

Impact of the Immediate Release of Clinical Information Rules on Health Care Delivery to Patients With Cancer

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QUESTION ASKED: How do academic oncology providers feel about the immediate release of clinical information (IRCI) to patients with cancer, and are there unintended consequences for patients or providers?

SUMMARY ANSWER: IRCI was not favored by 75% of the oncology providers surveyed. Only half of the hospitals had a plan in place to deal with the new IRCI requirements.

WHAT WE DID: The Association of American Cancer Institutes Physician Clinical Leadership Initiative Steering Committee designed a 22-question REDCap survey to nationally explore oncology providers' opinions on IRCI policy implementation. It was administered twice in 2021 with a 3-month interval. A third survey with a single question seeking providers' opinions about their adaptation to the IRCI mandate was administered 1 year later to those who had responded to the earlier surveys. The data were analyzed using descriptive statistics such as chi-squared or Fisher's exact tests for categorical variables.

WHAT WE FOUND: In the first or second administration, 167 practitioners answered the survey; 31 responded to the third survey. Three quarters of the oncology providers surveyed had a negative perception of IRCI on the first and second surveys ($P < .001$). Most providers preferred to discuss test results with patients

before release. Of the providers surveyed, 85.5% and 78.8% favored excluding biopsy and imaging results, respectively. Half of the oncology providers mentioned they were unaware of their hospitals' plans to deal with IRCI implementation.

BIAS, CONFOUNDING FACTOR(S): Limitations include a low survey response rate, the academic nature of most of the oncology institutions and providers surveyed, and that the majority of the respondents were hematology/medical oncology providers. Surveys were sent shortly after the implementation of IRCI, and views on new policies might change with time.

REAL-LIFE IMPLICATIONS: Patients' right to have access to their health information is critical and should not be disputed. However, IRCI for patients with cancer could result in unintended and potentially harmful consequences for the patients and oncology providers. Most oncology providers were not in favor of IRCI after it was implemented, and they felt their patients would have the same view on IRCI. This makes it necessary to re-examine the real-life outcomes of IRCI on patients with cancer, oncology providers, and hospitals and to appropriately consider some precautionary changes to IRCI policies in the case of life-threatening diseases, such as cancer, which induce life-changing attitudes for most patients.

ASSOCIATED CONTENT

Data Supplement

Author affiliations and disclosures are available with the complete article online.

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PURPOSE The 21st Century Cures Act mandates the immediate release of clinical information (IRCI) to patients. Immediate sharing of sensitive test results to patients with cancer might have serious unintended consequences for patients and providers.

METHODS A 22-question REDCap survey was designed by the Association of American Cancer Institutes Physician Clinical Leadership Initiative Steering Committee to explore oncology providers' opinions on IRCI policy implementation. It was administered twice in 2021 with a 3-month interval. A third survey with a single question seeking providers' opinions about their adaptation to the IRCI mandate was administered 1 year later to those who had responded to the earlier surveys. The data were analyzed using descriptive statistics such as chi-squared or Fisher's exact tests for categorical variables. The survey was sent to all Association of American Cancer Institutes cancer center members. In the first or second administration, 167 practitioners answered the survey; 31 responded to the third survey.

RESULTS Three quarters of the providers did not favor the new requirement for IRCI and 62% encountered questions from patients about results being sent to them without provider interpretation. Only half of the hospitals had a plan in place to deal with the new IRCI requirements. A third survey, for longitudinal follow-up, indicated a more favorable trend toward adoption of IRCI.

CONCLUSION IRCI for patients with cancer was perceived negatively by academic oncology providers after its implementation. It was viewed to be associated with higher levels of patient anxiety and complaints about the care delivered. Providers preferred to discuss test results with patients before release.

