Challenges, Barriers, and Successes of Standardized Report Templates: Results of an SIR Survey

Paul Bennett Lewis, Resmi Ann Charalel, Aliaksei Salei, Andrew J. Cantos, Greg Dubel, Michael T. Kassin, Tushar Garg, Hafsa Shahwaiz Babar, Olga R Brook, Rajesh P. Shah, Neil Halin, Mark Kleedehn, Matt Johnson

Paul Bennett Lewis, MD, MBA*

Interventional Radiology, University of Pittsburgh Medical Center, Pittsburgh, PA 15213

Resmi Ann Charalel, MD, MPH

Interventional Radiology and Population Health Sciences, Weill Cornell Medicine, New York, NY 10065

Aliaksei Salei, MD

Division of Interventional Radiology, Department of Radiology, The University of Alabama at Birmingham Heersink School of Medicine, Birmingham, AL 35249

Andrew J. Cantos, MD

Department of Imaging Sciences, University of Rochester, Rochester, NY 14642

Gregory J. Dubel, MD

This is the author's manuscript of the article published in final edited form as:

Lewis, P. B., Charalel, R. A., Salei, A., Cantos, A. J., Dubel, G. J., Babar, H. S., Kassin, M. T., Garg, T., Brook, O. R., Shah, R. P., Halin, N. J., Kleedehn, M., & Johnson, M. (2023). Challenges, Barriers, and Successes of Standardized Report Templates: Results of an SIR Survey. Journal of Vascular and Interventional Radiology. https://doi.org/10.1016/j.jvir.2023.08.020

Division of Vascular and Interventional Radiology, Alpert Medical School of Brown University/RI Hospital, Providence, RI 02903

Hafsa Shahwaiz Babar

University of California, San Diego, CA 92093

Michael T. Kassin, MD

Center for Interventional Oncology, Radiology and Imaging Sciences, NIH Clinical Center and National Cancer Institute, National Institutes of Health, Bethesda, MD 20892

Tushar Garg, MD

Division of Vascular and Interventional Radiology, The Johns Hopkins University School of Medicine, Baltimore, MD 21287

Olga R Brook, MD

Department of Radiology, Beth Israel Deaconess Medical Center, Boston, MA 02215

Rajesh P Shah, MD

Veterans Affairs Palo Alto Health Care System, Palo Alto, CA 94304

Department of Radiology, Stanford University, Stanford, CA 94305

Neil J. Halin, DO, FSIR, FAOCR

Associate Professor in Radiology, Tufts University School of Medicine, Boston, MA 02111

Mark Kleedehn, MD

Department of Radiology, University of Wisconsin School of Medicine and Public Health, Madison, WI 53792

Matt Johnson, MD

Interventional Radiology, Indiana University School of Medicine, Indianapolis, IN 46202

*Corresponding Author

Mail: 2775 Mosside Blvd. Monroeville, PA 15146

Email: paul@lewismd.com

Phone: 312-209-7285

No conflicts of interest and no financial disclosures.

Funding sources: None.

Trial registration: None.

Acknowledgment: We would like to acknowledge the Society of Interventional Radiology Standardized Reports Committee, Registry Advisory and Oversight Committee, and staff members Liza D'Onofrio and Joy Gornal for creating and distributing the survey.

Material was presented at the 2023 SIR Annual Scientific Meeting. Material was not presented at any other conference or posted as a preprint.

ABSTRACT

Registry data are being increasingly used to establish treatment guidelines, set benchmarks, allocate resources and make payment decisions. While many registries rely on manual data entry, the Society of Interventional Radiology (SIR) is using automated data extraction for its VIRTEX registry. This relies on participants using consistent terminology with highly structured data in physician-developed Standardized Reports (SR). To better understand barriers towards adoption, a survey was sent to 3,178 SIR members. Responses were obtained from 451 IR practitioners from 92 unique academic and 151 unique private practices. Of these, 75% use structured reports and 32% use the SIR SR. The most common barriers to usage include SR length (35% of respondents), lack of awareness of the SR (31%), and lack of agreement on adoption within practices (27%). The results demonstrate insights regarding barriers in using and/or adoption of SR, as well as potential solutions.

INTRODUCTION

The field of Interventional Radiology (IR) has led the frontier in minimally-invasive, image-guided procedures but lagging in proving value compared to other medical specialties(1). Several specialties have used data registries to illustrate their value(2-7). Registry success relies on implementing standard terminology across practices to generate real world data (RWD). Bringing these data together through a medical registry can lead to positive changes on the individual and population level in patient survival, safety, quality and reimbursement(1).

Since imaging reports represent the central communication method in IR, they provide a natural target for implementation of data structuring. The ideal structured report(8) is formatted with headings, has a consistent organization, and uses standardized terminology *as in American College of Radiology (ACR)-endorsed Reporting And Data Systems (RADS):* Bi-RADS, Ti-RADS, Pi-RADS and Li-RADS(9). While application of these structured reports with standardized language can be arduous and time-consuming, studies have shown structured reports are more complete(8), more clear(10), more consistent(3), less time-consuming(11), mitigate potential revenue loss(12), allow for better research(7) and preferred by both ordering clinicians and radiologists(6). With these considerations, SIR has been working to implement its own version of Standardized Reports (SR) since 2015 (11).

Despite the above-mentioned advantages, there is apprehension or resistance to incorporate SR into practice. The purpose of this survey was to identify the challenges and barriers that exist for, or perceived by, IR practitioners in adopting and using SIR SR.

