Creation of an Open Framework for Point-of-Care Computer-Assisted Reporting and Decision Support Tools for Radiologists

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Abstract

Decreasing unnecessary variation in radiology reporting and producing guideline-concordant reports is fundamental to radiology's success in value-based payment models and good for patient care. In this article, we present an open authoring system for point-of-care clinical decision support tools integrated into the radiologist reporting environment referred to as the computer-assisted reporting and decision support (CAR/DS) framework. The CAR/DS authoring system, described herein, includes: (1) a definition format for representing radiology clinical guidelines as structured, machine-readable Extensible Markup Language documents and (2) a user-friendly reference implementation to test the fidelity of the created definition files with the clinical guideline. The proposed definition format and reference implementation will enable content creators to develop CAR/DS tools that voice recognition software (VRS) vendors can use to extend the commercial tools currently in use. In making the definition format and reference implementation software freely available, we hope to empower individual radiologists, expert groups such as the ACR, and VRS vendors to develop a robust ecosystem of CAR/DS tools that can further improve the quality and efficiency of the patient care that our field provides. We hope that this initial effort can serve as the basis for a community-owned open standard for guideline definition that the imaging informatics and VRS vendor communities will embrace and strengthen. To this end, the ACR Assist initiative is intended to make the College's clinical content, including the Incidental Findings Committee White Papers, available for decision support tool creation based upon the herein described CAR/DS framework.

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INTRODUCTION

Radiologists practice in a broad field, where even a single imaging examination can present significant findings that cross multiple systems and specialty guidelines. For example, an abdominal CT might show congenital pathology of the hepatobiliary system, traumatic injury to the musculoskeletal system, or an infectious disease of the genitourinary tract. Thus, a radiologist must feel comfortable interpreting across a wide range of imaging findings complicated by an even wider range of clinical contexts to produce diagnostic impressions that meaningfully guide clinical care and remain concordant with the variety of prevailing clinical standards. To provide the necessary flexibility to meet this challenge, radiology has traditionally embraced an open-ended style of reporting. However, this open-ended reporting practice has also resulted in undesirable variability between radiologists that can frustrate referring physicians and complicate patient care [1-4].

To reduce unnecessary report variability, there has been a robust push in recent years toward increased structure and standardization in radiology reporting. The most notable example is in the field of breast imaging where the ACR developed and promulgated the BIRADS. BI-RADS includes a standardized lexicon for description of breast

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imaging findings and their clinical management. Backed by a federal mandate, the BI-RADS system has achieved ubiquitous use throughout the United States, resulting in a much lower degree of variability in the reporting of breast imaging findings.

Partially driven by the success of BI-RADS, other areas of radiology have promulgated similar report standardization efforts across a variety of clinical scenarios. For instance, CMS has required since 2015 the use of standardized lung nodule identification, classification, and reporting system for reimbursement for lung cancer screening. Many screening programs are using the Lung CT Screening Reporting and Data System (Lung-RADS) to meet this requirement—a structured reporting system similar to BI-RADS [5,6]. Likewise, professional groups have developed a panoply of evidence- and consensus based guidelines, practice parameters, and technical standards (henceforth referred to in aggregate as "clinical guidelines" for the sake of simplicity), including the ACR white papers on incidental findings, the Fleischner Society for Thoracic Radiology guidelines for management of pulmonary nodules, and the Society of Radiologists in Ultrasound guidelines on the management of thyroid nodules, just to name a few [7-9]. However, unlike BIRADS and Lung-RADS, use of these clinical guidelines and practice standards has been inconsistent at best, with a high degree of report variability persisting in these imaging areas [10-15].

ADDRESSING UNNECESSARY REPORT VARIABILITY IN RADIOLOGY

Many explanations have been proffered for the ongoing widespread variation in radiologist practice from published guidelines. One important contributing factor has been the limited integration of clinical guidelines into the radiologist workflow. Point-of-care clinical decision support solutions, such as electronic medical record (EMR)-based "best practice alerts," have been shown to improve compliance with guidelines in other areas of medicine [16,17]. However, these EMR-based systems are less likely to be effective in meaningfully impacting radiologist practice given that the EMR is not typically central to the radiologist workflow. A more successful point-of-care integration strategy in radiology would instead focus on the PACS or voice recognition software (VRS).