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INTRODUCTION

The 21st Century Cures Act (Cures Act),¹ a bipartisan bill, was signed into law on December 13, 2016. It included several provisions that mandate the application of immediate release of clinical information (IRCI) to patients, including those with a cancer diagnosis, and prohibit information blocking.²⁻⁴

Although IRCI's purpose was to increase transparency in the medical care delivered to patients, many in the oncology community had advocated that IRCI should be approached cautiously in oncology given the special circumstances that surround cancer diagnosis and management. Establishing procedures that allow for the timely delivery of test results to patients with cancer

without jeopardizing their well-being might mitigate undue consequences of IRCI and the disruption of oncology practice workflows.⁵⁻⁷

With the realization by hospitals and oncology providers that they must comply with the Cures Act allowing for IRCI, which includes clinical notes and test results, concerns were raised about the impact of IRCI on patients with cancer and workflows in cancer centers. Kentucky legislation passed a state law that gives providers 72 hours to discuss some test results with their patients before release.⁸

This survey assesses the perceptions and impact of IRCI on oncology providers. The impact of IRCI diverges between patients and providers^{6,9-13} and might require

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additional research. In this publication, we report the findings of a survey conducted by the Association of American Cancer Institutes (AACI) Physician Clinical Leadership Initiative to explore the effects of IRCI on oncology providers and cancer clinical practice.

METHODS

Study Sample

Data were collected from AACI members over three time points. The full 22-question survey was sent out twice, on July 27, 2021 (time point-1) and on October 26, 2021 (time point-2). A third survey was sent out on July 30, 2022 (time point-3) and included only one question: "After practicing within the IRCI rules for a few months, are you in favor of the IRCI policy for patients with cancer?" Possible answers were *yes* or *no*. REDCap surveys were sent electronically to the cancer center administrators for distribution to their members. A copy of the survey is in the Data Supplement (online only). Eight of the respondents who indicated no awareness of the Cures Act were omitted from the main analysis. Thus, 159 respondents (75 for time point-1 and 84 for time point-2) were included in the final analytic cohort. In separate analyses of the awareness of the Cures Act variable between the first and second time points, the responses from all 167 participants were used.

Statistical Analysis

Descriptive statistics were used to compare baseline characteristics of all participants using chi-squared or Fisher's exact tests for categorical variables. In addition, a two-sample proportion test was performed to compare the percentage of participants with awareness of IRCI between the two data collection time points. All analyses were performed using SPSS version 28 software (IBM Corp, Armonk, NY). Statistical significance was defined as a two-sided $P < .05$. Figures were produced using the ggplot package in R version 4.2.

RESULTS

Response Rates to the Surveys

The survey was sent to directors of 95 cancer centers across the country for onward distribution to their staff. A total of 78 and 89 cancer providers from 25 and 22 centers uniquely responded to the survey in time point-1 and time point-2, respectively. The response rate on the basis of cancer centers for the first and second administration was 26.3% and 23.2%, respectively. Thirty-one of these cancer providers from 22 centers responded to the one-question survey in time point-3. On the basis of cancer centers, the response rate for the third administration was 23.2%.

Characteristics of Analytic Cohort

The overall characteristics of the cohort and those stratified by the data collection time points (time point-1 and time point-2) are presented in Table 1. Of the 159 knowledgeable participants, 98 (61.6%) were experts in hematology/medical

oncology and 133 (83.7%) were MD/MBBS/DO providers. Most of the oncology practices were National Cancer Institute-designated academic institutions ($n = 144$; 90.6%). There were no differences in characteristics between time point-1 and time point-2.

Impact of IRCI Policy: Oncology Providers' Perceptions

As shown in Figure 1, the opinion of most of the providers was negative when they were asked to indicate the impact that IRCI policy had on their practice and their subjective perception. Eighty-two percent of the non-hematology/medical oncology providers compared with 72.4% of hematology/medical oncology providers noted that the IRCI policy had a negative impact on their patients. At time points-1 and -2, 75% and 73% of the respondents, respectively, believed that the policy had a negative impact on their practice or on their patients who were informed about their test results before discussion with a provider. For both time points, examination of statistical differences between the proportion of the three response categories (positive, negative, and no difference) showed that the proportion of providers who perceived IRCI negatively or no difference was significantly higher than those who noted a positive impact ($P < .001$). The negative impact of IRCI expressed by the providers correlated with their perception of heightened levels of patient anxiety after IRCI was implemented (88% and 83.3% for time points-1 and -2, respectively; $\chi^2[2, 159] = 32.29$; $P < .001$). Additionally, around 60% of the respondents indicated that there had been an increase in patient complaints since IRCI implementation. Testing for association between perceived patient anxiety and number of patient complaints showed that respondents who indicated a higher level of patient anxiety were more likely to suggest increased patient complaints ($\chi^2[1, 159] = 28.63$; $P < .001$; 95% CI, 4.66 to 58.99).