MATERIALS AND METHODS

The survey was a quality improvement initiative and the institutional review board from one of the senior authors (BLINDED) deemed the study did not require approval. This was a single event, cross-sectional exploratory 17-question online survey (Survey Monkey, San Mateo, California) with a voluntary response sample of interventional radiologists. Survey questions were developed through an iterative design methodology by individual SIR personnel and committees. Participants were invited through a direct email hyperlink sent to 3,178 interventional radiologists and a hyperlink posted in the "Open Forum" section of SIRConnect, an online discussion board for members of SIR. This sample size represents 91% of the 2021 estimated population of 3,500 IR physicians in the United States(13). The data was collected over a 28-day period (2/18/22 to 3/18/22). All descriptive statistical analysis was performed using Microsoft Excel (Redmond, Washington, United States). The analysis of respondent location and/or practice type was independent and blinded from any and all other survey responses. Practices were classified as academic or non-academic based on the presence or absence of a diagnostic and/or interventional radiology training program found through an internet search. Thematic analysis was performed on the free comments.

RESULTS

Respondent group

The direct email hyperlink had a response rate of 13% (406/3178) and was the source for the majority of the survey participants (406/451, 90%). From the 451 total respondents, 88%

(398/451) entered information on their practice nature, location, or name. After removing incomplete answers, there were 333 respondents (84%, 333/398). Three of these respondents were international, leaving a total of 330 practices known to be located within the United States (73%, 330/451).

From those 330 respondents, 49 institutions had more than one responder. After accounting for these, a total of 243 unique U.S.-based practices were identified. Non-academic practices constituted 62% (151/243); and academic practices, 38% (92/243). The geographic distribution of US practices is illustrated in Figure 1 (Figure 1: Respondent Locations). There were three groups of respondents in this survey: those that (1) use SIR SR, (2) use non-SIR SR, and (3) do not use any standardized reporting.

Use of standardized templates for IR procedures

The survey participants' responses to their use of SR, source of SR and version of SIR SR used are detailed in Table 1. On questions more specific to not using SIR SR templates, 215 respondents answered in 1 of 11 different combinations of "Institution created templates", "SIR SR templates (for only a few select reports)", "Practice created templates", and/or "Other". The two most common types of templates used in these combinations were "Practice created templates" (79%, 169/215) and "Institution created templates" (16%, 35/215). "Other" which was most often specified as personally-made templates, accounted for 13% of entries (27/215).

Use of standardized templates for clinic notes

The use of SR for clinical encounters (consults, follow-ups, observation, etc) are summarized in Table 2. For the respondents that used non-SIR structured reports for IR procedures, 67% used structured clinic notes (144/215). For respondents that used SIR SR templates for most IR procedure reports, 46% used structured clinic notes (49/106).

Challenges using & barriers preventing use of SIR templates

Across all respondents, 94% (426/451) identified at least one challenge using or one barrier adopting the SIR SR. The most common concern was that the SR are too long (35%, 150/426); the least common concern was the dictation or electronic medical record (EMR) system did not support implementation (8%, 33/426).

The challenges and barriers shared between the 3 respondent groups are represented in Table 3 and Figure 2 (Figure 2: Challenges using and barriers adopting SIR standardized report templates). The free text "Other" comments were separated into 14 categories that can be organized into one of three areas: (1) content, (2) user, or (3) information technology (Table 4). Though not particularly specific, each of the comments is worth reviewing and demonstrate many of the challenges to both developing and increasing utilization of the SIR SR.

Dictation Systems and Electronic medical records

The dictation systems used by respondents is summarized in Table 5. Most respondents used a combination of dictation systems. Similarly, most respondents used a combination of EMR systems (Table 6).

Interest in learning more about VIRTEX

From the respondents that answered this question (81%, 364/451), 55% of the respondents were interested in learning more about VIRTEX (202/364).

DISCUSSION

Standardized reporting is the foundation of clinical registries. Since the inception of Bi-RADS as a "brief mammography lexicon" in 1992, it has evolved to take a primarily role in multiple imaging modalities as well as in clinical treatment, management and follow-up.(3) Similar standardized language has proven successful for clinicians as well. The first clinical registry established by the Society of Thoracic Surgery in 1989 serves as a gold standard today and has been credited for over 500 investigations and advancements between 2010 and 2020(2).

Early investigations of standardized report utilization in IR have communicated its value and barriers.(14, 15) A 2016 study found high satisfaction rates from referring physicians across 10 different practice sites using the initial SIR SR (version 1).(14) While the investigators also found participants identified SR to be superior in terms of billing, quality improvement and research; participants ranked SR inferior in ease of use, speed, high number of data elements and ease of reading. A more recent study analyzing locally created reports from a single center reported participants found SR to be easier (89%) and faster (81%) to complete and had a similar or higher level of detail (73%) as compared to non-structured reports.(15) That study also found referring physicians preferred structured over free text reports.

This work surveyed challenges and barriers towards implementation of standardized reporting in IR. The survey found SR to be widely used (75% of respondents) and over 30% of SIR members have adopted SIR SR. These numbers are encouraging in the initial stages of IR data harmonization, but indicate there remains work to be done to increase SIR SR utilization. The key barriers for usage of the SIR SR were report length, lack of agreement on implementation within practices, and report customization. An important strength of the SIR SR was its adoption across a broad range of dictation and EMR systems.

This survey had a respondent group that was geographically diverse and representative of SIR membership with both academic and non-academic settings. Templates decreasing the users' autonomy was a barrier to adopt SIR SR in 42% of non-SR users. That challenge was seen in 9% of SR users and further decreased to 8% of those that used the SIR SR. That pattern was also seen in templates being too long (Figure E1: CT Biopsy Report Template), data elements not having relevance, dictation/EMR not supporting implementation, and lack of IT and/or administrative support. On the other hand, the concern that templates did not allow for enough narrative or free text was a concern in 40% of non-SR users and 39% of the SIR SR users. This concern may be addressed by education of SIR SR users that customization, including re-ordering of modules and addition of narrative text, is supported. Some feedback from this survey is based on the older versions of the SIR SR. Many of these critiques have been addressed in the most current version of the SIR SR (Version 3.1).