Our group set out to develop a computer-assisted reporting and decision support (CAR/DS) framework that could systematically integrate clinical guidelines into the VRS, the radiologist's tool for report generation [18]. Our CAR/DS framework is intended to allow guideline creating groups, like the ACR, to define clinical guidelines in a standard, open definition language. Commercial VRS and PACS could then leverage these guideline specific definitions to present the clinical guidelines as a clinical decision support interaction at the time of interpretation.

For example, the ACR could encode the available ACR white paper guidelines for the workup/management of an incidentally discovered adrenal nodule on CT into the CAR/DS framework. Then, when a radiologist encounters an incidental adrenal nodule in clinical practice, the CAR/ DS tool within the VRS could aid the radiologist to provide the necessary descriptions of the adrenal nodule (eg, size, presence of macroscopic fat, stability from prior imaging examinations), determine the appropriate workup/management based on the guidelines, and automatically generate and insert standardized language of the imaging findings and necessary clinical follow-up into the report. We believe that this type of workflow-integrated tool would improve standardization of radiologist descriptions across clinical scenarios and result in significantly higher compliance with prevailing care guidelines [19].

CAR/DS GUIDELINE DEFINITION LANGUAGE

A CAR/DS guideline must define all the potential data elements that serve as the inputs and outputs of radiologic clinical guidelines. Likewise, it must define the branching logic rules by which inputs are turned into outputs and specify the appropriate report language for each of these potential outputs. Therefore, at the highest level, a CAR/DS guideline definition contains descriptive metadata, data element definitions, a flowchart-like logic tree, and a set of templates associated with the possible end points. Extensible Markup Language (XML) with a defined schema was chosen as the default base file format to express the clinical guidelines as structured, machine-readable definition documents [20]. We used RelaxNG Compact Syntax as the syntax for expressing the guideline definition language schema [21]. RelaxNG Compact Syntax has the advantages of compactness and ease of use, with freely available tools that permit the transformation of this schema into the more widely supported XML Schema Definition syntax.

In the next sections, we provide a brief description of the components of the CAR/DS guideline definition language with the intention of empowering interested parties to encode their own clinical guidelines into this CAR/DS framework.