At time point-3, around 1 year after implementing IRCI, the one-question survey that tested acceptance of IRCI showed a more positive response to the adaptation of the IRCI policy. However, the number of respondents at time point-3 was only 31.

Awareness of the IRCI Policy

Most respondents (95.2%) mentioned that they had some knowledge of the new IRCI changes. Only eight respondents (4.8%) indicated no knowledge of IRCI. There was no statistically significant relationship between the providers' areas of expertise and their knowledge of IRCI ($\chi^2[2, 167] = 1.73$; $P = .429$), indicating that awareness of IRCI was not associated with the provider's area of expertise. There was also no statistical difference in awareness of the IRCI between time points-1 and -2 ($P = .725$).

Informing Patients About IRCI

Considering plans made by hospitals to inform patients with cancer about IRCI, 52.2% of the survey respondents stated that their hospital had a plan, 5.7% noted that their hospital did not have a plan, and 42.1% said they did not know if such

TABLE 1. Background Information of Respondents

Characteristic	All Participants (N = 159) No. (%)	Time Point-1 (n = 75) No. (%)	Time Point-2 (n = 84) No. (%)	P
Area of expertise				.479
Hematology/medical oncology	98 (61.6)	48 (64.0)	50 (59.5)	
Surgical oncology	26 (16.4)	12 (16)	14 (16.7)	
Radiation oncology	6 (3.8)	2 (2.7)	4 (4.8)	
Gynecological oncology	7 (4.4)	3 (4.0)	4 (4.8)	
Neuro oncology	3 (1.9)	2 (2.7)	1 (1.2)	
Pathology	2 (1.3)	0 (0.0)	2 (2.4)	
Radiology	1 (0.6)	0 (0.0)	1 (1.2)	
Others ^a	16 (10.0)	8 (10.7)	8 (9.5)	
Role as a provider				.136
MD/MBBS/DO	133 (83.7)	60 (80.0)	73 (86.9)	
Certified nurse practitioner	11 (6.9)	5 (6.7)	6 (7.1)	
Physician assistant	8 (5.0)	5 (6.7)	3 (3.6)	
Others ^b	7 (4.4)	5 (6.7)	2 (2.4)	
Description of oncology practice				.171
Academic institution (NCI-designated)	144 (90.6)	67 (89.3)	77 (91.7)	
Academic institution (not NCI-designated)	12 (7.5)	5 (6.7)	7 (8.3)	
Hospital-based community practice	3 (1.9)	3 (4.0)	0 (0.0)	
Awareness IRCI ^c				.725
Yes	159 (95.2)	75 (96.2)	84 (94.4)	
No	8 (4.8)	3 (3.8)	5 (5.6)	

NOTE. Numbers represent frequency of respondents in each category. Corresponding percentages are presented in parentheses.

Abbreviations: IRCI, immediate release of clinical information; NCI, National Cancer Institute.

^aOther areas of expertise indicated by the respondents include those in the field of pediatric oncology, gastroenterology, pulmonary, urologic oncology, practice management, cancer rehabilitation, and lung cancer screening.

^bOther options indicated were nurse clinicians and administrators, genetic counselors, administrators, and research managers.

^cFor this variable, we included all participants who responded to the survey.

a plan existed. The mode of communicating these plans to patients according to the respondents was largely through electronic messaging, followed by brochures and letters. There was no difference in the mode of communicating the IRCI changes to patients between the two time periods. Selecting from multiple options, most providers indicated that they were informed about IRCI through emails (52%), during staff meetings (40%), and through hospital websites (14%). Eleven percent (11%) noted that they did not have information on how providers were notified about IRCI, and 0.6% stated that they had not received any notification.