This study did have limitations. While the respondent sample was likely representative of the study population; results from small rural, community hospital practitioners may not be represented. Similarly, invitation to participate was done through SIR membership channels and this method limits, if not lacks, feedback from non-SIR members. Additionally, the email addresses on file may have been out of date. While recruitment efforts were repeated, no other networks for invitation were used in this study. Further caution is needed in the interpretation of these results given the response rate. Even though there were more than 400 respondents, this response rate as a percentage of the population was 14% (451/3,178) and can be considered low and a major source of bias. Separately, not every question was answered and this changes the denominator between questions. Transparency was maintained by including the numerator and denominator for each queried variable. On the other hand, there may have been questions answered *"for the sake of it"* just to complete the survey. Such questions could not be identified in this survey.

Some free text comments expressed concern that the purpose of SIR SR templates to be serving individual research interests. That is not the goal of SIR SR templates or VIRTEX.(1) The intent of the SIR SR templates is to establish standardized language for IR and compile a national level sample size of pre-, intra- and post-procedure data to help improve quality of care/outcomes, understand gaps in care that can be answered via research, drive reimbursement decisions, and keep IR at the leading edge of medicine.

The current focus on standardized language and SR reflects the early state of VIRTEX. The registry is gaining attention and has now been launched at select sites across the country with others enrolled. Sustaining its success and demonstrating its value to the society and individual practices relies on standardized language and granularity (Figure E2: Leg Angio Report Template).

The SIR SR with standardized language is the first step in strengthening the IR position, demonstrating value, and allowing IR to compete using RWD. This RWD will ultimately enhance our practice on all levels and better serve our patients.

REFERENCES

1. Shah RP, Johnson M. Interventional Radiology: Blazing New Trails or Playing Catch Up? J Vasc Interv Radiol. 2022;33(7):743-5.

2. Brocklebank PW, Achurch MM, Sbrocchi AJ, Rauls G, Kilic A. Quality and Impact of Manuscripts Using The Society of Thoracic Surgeons National Databases. Ann Thorac Surg. 2023.

3. Eghtedari M, Chong A, Rakow-Penner R, Ojeda-Fournier H. Current Status and Future of BI-RADS in Multimodality Imaging, From the AJR Special Series on Radiology Reporting and Data Systems. AJR Am J Roentgenol. 2021;216(4):860-73.

4. Gaies M, Pasquali SK, Banerjee M, Dimick JB, Birkmeyer JD, Zhang W, et al. Improvement in Pediatric Cardiac Surgical Outcomes Through Interhospital Collaboration. J Am Coll Cardiol. 2019;74(22):2786-95.

5. Hall BL, Hamilton BH, Richards K, Bilimoria KY, Cohen ME, Ko CY. Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. Ann Surg. 2009;250(3):363-76.

6. Jorg T, Halfmann MC, Arnhold G, Pinto Dos Santos D, Kloeckner R, Duber C, et al. Implementation of structured reporting in clinical routine: a review of 7 years of institutional experience. Insights Imaging. 2023;14(1):61.

7. Jorg T, Halfmann MC, Rolz N, Mager R, Pinto Dos Santos D, Duber C, et al. Structured reporting in radiology enables epidemiological analysis through data mining: urolithiasis as a use case. Abdom Radiol (NY). 2023.

8. Marcovici PA, Taylor GA. Journal Club: Structured radiology reports are more complete and more effective than unstructured reports. AJR Am J Roentgenol. 2014;203(6):1265-71.

9. An JY, Unsdorfer KML, Weinreb JC. BI-RADS, C-RADS, CAD-RADS, LI-RADS, Lung-RADS, NI-RADS, O-RADS, PI-RADS, TI-RADS: Reporting and Data Systems. Radiographics. 2019;39(5):1435-6.

10. Schwartz LH, Panicek DM, Berk AR, Li Y, Hricak H. Improving communication of diagnostic radiology findings through structured reporting. Radiology. 2011;260(1):174-81.

11. Hanna TN, Shekhani H, Maddu K, Zhang C, Chen Z, Johnson JO. Structured report compliance: effect on audio dictation time, report length, and total radiologist study time. Emerg Radiol. 2016;23(5):449-53.

12. Duszak R, Jr., Nossal M, Schofield L, Picus D. Physician documentation deficiencies in abdominal ultrasound reports: frequency, characteristics, and financial impact. J Am Coll Radiol. 2012;9(6):403-8.

13. Garg T, Bajaj S, Dayan MJ, Makary MS, Smirniotopoulos JB, Silk M, et al. Temporal and geospatial variations among the interventional radiology physician workforce in the United States. Clin Imaging. 2021;78:105-9.

14. McWilliams JP, Shah RP, Quirk M, White SB, Dybul SL, Ahrar J, et al. Standardized Reporting in IR: A Prospective Multi-Institutional Pilot Study. J Vasc Interv Radiol. 2016;27(12):1779-85.

15. Nguyen Q, Sarwar A, Luo M, Berkowitz S, Ahmed M, Brook OR. Structured Reporting of IR Procedures: Effect on Report Compliance, Accuracy, and Satisfaction. J Vasc Interv Radiol. 2018;29(3):345-52.

FIGURE LEGENDS

Figure 1: Respondent Locations. Pie chart of the geographic distribution of the 243 unique practices within the United States that responded to the survey.

Figure 2: Challenges using and barriers adopting SIR standardized report templates. Bar graph of the results to the nine survey questions.

Figure E1: CT Biopsy Report Template. SIR SR template for percutaneous biopsy with CT-guidance. The black text is the template text and the red text represents the user input text fields. All text however is customizable. This report is considered to be a relatively shorter report template.

Figure E2: Leg Angio Report Template. SIR SR template for lower extremity angiogram. The black text is the template text and the red text represents the user input text fields. This report has a high degree of granularity and considered to be a long template.