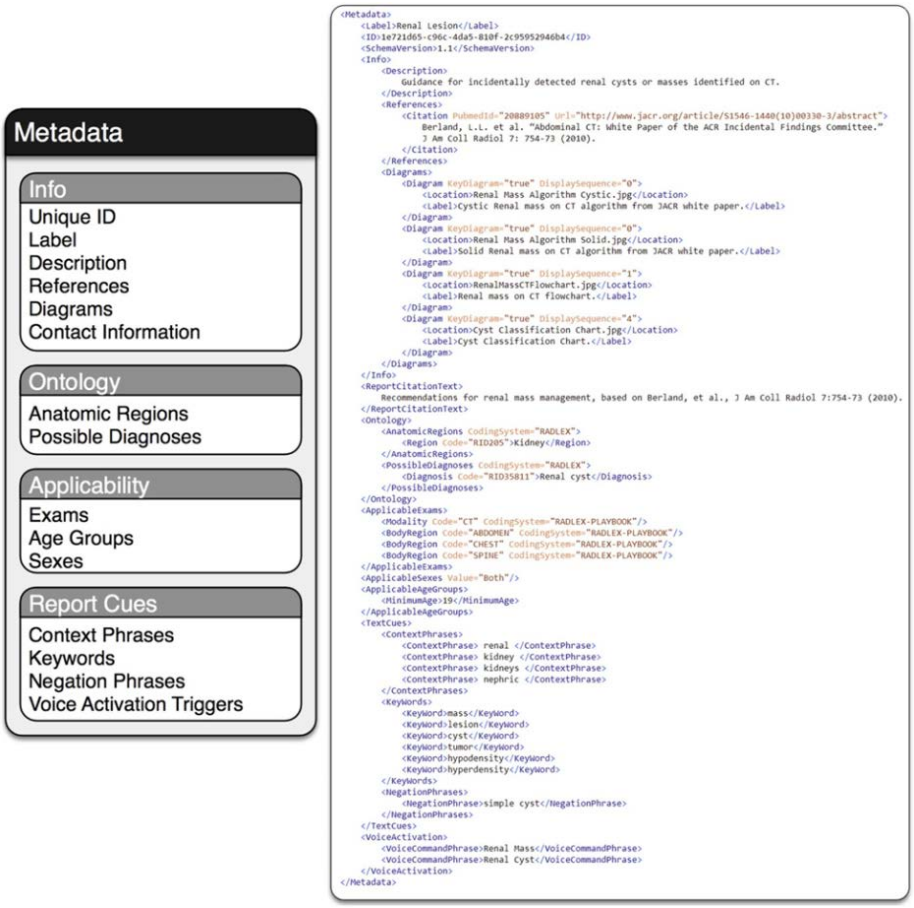


Figure 1: Structure of the metadata block in a guideline definition and example metadata for an incidentally detected renal mass guideline. The metadata block encompasses basic descriptive information about the guideline, ontological connections for the guideline, parameters regarding for which exams and patients the guideline applies, and hints on how the guideline might be activated within a reporting system.

Metadata

The metadata section contains general information about a CAR/DS guideline, which may or may not be used by any given implementation (Fig. 1). The first portion of the metadata section of the definition file is an information section that contains a short text label for the guideline, a text-based description of the guideline, and contact information for relevant authors of the document. Citations to relevant articles from the literature—ideally including the primary published source for the guidelines and figures and files such as the primary flowchart or the Portable Document Format of the actual reference—can also be specified in this subsection. This section may also contain links to other ontologies; for example, relevant Systematized Nomenclature of Medicine or RadLex data entries for possible diagnoses arrived at using the guideline might be listed.

A second import component of the metadata section is information specifying for which examination types and patient demographics the guideline would be relevant. For example, an algorithm might specify that it is intended for CT examinations of the abdomen (noting that these could be specified according to a standard coding scheme, such as RadLex Playbook or ACR Common). In addition, appropriate genders (male, female, or both) and an appropriate minimum and maximum age can be specified in this portion of the metadata. This information directs the VRS implementing application not to offer a guideline that is intended for adult female patients, when a user is dictating a report for a patient not meeting the age or gender criteria.

Finally, the metadata section provides clues as to how a reporting system might recognize when a user is describing a finding for which the guideline might be applicable. This takes the form of text cues that a radiologist might dictate and that would cue the VRS implementing application to offer a particular clinical guideline to the user. These text cues can be explicit phrases (adrenal nodule) or words used in the context of another word (cyst used in the context of kidneys). Negative text cues (ie, explicit phrases that should not prompt the application to offer a particular clinical guideline) can also be specified, such as simple hepatic cyst in relation to a liver lesion guideline.

Data Element Definitions

The data element definitions specify the input values used to drive the clinical decision tree and possibly intermediate or output values associated with an algorithm. Three main types of data elements can be described using the data format: external and fixed values, user-provided data, and results of computation.

The current schema allows the definition of global values, similar to constants in the C programming language that can be referred to elsewhere in the guideline. These are intended to be used to define threshold values or parameters in a linear regression. In keeping with the "don't repeat yourself" principle of computer programming, these can be specified once in a guideline definition. When thresholds change, the value needs only to be updated in a simple location in the definition.

In addition, the schema allows for the specification of basic patient and examination data, such as age, gender, modality, and body part. In this way, a guideline's logic can branch based on a patient's age—for example, offering different recommendations for patients younger and older than 35 years of age. We envision future versions of the schema specifying the inclusion of more complex patient data extracted from an EMR, such as smoking status or history of malignancy, as well as laboratorial and genetic tests results. As future artificial intelligence diagnostic systems and applications are developed, integrating all of the available patient information, including data from wearable devices, could further improve the value of the radiologist report.

The definition format also allows for data elements to be collected from the radiologist at reporting time. These elements can be numeric values (eg, the size of a lesion), integers (eg, the series or image number a finding is seen on), Boolean values (eg, the presence or absence of a finding), single-choice values (eg, categorization of a finding), or multiple-choice values (eg, presence or absence of findings in multiple locations). For each data element, associated data can be specified: whether an element is required for the guideline to return a result, where it should be displayed, how the user should be prompted to reply. In addition, more detailed text or images can be included, which might be offered by a given implementation as a tool-tip or reference image. Different data elements can also include more typespecific information, such as the values and textual representations of the different possible choices for a choice-based data element. Simple data element definitions are illustrated in Figure 2 with the reference implementation rendering of that data element as a question.