Advising Patients on IRCI Policy: Preference for Discussing Test Results

There was a statistically significant association between providers' awareness of IRCI and their decision to advise patients about it ($P < .001$). Most respondents ($> 60\%$) indicated that they had been advising patients of the possibility of seeing their results before discussing them with providers. More than 80% stated that their patients'

preference would be to discuss medical tests before the results are released. There was no statistically significant difference between providers who responded to the survey in time points-1 and -2 with respect to advising patients on IRCI ($\chi^2[1, 159] = 0.94$; $P = .331$).

There was no association between providers' areas of expertise and advising patients on IRCI ($\chi^2[2, 159] = 1.16$; $P = .560$). Another test explored the association between the provider's role (physician, physician assistant, etc) and advising patients on IRCI, which was not statistically significant ($\chi^2[4, 159] = 7.63$; $P = .106$).

Excluding Clinical Data From IRCI Policy

Responses from the providers, with the option of choosing more than one response, favored excluding biopsy results (85.5%), imaging results (78.8%), laboratory results (33.3%), and clinic notes and documentation (20.8%) from IRCI. Less than 1% preferred to have no specific results excluded from IRCI.

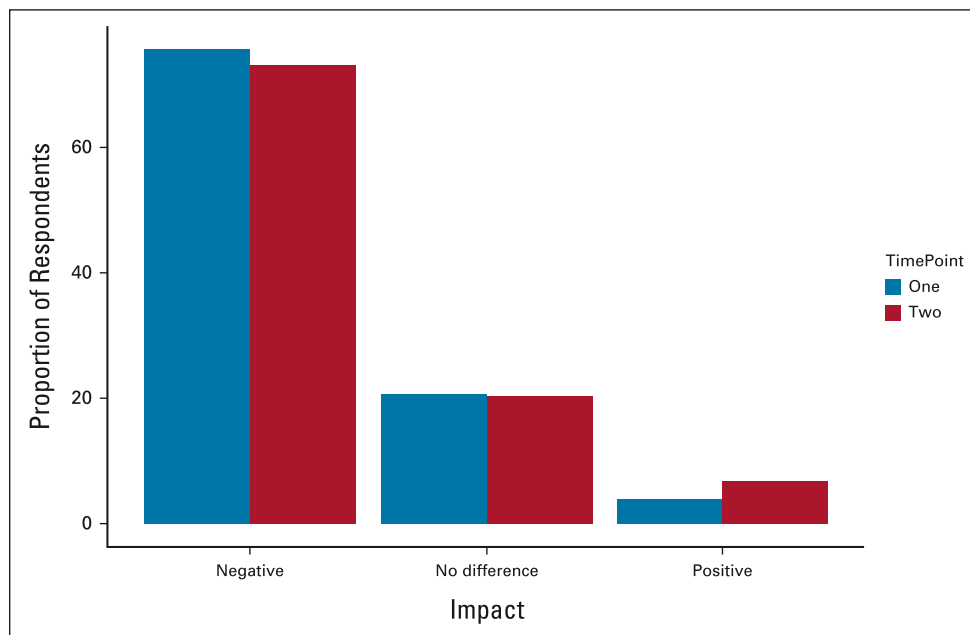


FIG 1. Impact of immediate release of clinical information policy as perceived by oncology providers.

Providers' Ideal Time to Discuss Results With Patients

As shown in Figure 2, most providers preferred to discuss test results with patients before release. Comparing preference for the ideal time of discussing test results (after release of test results, at the same time test results were released, and before release of test results) showed a statistically significant difference ($P < .001$) in the combined data for time points-1 and -2 in favor of discussing test results before they are released.

Providers' Opinion of the IRCI Policy Over Time

The third survey at time point-3, sent 1 year after the initial survey at time point-1, showed that 31 of 32 responses were linked to the previous data and used for this part of the analysis. Figure 3 shows the pattern of responses over the three time points the survey was administered. The proportion of practitioners who were not in favor of the policy after implementing IRCI was 82% at time point-2 and decreased to 58% at time point-3. Those in favor of IRCI increased from 18% to 42% from time point-2 to time point-3. Data from Figure 3 indicate that of the 31 providers who responded to the time point-3 survey and to either time point-1 or -2 surveys, 25.81% changed from not favoring the policy to supporting it, 3.23% changed from supporting the policy to not favoring it, and 70.97% did not change their opinion about IRCI, which was mostly negative.