Table 1: Respondent Procedure SR Use

Total Respondents to this question (n=451)		
Use SR for IR procedures	75%	(338/451)
Do not use SR for IR procedures	25%	(113/451)
Of those that use SR for IR procedures (n=338)		
Use non-SIR SR or SIR SR for only a few reports	67%	(228/338)
Use SIR SR for most reports	31%	(106/338)
Unanswered	1%	(4/338)
SIR SR Version used (n=106)		
Unaware	30%	(32/106)
Version 1	2%	(2/106)
Version 2	25%	(26/106)
Version 3	25%	(27/106)
Version 3.1	12%	(13/106)
Unanswered	6%	(6/106)

Table 2: Respondent Clinical SR Use

Total Respondents to this question (n=427)		
Use SR for clinic notes	55%	(233/427)
Do not use SR for clinic notes	45%	(194/427)
Of those that use SR for clinic notes (n=233)		
Use SR for procedures	83%	(193/233)
Do not use SR for procedures	17%	(40/233)
Of those that do not use SR for clinic notes (n=194)		
Use SR for procedures	63%	(123/194)
Do not use SR for procedures	37%	(71/194)

Table 3: Challenges using and barriers adopting SIR standardized report templates

	SIR SR	Non-SIR SR	No SR
Templates are too long	19% (20/106)	32% (73/228)	50% (57/113)
Data elements are not relevant	19% (20/106)	24% (54/228)	33% (37/113)
Templates do not allow for enough customization	23% (24/106)	20% (46/228)	39% (44/113)
Templates decrease my autonomy	8% (8/106)	9% (21/228)	42% (47/113)
Templates do not allow for enough narrative or free text	39% (41/106)	18% (41/228)	40% (45/113)
There are not templates specific for the procedures performed	26% (28/106)	13% (30/228)	22% (25/113)
Colleagues and/or institution do not agree on adoption	22% (23/106)	25% (57/228)	27% (30/113)

Dictation/EHR/RIS system does not support implementation	4% (4/106)	7% (16/228)	12% (13/113)
Lack of IT and/or administrative support for implementation and maintain	11% (12/106)	20% (46/228)	23% (26/113)
Unanswered or no challenge or barrier selected	6% (6/106)	7% (17/228)	2% (2/113)

Table 4: Open comments

	SIR SR	Non-SIR SR	No SR
Content			
Reports are too long	0	3	1
Reports read poorly	4	4	1
Reports not better than what I already have now	0	6	1
Reports are missing important clinical and/or device information	4	3	3
Reports are more difficult for referring providers or billers to understand	3	4	7
Reports are too detailed and/or are not practical	1	3	3
User			
Lack of experience with SR	0	2	0
Unsure of how to modify SR to better suit needs	1	0	0
Prefer no template/current template and see no reason to change	2	8	0

Resource unknown, no templates available for desired procedure(s)	2	1	0
The whole endeavor is not valuable	1	0	2
Information technology			
Local difficulty in modifying SIR SR to meet local needs	0	2	1

Table 5: Dictations Systems Used

Dictation Systems	*Respondents who use any standardized reports**	*Respondents who use SIR standardized reports***
Nuance PowerScribe	*84% (215/294)*	*90% (86/96)*
*3M M*Modal Fluency*	*10% (29/294)*	*6% (6/96)*
Epic/Epic Radiant	*10% (29/294)*	*7% (7/96)*
Voice2Dox	*0.7% (2/294)*	*1% (1/96)*
eClinicalWorks	*0.7% (2/294)*	*1% (1/96)*
Philips Vue (Carestream Vue)	*0.4% (1/294)*	*0*
StreamlineMD	*0*	*0*
HI-IQ	*0*	*0*
Other	*5% (14/294)*	*1% (1/96)*

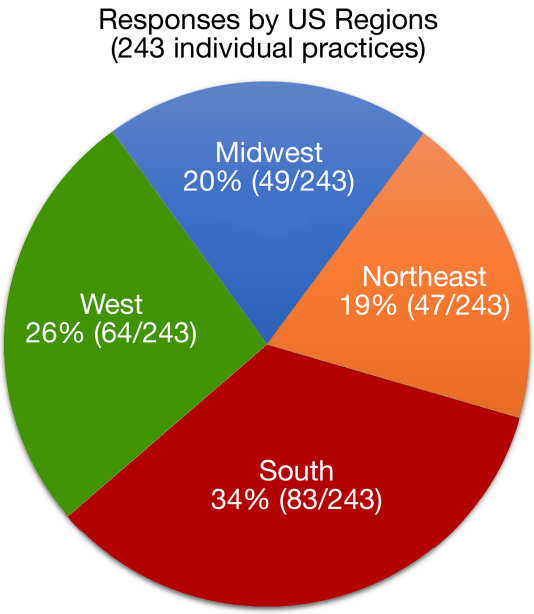
*Note: From the 338 respondents that used a SR for IR procedure, only 294 of them responded to this question.