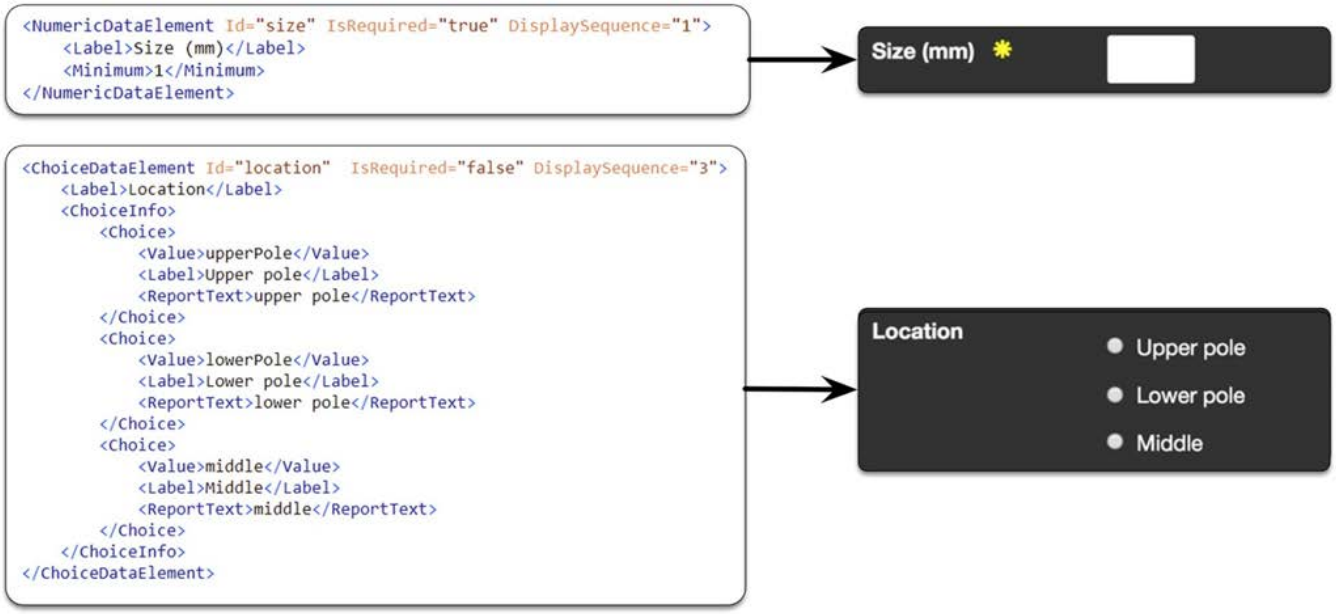
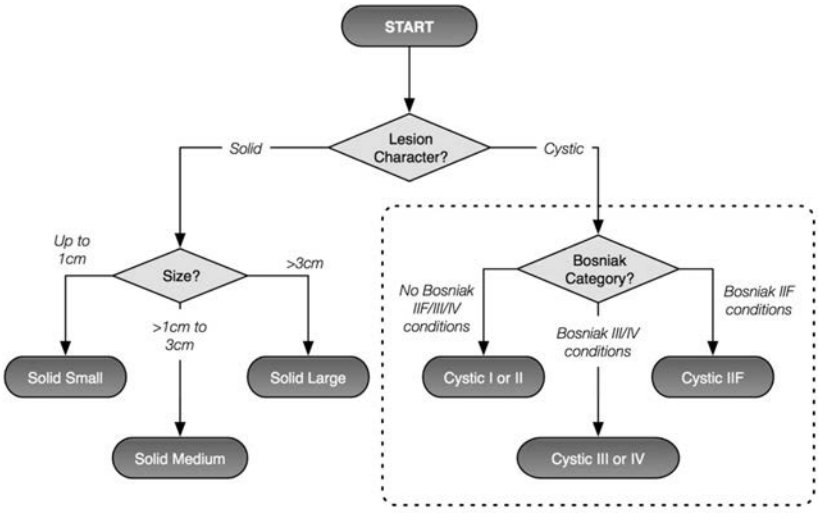


Figure 2: Data elements defined in the guideline definition language and rendered using the reference application. The first pair demonstrates a data element designed to request and hold a number value entered by the end user. The second demonstrates a choice data element, where the end user selects one of several defined values. Note that the data element definitions include user interface elements, such as the text of the question label and choices and processing data such as whether a data element is required or not.