DISCUSSION

This survey conducted in AACI cancer centers showed that the implementation of IRCI in the year 2021 in compliance with the Cures Act¹ was perceived negatively by academic oncology providers ($P < .001$; 95% CI, 5.5 to 65.4). The findings of this survey are noted in the context of most

providers indicating awareness of IRCI and advising patients about it. The survey results were similar at the two early time points in the year 2021; however, a trend toward improved perception of IRCI by providers was observed after 1 year of implementation in July 2022. IRCI was viewed as a source of higher levels of patient anxiety ($\chi^2[2, 159] = 32.29$; $P < .001$) and was associated with more complaints by patients about the care they received ($\chi^2[1, 159] = 28.63$; $P < .001$). Most providers were in favor of discussing test results with patients before their release, especially biopsy and imaging reports. The providers also sensed that their patients favored a non-immediate release of tests results.

Perspectives about IRCI may vary according to subspecialty. Most of the respondents to the survey were experts in hematology/medical oncology who usually treat patients with advanced cancers. This patient population is more likely to have abnormal tests that show cancer progression or other setbacks during the cancer treatment journey. It is also important to note that most of the practices surveyed are National Cancer Institute–designated cancer centers within academic institutions, where the most complex cases are usually treated. Thus, customized IRCI implementation plans for different settings on the basis of provider specialty and cancer center type are worth exploring.

Sharing system-wide information about IRCI was also addressed in our survey. Effectively communicating changes in health care systems with patients and providers is a topic of many published studies.^{10,14-16} Although most providers in our survey indicated they were aware of IRCI, only 52% knew of plans by their hospitals to share information with patients. Either hospitals did not actually have thorough plans to share the IRCI changes with their workforce or the communication

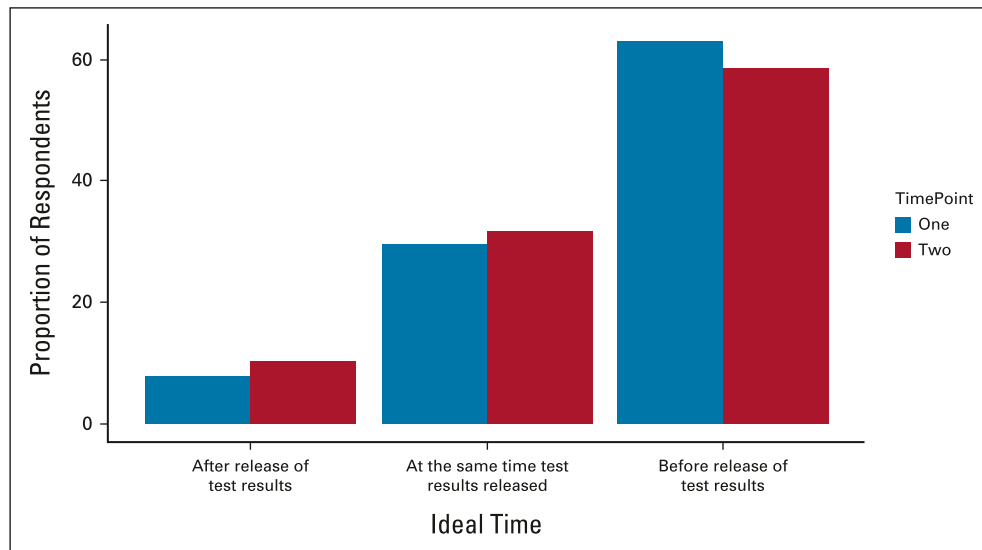


FIG 2. Ideal time for providers to discuss test results.

used to inform providers was ineffective. Sharing information about IRCI was mostly done through emails and staff meetings for providers and electronic messaging using EMRs for patients. Social media was the least-used method for sharing information. Health care systems should look into the optimal methods for sharing information with patients and providers, taking into consideration barriers such as age, race, sex, and electronic portal access in underserved areas.^{11,17,18} This is especially important as a significant association between provider awareness of IRCI and discussions about it with patients was seen in our survey.