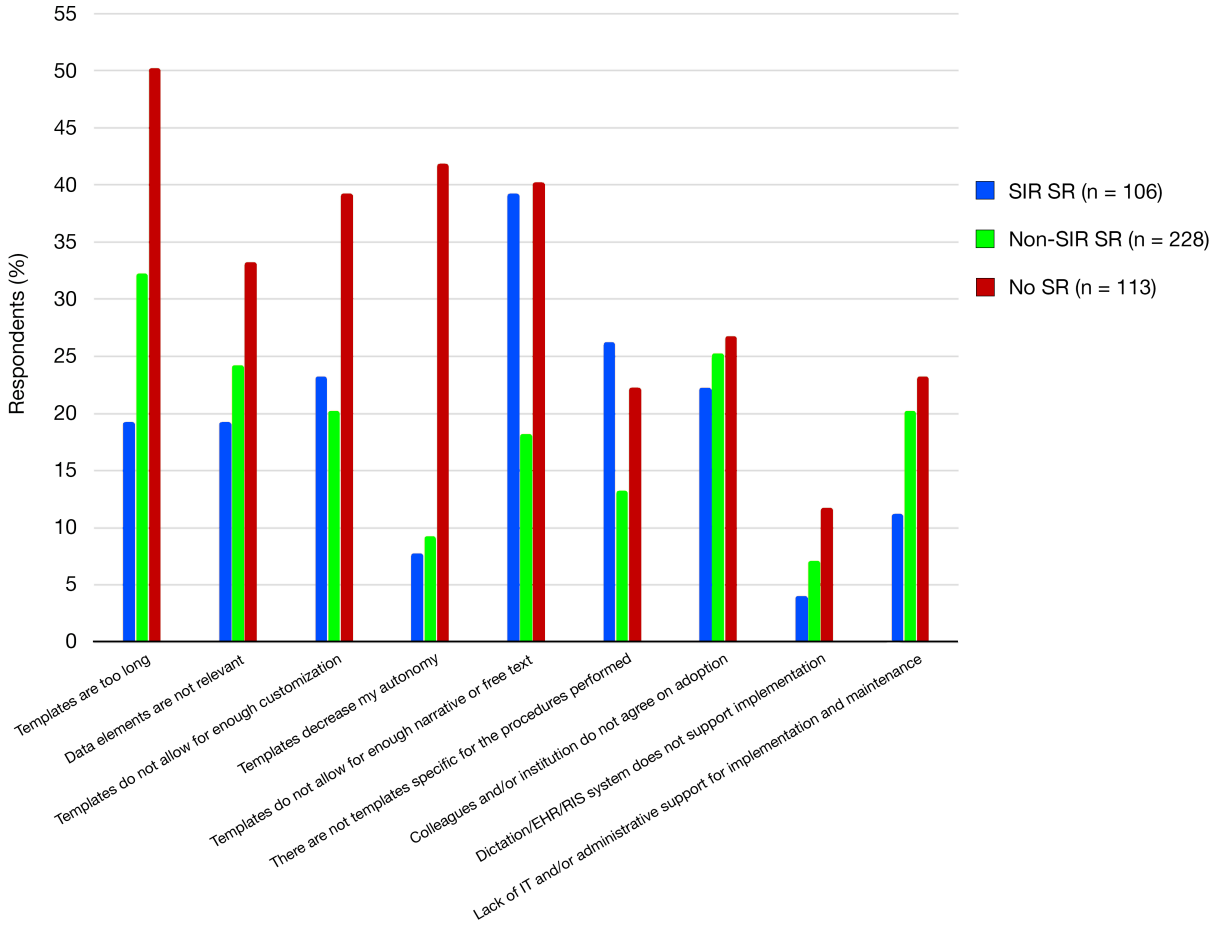
**Note: Of the 106 survey participants that use SIR SR for most reports, only 96 of them answered this question.

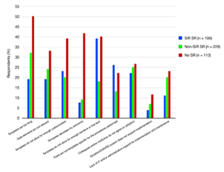
Table 6: EMR Used

EMR	*All Respondents to the question**	*Respondents who use SR that are not SIR templates*	*Respondents who use SIR standardized reports*
Epic	*60% (239/396)*	*64% (127/198)*	*60% (58/96)*
Cerner	*24% (94/396)*	*21% (42/198)*	*30% (29/96)*
MEDITECH	*9% (36/396)*	*11% (21/198)*	*4% (4/96)*
Allscripts	*7% (26/396)*	*5% (9/198)*	*13% (12/96)*
Other	*7% (29/396)*	*7% (13/198)*	*8% (8/96)*

*Note: All respondents (n=396) included respondents from all three groups and represent 198 respondents who use SR that are not SIR templates, 96 respondents who use SIR SR and 102 respondents that do not use any type of standardized reporting.


Responses by US Regions
(243 individual practices)
Midwest
20% (49/243)
Northeast
19% (47/243)
South
34% (83/243)
West
26% (64/243)


55
50
45
40
35
30
25
20
15
10
5
0
Respondents (%)
SIR SR (n = 106)
Non-SIR SR (n = 228)
No SR (n = 113)
Templates are too long
Data elements are not relevant
Templates do not allow for enough customization
Templates decrease my autonomy
Templates do not allow for enough narrative or free text
There are not templates specific for the procedures performed
Colleagues and/or institution do not agree on adoption
Dictation/EHR/RIS system does not support implementation
Lack of IT and/or administrative support for implementation and maintenance


Respondents (%)
55
50
45
40
35
30
25
20
15
10
5
0
SIR SR (n = 106)
Non-SIR SR (n = 228)
No SR (n = 113)

PROCEDURE: CT-guided biopsy

Procedural Personnel
Attending physician(s): Attending Name
Fellow physician(s): Fellow
Resident physician(s): Resident
Advanced practice provider(s): APP

Procedure Date (mm/dd/yyyy): Report Create Date
Pre-procedure diagnosis: Diagnosis
Post-procedure diagnosis: Post Procedure
Indication: Indication:Histopathologic diagnosis/Staging/Organ dysfunction/Treatment follow-up/Histopathologic diagnosis and molecular characterization/Research protocol/Other-
Previous biopsy of same target (QCDR): Previous biopsy:Yes- repeat biopsy due to sample inadequacy from prior biopsy at this institution/Yes- repeat biopsy due to sample inadequacy from prior biopsy at outside institution/Yes- repeat biopsy due to atypia of undetermined significance/Yes- repeat biopsy due to other reason/No
Additional clinical history: Additional history

Complications: No immediate complications.

IMPRESSION:

CT-guided biopsy of target.

Plan:

Specimen(s) sent for evaluation.

PROCEDURE SUMMARY:
- Percutaneous CT-guided biopsy type:coaxial core needle/coaxial FNA/core and FNA/core needle/FNA biopsy
- Additional procedure(s): Additional procedures:Other-/None

PROCEDURE DETAILS:

Pre-procedure
Reference imaging for biopsy target: Comparison imaging
Consent: Informed consent for the procedure including risks, benefits and alternatives was obtained and time-out was performed prior to the procedure.
Preparation: The site was prepared and draped using maximal sterile barrier technique including cutaneous antisepsis.