Computed data elements, whose values depend on other data, can also be defined. These can be simple Boolean values or more sophisticated textual constructs or arithmetical calculations. These take advantage of the same logic syntax described later for defining the overall logic tree of the definition. There are several uses for these computed elements. One common case is to allow for intermediate values in calculations or logic to prevent respecifying the same logic or calculation repeatedly. For example, a cancer staging guideline might include a computed element that determines the T-stage for the examination, which can then be used and reused in the logic tree without having to respecify the logic for determining T-stage at every decision point that depends on it. Alternatively, a regression model (eg, the Brock University cancer prediction equation for pulmonary nodules) might be encoded as a computed data element to offer a prediction of an outcome, which could be included [22]. A second common use is to more carefully craft text to be included in a report where the text has complex dependencies on the data inputs.

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<DecisionPoint>
    <Label>Bosniak criteria?</Label>
    <Branch>
        <Label>Bosniak III/IV</Label>
        <OrCondition>
            <EqualCondition DataElementId="enhancement" ComparisonValue="ofSeptaeSolidPart"/>
            <EqualCondition DataElementId="cystSolidPart" ComparisonValue="true"/>
            <EqualCondition DataElementId="cystSeptae" ComparisonValue="thickOrIrregular"/>
            <EqualCondition DataElementId="cystWalls" ComparisonValue="irregularOrThick"/>
        </OrCondition>
        <EndPointRef EndPointId="cysticBosniak3or4"/>
    </Branch>
    <Branch>
        <Label>Bosniak IIF</Label>
        <OrCondition>
            <EqualCondition DataElementId="cystCalcifications" ComparisonValue="thickOrNodular"/>
            <EqualCondition DataElementId="cystSeptae" ComparisonValue="manyThin"/>
            <AndCondition>
                <GreaterThanCondition DataElementId="size" ComparisonValue="30"/>
                <EqualCondition DataElementId="cystDensity" ComparisonValue="hyperdense"/>
            </AndCondition>
        </OrCondition>
        <EndPointRef EndPointId="cysticBosniak2f"/>
    </Branch>
    <DefaultBranch>
        <Label>Bosniak I/II</Label>
        <EndPointRef EndPointId="cysticBosniak1or2"/>
    </DefaultBranch>
</DecisionPoint>
```

Figure 3: Logic is represented in the guideline definition language. The flowchart based on algorithm outlined in the ACR white paper for Managing Incidental Findings on Abdominal CT represents the logic for a guideline outlining management of an incidental renal mass as a series of decision points, branches, and end points . The Extensible Markup Language represents the decision points, branches, and end points within the dashed line on the flowchart.

Logic Tree

Clinical guidelines are frequently defined as flowchart-like decision trees. For representation in the CAR/DS format, this logic must be formally encoded as a branching structure of binary decision points based on Boolean logic and associated outputs or further decision points. This branch point logic is illustrated in Figure 3, showing a flowchart-like graphic and an example of the representation in the CAR/DS format for characterization of incidental renal masses on CT scans that is a reflection of the content in the ACR white paper for managing incidental findings on abdominal CT [7].

The building blocks of the logic structure are decision points and branches, corresponding to the diamond shape and emanating lines on a flowchart. Each decision point contains a series of branches, where a branch is composed of a condition and either a nested decision point or a pointer to a flowchart end point. Depending on the current state of the system (ie, the values of the data elements), one of the several branches may be followed. The condition is built up using fundamental conditional operators (equals, less than, greater than or equal to, contains) and composite operators (ie, and, or, not). These conditions allow for comparison of the values of data elements against constants or other data elements. For each decision point, a default branch can be specified that will be followed if no other branch's condition evaluates to true.