Our survey examined the provider's attitude toward the different types of clinical data to be shared with patients. Access to medical information, especially clinical notes, through patient portals has evolved over the past few decades.¹⁹⁻²⁷ In 2010, OpenNotes, a quasiexperimental study in the primary care setting, showed that granting patients access to clinical notes through secure digital portals increased their feeling of control of their care and adherence to medications; most elected to continue with the OpenNotes approach.²⁰ In our survey, immediate access to clinic notes was the least concerning for oncology providers compared with biopsy,

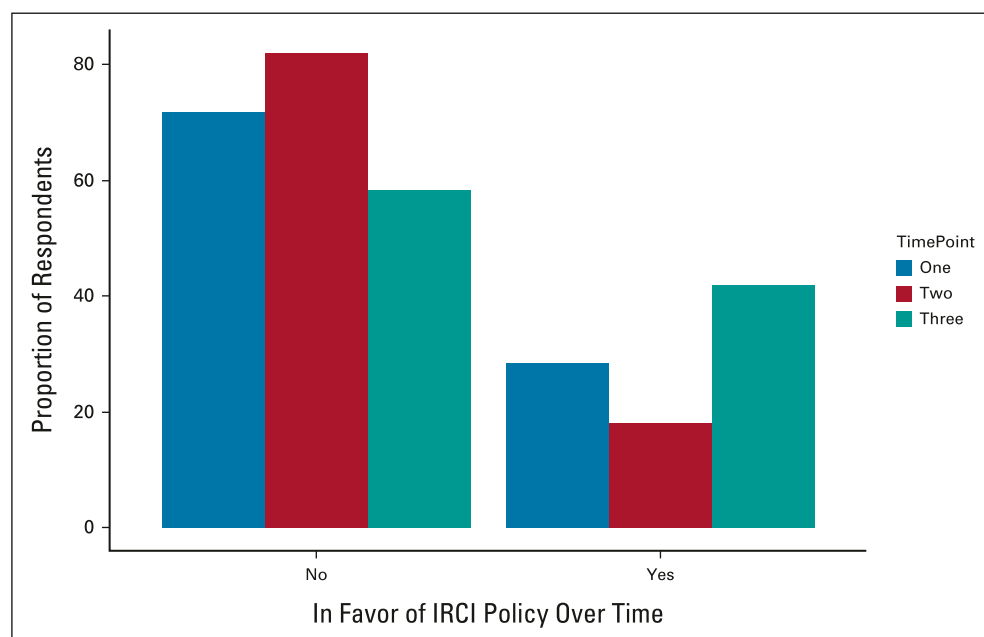


FIG 3. Practitioners' opinion of IRCI policy over time. IRCI, immediate release of clinical information.

imaging, or laboratory results. There was a steady increase in the proportion of providers who wanted to delay the release of test results for 24, 48, and 72 hours, with the majority requesting to discuss the results with patients ($P < .001$) before release, regardless of the time frame.

This survey has limitations. The response rate to the survey was low, which is a known issue in health care surveys.²⁸ There are several potential explanations for the low response rate: (1) It is unknown whether the surveys were actually emailed to the oncology providers in all of the cancer centers contacted; (2) providers have limited time and answering surveys was not viewed as a priority; (3) email fatigue because of the large number of emails providers receive; and (4) the length of the survey. Addressing these issues will be important in designing future surveys.

It is also important to note that the majority of the respondents were medical hematology/medical oncology providers, and the institutions surveyed were mostly academic cancer centers. Extending our conclusions to other settings should be practiced with caution. Additionally, this survey was not sent to patients, but reflects the providers' impressions of patient attitudes toward IRCI.

In conclusion, this survey showed that academic cancer providers had an initial negative experience with the implementation of IRCI. Recognizing the patient's right to have timely access to personal health information and allowing for interoperability should be balanced with specific interventions to mitigate potentially harmful consequences of IRCI in the oncology field. Cancer centers should continue exploring optimal approaches for sharing relevant health care information with providers and patients.

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