Anesthesia/sedation
Level of anesthesia/sedation: Anesthesia/sedation:No sedation/Minimal sedation (anxiolysis)/Moderate sedation (conscious sedation)/Deep sedation/General anesthesia/Monitored anesthesia care/Other-
Anesthesia/sedation administered by: Anesthesia admin:Anesthesiology/Nurse or other independent trained observer/Performing provider/Other-/Not applicable
Total intra-service sedation time (minutes): Face-to-face sedation time

Imaging prior to biopsy
The patient was positioned Position:supine/left lateral decubitus oblique/left lateral decubitus/right lateral decubitus oblique/right lateral decubitus/semi-prone/prone. Initial imaging was performed.
Biopsy target:
- Organ or target location: Target location:Lung/Liver/Kidney/Lymph Node/Other-
- Laterality: Laterality:Right/Left/Single Organ
- Maximal diameter (cm): Lesion size
Other findings: Other pre-procedure findings

Biopsy
Local anesthesia was administered. Under CT guidance, the biopsy needle was advanced to the target and biopsy was performed.
Coaxial needle: Coaxial needle size:10 gauge/11 gauge/13 gauge/15 gauge/17 gauge/19 gauge/Other-/None

Core needle biopsy device: Manufacturer and device name
Core needle size: Core needle gauge:14 gauge/16 gauge/18 gauge/20 gauge/Other-/Not applicable
Number of core specimens: Number of cores obtained or N/A

Fine needle aspiration device: Manufacturer and device name
Fine needle size: FNA needle gauge:21 gauge/22 gauge/23 gauge/25 gauge/Other-/Not applicable
Number of FNA specimens: Number of FNAs obtained or N/A

On-site assessment of biopsy adequacy: Yes/No:Yes/No
Additional sampling recommendations: Additional sampling recommendations:None/Core requested after FNA/FNA requested after core
Preliminary assessment of sample adequacy: Sample adequacy:Adequate/Adequacy not confirmed/Not applicable

Needle removal
The biopsy needle was removed and a sterile dressing was applied.
Tract embolization: Tract embolization:None/Gelfoam slurry/Gelfoam pledgets/Blood patch/Hydrogel plug/Saline/Other-/Not applicable

Imaging following biopsy
Immediate post-biopsy imaging was performed using Post-biopsy CT:noncontrast CT/contrast CT.
Post-biopsy imaging findings: Post-biopsy findings

Contrast
Contrast agent: Contrast agent:Omnipaque 300/Omnipaque 350/Visipaque 320/Isovue 250/Isovue 300/Isovue 370/Ultravist 370/Other-/None
Contrast volume (mL): Contrast volume

Radiation Dose
CT dose length product (DLP units:mGy-cm/cGy-cm/Not applicable/Not available): DLP

Additional Details
Additional description of procedure: Additional description
Registry event: Intraprocedure events:None/Air Embolism/Bleeding/Bone fracture/Contrast reaction/Device fracture/Device Malfunction/Hemoptysis/Hemothorax/Injury to adjacent structure/Pneumothorax/Sedation requiring reversal/Cause of registry event:Not device related/Device related without device failure/Device related with device failure/Not applicable/Event treatment:Endovascular/Non vascular Image guided intervention/Surgical/Medical management/Transfusion/Observation/Not applicable
Device used: Registry event device manufacturer and device name
Equipment details: Useful or additional equipment
Unique Device Identifiers: Comma Separated UDI numbers for implants or devices used
Specimens removed: Biopsy samples as detailed above
Estimated blood loss (mL): Blood Loss:Less than 10/11-50/51-100/101-200/201-500/501-1000/1001-2000/Greater than 2000
Standardized report: SIR_BiopsyCT_v3.1

Attestation
Signer name: Signer Name
I attest that I Presence:was present for the entire procedure/was present for the key elements of the procedure and immediately available/supervised the procedure and was immediately available. I reviewed the stored images and agree with the report as written.

PROCEDURE: Lower extremity angiography and interventions

Procedural Personnel
Attending physician(s): Attending Name
Fellow physician(s): Fellow
Resident physician(s): Resident
Advanced practice provider(s): APP

Procedure Date (mm/dd/yyyy): Report Create Date

Pre-procedure diagnosis: Diagnosis
Post-procedure diagnosis: Post Procedure
Procedure urgency: Procedure Urgency:Elective/Urgent/Emergency
Indication: Indication:Claudication/Rest pain/Ulceration/Critical limb ischemia/Thrombosis/Mapping angiography for future procedure/Bleeding/Suspected stenosis or occlusion/Arteriovenous malformation/Arteriovenous fistula/Aneurysm/Other-
Additional clinical history: Additional clinical history

Complications: No immediate complications.

IMPRESSION:

Angiography of the interrogated vessels demonstrates summary of findings. Summary of interventions performed and outcome

Plan:

Plan

PROCEDURE SUMMARY:
- Arterial access Guidance:with ultrasound/without ultrasound guidance
- Unilateral or bilateral:Unilateral/Bilateral lower extremity angiography as described below
- Arterial interventions as described below
- Additional procedure(s): Additional procedure(s):Aortography/Additional arterial access/Intravascular ultrasound/Use of re-entry device/Use of crossing device/Other-/None

PROCEDURE DETAILS:

Pre-procedure
Consent: Informed consent for the procedure including risks, benefits and alternatives was obtained and time-out was performed prior to the procedure.
Preparation: The site was prepared and draped using maximal sterile barrier technique including cutaneous antisepsis.