Starting at the first decision point in the branch logic, implementing software finds the contained branches and evaluates the condition of each sequentially. The first branch whose condition evaluates to true is then followed, leading to only one possible true path based on the available choices. If the branch leads to an end point, then that end point is the output of the algorithm. If the branch contains a nested decision point, then that decision point is evaluated recursively according to the same logic until an end point is reached. Implementing software can therefore walk recursively through the defined logic tree for a given set of inputs and eventually arrive at an end point for a given set of inputs. When the state changes (ie, because the system's user inputs new or changed data), the implementing software re-evaluates the logic tree to determine the new end point.

In addition to the decision points, branches, conditions, and end point references that make up the structure of the logic tree, other elements for user interaction can be specified within the logic tree. Specifically, at each branch, data elements can be specified as "not relevant," which would cue implementing software to either hide or disable the inputs associated with those data elements. Different elements can be specified as required or not within a branch, and individual choices can be specified as being not available along particular branches of the logic tree.

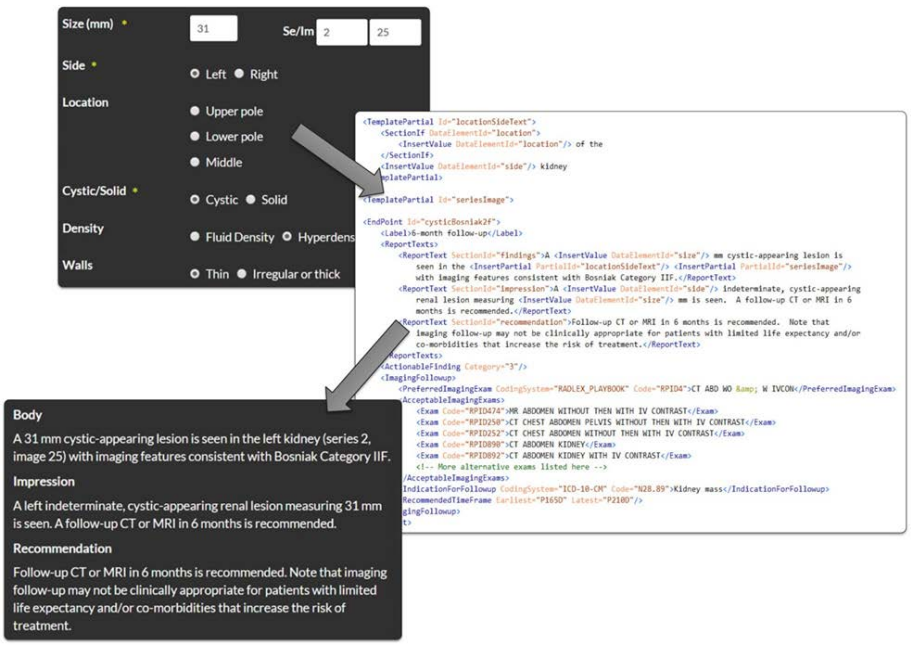

Figure 4: End point definitions specify text to be inserted into the report. At the upper left, a radiologist has entered a series of inputs that result in an end point being selected. For the given end point, text templates are provided that specify the text to be included in the report, which can include findings, impression, and recommendation text. The templates can insert values from the inputs to improve the applicability of the text. An end point can also define other actions to be taken, such as activation of a critical results management system or a recommendation for follow-up imaging. Based on algorithm outlined in the ACR white paper for Managing Incidental Findings on Abdominal CT .

End Point Definitions

Each end point of the defined logic tree specifies actions to be taken when user inputs lead to that output. Primarily, these actions consist of pieces of text to be inserted into the report, possibly with input or computed values inserted at appropriate places within the text. However, other kinds of clinical actions, including a structured recommendation for further imaging, can also be defined as part of each end point. A sample end point definition is illustrated in Figure 4.

An end point definition lays out the text to be inserted in a report by an implementing reporting system. Pieces of text can be defined to insert into the findings section of the report, into the impression section, and into a recommendation section (if available). The definition of the text to be inserted is based on a simple template language that permits the insertion of data element values and the conditional insertion of text.

In addition, "partial" templates can be defined that act as template subroutines and can be reused in multiple end point definitions. In addition to the text to be inserted into the report, more structured information can be included in the end point for the potential use of the implementing software. One of the most important types of structure information is a structured recommendation, especially a structured recommendation for additional imaging. This data structure includes encoded information on the reason for the recommendation, a specification of the imaging examination being recommended, acceptable alternatives to the preferred examination, and the time frame during which the recommended examination should be obtained (an example is shown in Fig. 4).

