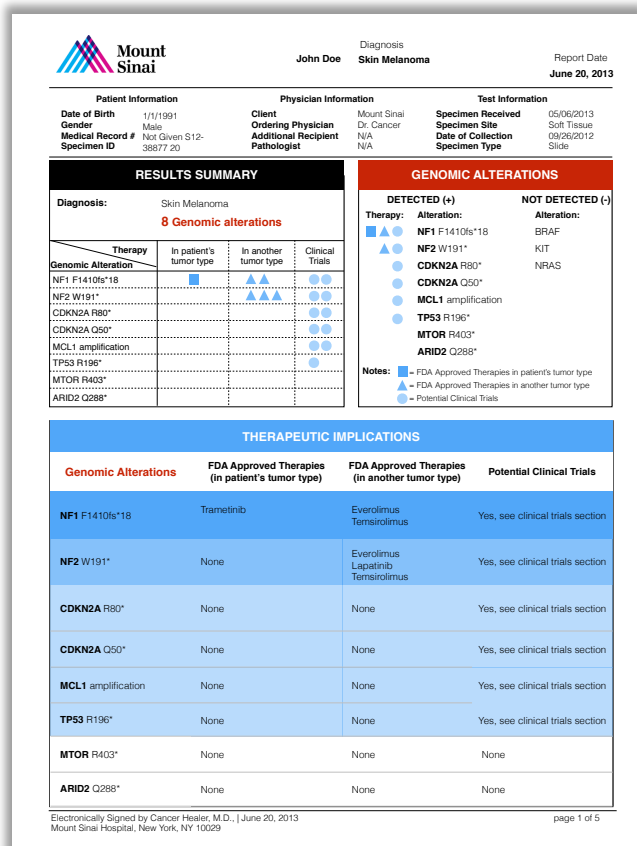


Figure 2: Our oncology report design informed by the design guidelines.

relevant alterations that were not detected. Associated therapy options are also displayed using the same visual elements, to help keep the consistency of notation and information across different sections (DG-4). Therapeutic Implications follow next, taking the whole page width, because of the type and amount of information it embeds. This section closely resembles the same section in the design of FoundationOne reports (DG-5), with the addition of color-encoded display of each row depending on whether the genomic alteration is clinically actionable. Finally, overall layout and organization of information displayed in this first page of RP follows from DG-2.

4 DISCUSSION AND CONCLUSION

In this study, we introduced a set of design guidelines for improving the effectiveness of precision oncology reports. To derive these guidelines, we conducted both one-on-one interviews and a systemic survey with clinical oncologists. We present here a new oncology report design informed by the derived guidelines.

How effective is our new report design? Our future work will assess the comparative merits and limitations of our design with respect to frequently used reports through a quantitative user study. Currently, like many medical reports, oncology reports are generated for clinicians. Another avenue of future research is to improve the effectiveness of these reports for patients, enabling their more informed involvement in the decision making process. Furthermore, while oncology reports are invariably viewed as static presentations in current clinical practice, we expect their evolution into interactive mediums. Therefore, future investigations on the effective design of interactive visual reports are warranted. In the meantime, our work here provides insights and visual improvements for the increased effectiveness of static reports as a reference for future studies.

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