Anesthesia/sedation
Level of anesthesia/sedation: Anesthesia/sedation:No sedation/Minimal sedation (anxiolysis)/Moderate sedation (conscious sedation)/Deep sedation/General anesthesia/Monitored anesthesia care/Other-
Anesthesia/sedation administered by: Anesthesia admin:Anesthesiology/Nurse or other independent trained observer/Performing provider/Other-/Not applicable
Total intra-service sedation time (minutes): Face-to-face sedation time

Access
Local anesthesia was administered. Vascular access was obtained and a Sheath type was placed.
Access guidance: Access:Ultrasound access with permanent image stored/Ultrasound access without permanent image stored/Manual palpation/Fluoroscopy/Open exposure/Concomitant endarterectomy/Other-
Largest sheath size (French): Largest sheath size
Laterality: Access Laterality:Right/Left
Access direction: Access direction:Antegrade/Retrograde/Anterograde to retrograde/Retrograde to anterograde
Vessel accessed: Vessel accessed:Femoral artery/Superficial femoral artery/Popliteal artery/Anterior tibial artery/Posterior tibial artery/Dorsalis pedis artery/Peroneal artery/Axillary artery/Brachial artery/Radial artery/Graft/Other
Access technique: Access technique:Micropuncture set with 21 gauge needle/19 gauge access needle/18 gauge access needle/Other-

Aortography
Indication for aortography: Indication for aortography:Diagnostic - no prior angiographic study/Diagnostic - change in patient condition/Diagnostic - inadequate visualization on prior/Diagnostic - clinical change during procedure/Non-diagnostic - roadmapping, guidance, or measurement/Other-
Vessel catheterized: Aorta:Abdominal aorta at or above the level of the renal arteries/Abdominal aorta below the level of the renal arteries
Findings: Aortogram findings

Left lower extremity angiography and interventions
The left lower extremity arterial system was catheterized using combination of catheter(s) and wire(s) used.
Indication for angiography: Indication for angiography:Diagnostic - no prior angiographic study/Diagnostic - change in patient condition/Diagnostic - inadequate visualization on prior/Diagnostic - clinical change during procedure/Non-diagnostic - roadmapping, guidance, or measurement/Other-

Vessel catheterized: Left lower extremity artery:Left common iliac artery/Left external iliac artery/Left common femoral artery/Left superficial femoral artery/Left popliteal artery/Left tibioperoneal trunk/Left posterior tibial artery/Left anterior tibial artery/Left peroneal artery/Left dorsalis pedis artery/Other-
Findings: Angiography findings

Vessel catheterized: Additional vessel catheterized
Findings: Angiography findings

~Lesion
~Lesion number: Lesion number
~Artery segment of target lesion: Artery segment of target lesion:Infrarenal abdominal aorta/Common iliac artery/Internal iliac artery/External iliac artery/Common femoral artery/Profunda fermoris artery/Superficial femoral artery/Popliteal artery above the knee (above proximal patella)/Popliteal artery at the knee (between proximal patella and center of joint)/Popliteal artery below the knee (center of the knee joint to origin of the anterior tibial)/Anterior tibial artery/Tibioperoneal trunk/Posterior tibial artery/Peroneal artery/Dorsalis pedis artery/Plantar artery
~Lesion length (cm): Lesion length
~Percent stenosis (%): Percent stenosis
~Technical details: Technical details
~Treatment aborted or incomplete: Treatment aborted:Yes/No

~~Angioplasty
~~Angioplasty balloon type: Balloon type:Conventional/Drug-eluting/Cutting/Cryoballoon/None
~~Angioplasty balloon: Balloon manufacturer and device name
~~Lot number: Balloon Lot number
~~Balloon length (mm): Balloon length
~~Balloon diameter (mm): Balloon diameter

~~Stent
~~Stent type: Stent type:Self-expanding bare metal stent/Balloon-expandable bare metal stent/Self-expanding covered stent/Balloon-expandable covered stent/Drug-eluting bare metal stent/Bio-resorbable
~~Stent: Stent manufacturer and device name
~~Lot number: Lot number
~~Stent length (mm): Stent length
~~Stent diameter (mm): Stent diameter

~~Chronic total occulusion
~~Chronic total occlusion: Chronic total occlusion:Recanalization/Re-entry/None
~~Chronic total occlusion device: Chronic total occlusion device manufacturer and device name
~~Lot number: CTO Lot Number

~~Atherectomy
~~Atherectomy type: Atherectomy type:Orbital/Rotational/Laser/Directional/Aspiration/Cutting/Suction rotation/None
~~Atherectomy device: Atherectomy manufacturer and device name
~~Lot number: Atherectomy Lot number
~~Atherectomy device length (mm): Atherectomy device length
~~Atherectomy device diameter (mm): Atherectomy device diameter
~~Distal protection device: Distal protection device:Yes/No

~~Thrombectomy
~~Thrombotic intervention: Thrombotic Intervention:Thrombolysis/Mechanical thrombectomy/Aspiration thrombectomy/Open surgery/Lower extremity bypass/Endarterectomy/Embolectomy/None
~~Thrombotic intervention device: Catheter or device manufacturer and device name with length if applicable
~~Distal protection device: Distal protection device:Yes/No
~~Intraprocedural Thrombolytic agent: Thrombolytic agent:tPA/urokinase/tenecteplase/None
~~Intraprocedural Thrombolytic dose: Thrombolytic dose if applicable
~~Fibrinogen monitoring: Fibrinogen monitoring:Yes/No/Not applicable

~Angiography
~Post-intervention angiography: Post-intervention angiography findings

Right lower extremity angiography and interventions
The right lower extremity arterial system was catheterized using combination of catheter(s) and wire(s) used.
Indication for angiography: Indication for angiography:Diagnostic - no prior study/Diagnostic - change in patient condition/Diagnostic - inadequate visualization on prior/Diagnostic - clinical change during procedure/Non-diagnostic - roadmapping, guidance, or measurement/Other-

Vessel catheterized: Right lower extremity artery:Right common iliac artery/Right external iliac artery/Right common femoral artery/Right superficial femoral artery/Right popliteal artery/Right tibioperoneal trunk/Right anterior tibial artery/Right peroneal artery/Right posterior tibial artery/Right dorsalis pedis artery/Other-
Findings: Angiography findings

Vessel catheterized: Additional vessel catheterized
Findings: Angiography findings

~Lesion
~Lesion number: Lesion number
~Artery segment of target lesion: Artery segment of target lesion:Infrarenal abdominal aorta/Common iliac artery/Internal iliac artery/External iliac artery/Common femoral artery/Profunda fermoris artery/Superficial femoral artery/Popliteal artery above the knee (above proximal patella)/Popliteal artery at the knee (between proximal patella and center of joint)/Popliteal artery below the knee (center of the knee joint to origin of the anterior tibial)/Anterior tibial artery/Tibioperoneal trunk/Posterior tibial artery/Peroneal artery/Dorsalis pedis artery/Plantar artery
~Lesion length (cm): Lesion length
~Percent stenosis (%): Percent stenosis
~Technical details: Technical details
~Treatment aborted or incomplete: Treatment aborted:Yes/No

~~Angioplasty
~~Angioplasty balloon type: Balloon type:Conventional/Drug-eluting/Cutting/Cryoballoon/None
~~Angioplasty balloon: Balloon manufacturer and device name
~~Lot number: Balloon Lot number
~~Balloon length (mm): Balloon length
~~Balloon diameter (mm): Balloon diameter

~~Stent
~~Stent type: Stent type:Self-expanding bare metal stent/Balloon-expandable bare metal stent/Self-expanding covered stent/Balloon-expandable covered stent/Drug-eluting bare metal stent/Bio-resorbable
~~Stent: Stent manufacturer and device name
~~Lot number: Lot number
~~Stent length (mm): Stent length
~~Stent diameter (mm): Stent diameter

~~Chronic total occlusion
~~Chronic total occlusion: Chronic total occlusion:Recanalization/Re-entry/None
~~Chronic total occlusion device: Chronic total occlusion device manufacturer and device name
~~Lot number: CTO Lot Number

~~Atherectomy
~~Atherectomy type: Atherectomy type:Orbital/Rotational/Laser/Directional/Aspiration/Cutting/Suction rotation/None
~~Atherectomy device: Atherectomy manufacturer and device name
~~Lot number: Atherectomy Lot number
~~Atherectomy device length (mm): Atherectomy device length
~~Atherectomy device diameter (mm): Atherectomy device diameter
~~Distal protection device: Distal protection device:Yes/No

~~Thrombectomy
~~Thrombotic intervention: Thrombotic Intervention:Thrombolysis/Mechanical thrombectomy/Aspiration thrombectomy/Open surgery/Lower extremity bypass/Endarterectomy/Embolectomy/None
~~Thrombotic intervention device: Catheter or device manufacturer and device name with length if applicable
~~Distal protection device: Distal protection device:Yes/No
~~Intraprocedural Thrombolytic agent: Thrombolytic agent:tPA/urokinase/tenecteplase/None
~~Intraprocedural Thrombolytic dose: Thrombolytic dose if applicable
~~Fibrinogen monitoring: Fibrinogen monitoring:Yes/No/Not applicable

~Angiography
~Post-intervention angiography: Post-intervention angiography findings

Intravascular ultrasound
Vessel imaged: Vessel imaged with IVUS
Indication for IVUS: Indication for IVUS
Findings: IVUS findings

Intraprocedural Anticoagulation
Anticoagulation agent: Anticoagulation agent:Heparin/Argatroban/Bivalirudin/Other-
Dose: Dose
Dosing method: Dosing method:Weight based/Fixed
Anticoagulation monitoring: Anticoagulation monitoring:ACT/Thromboelastography/Not performed

Closure
Access site angiography performed: Closure site angiography:Yes/No
Findings: Closure site angiography findings
Arterial closure technique: Closure device:Manual compression/Angioseal/Perclose/Starclose/Mynx/Exoseal/Radial compression device/Fem-stop/Vascade/Not applicable/Other-
Hemostasis achieved from closure technique: Hemostasis from closure technique:Yes/Partial/No/Not applicable
Duration of manual compression (minutes): Manual compression duration

Contrast
Contrast agent: Contrast agent:Omnipaque 300/Omnipaque 350/Visipaque 320/Isovue 250/Isovue 300/Isovue 370/Ultravist 370/Other-/None
Contrast volume (mL): Contrast volume

Radiation Dose
Fluoroscopy time (Fluoro units:minutes/seconds/mm:ss): Fluoro time
Reference air kerma (AK units:Gy/mGy/Not provided by imaging equipment): Air Kerma
Kerma area product (KAP units:uGy-cm2/mGy-cm2/cGy-cm2/Gy-cm2/uGy-m2/mGy-m2/cGy-m2/Gy-m2/Not provided by imaging equipment): Kerma area product

Additional Details
Additional description of procedure: Additional description
Acute procedural success: Procedure success:Yes/No
Registry event: Intraprocedure events:None/Bleeding/Contrast reaction/Device misplacement/Distal embolization/Sedation requiring reversal/Vascular access site bleeding/Vessel dissection/Vessel perforation/Vessel thrombosis/Cause of registry event:Not device related/Device related without device failure/Device related with device failure/Not applicable/Event treatment:Endovascular/Non vascular image guided intervention/Surgical/Medical management/Transfusion/Observation/Not applicable
Device used: Registry event device manufacturer and device name
Equipment details: Useful or additional equipment
Unique Device Identifiers: Comma Separated UDI numbers for implants or devices used
Specimens removed: Specimens
Estimated blood loss (mL): Blood Loss:Less than 10/11-50/51-100/101-200/201-500/501-1000/1001-2000/Greater than 2000
Standardized report: SIR_AngioLowerExtremityInterventions_v3.1

Attestation
Signer name: Signer Name
I attest that I Presence:was present for the entire procedure/was present for the key elements of the procedure and immediately available/supervised the procedure and was immediately available. I reviewed the stored images and agree with the report as written.