REFERENCE IMPLEMENTATION

To enable testing of clinical guidelines encoded into CAR/DS definitions, reference software was created. This program loads guideline definition files, enacts the specified user interaction, processes the user-entered data according to the given logic, and generates and presents the defined report text. The software consists of a web application, where both server-side and client-side components are written using the JavaScript programming language. The server-side component can be run on most computing platforms using the Node.js runtime environment [23]. The client-side application can be run in most modern web browsers and uses a variety of common client-side frameworks, most notably the Angular.js framework [24]. The schema and the software implementation will be freely available for public usage via the GitHub code-sharing service.

The reference implementation of the software allows users to test the fidelity of clinical guidelines that they have encoded into a CAR/DS definition and to interact with the encoded CAR/DS guideline to test how different inputs lead to different outputs. Loading and running the reference implementation program starts a web application that users can access using a web browser (see Fig. 5). This application searches a local directory for XML files containing CAR/DS guidelines and creates a menu of them for the user to select. When the user selects a module, they are presented with a form of inputs corresponding to the defined data elements. When they provide values into the form, the software executes the logic tree for the inputted values and determines an end point. For that end point, the software fills in the relevant data into the templates and generates output text, which is shown to the user. As the user changes the inputs, the output end point and text are updated interactively.

Newly developed guideline definition files can be added to a standard directory. Existing XML files can be edited in place. After editing or adding a definition file, reloading the web browser session will cause the application to reflect the new data.

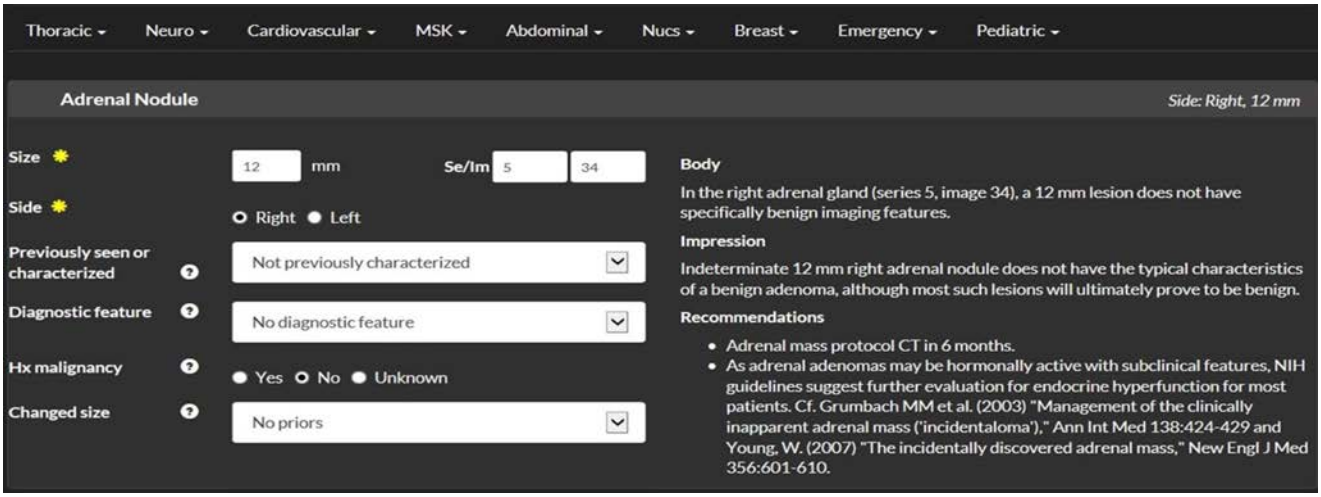

Figure 5: Reference implementation software loads computer-assisted reporting and decision support definition Extensible Markup Language files and allows the user to interact with them. Once the user has chosen a module to interact with, the inputs for relevant data elements are shown at the left. As the user changes the values, the output for the report text is updated on the right.

DISCUSSION

Decreasing unnecessary variation in radiology reporting and producing guideline-concordant reports is fundamental to radiology's success in value-based payment models and good for patient care. In this article, we present a robust format for representing radiology guidelines and computer-assisted reporting and decision support at the point of care for radiologists, as well as a user-friendly reference implementation. In making the definition format and the reference implementation software freely available, it is our intention to empower radiologists and expert groups across our field with a shared authoring environment so that we might work together to develop an ecosystem of CAR/DS modules. We hope this will serve as the starting point for an ongoing process of continuous quality improvement related to consistently providing clear, evidence-based interpretations in radiology.

Anyone interested in creating a CAR/DS module can download the definition file and use an XML editor of their choice to author a new module, possibly using an existing module as a template. They can then download and run the reference implementation software to test whether the code is correct and the desired output is generated for each possible set of inputs. Once the fidelity of the definition file with the clinical guideline is confirmed, the tool is ready to be implemented within a VRS that is empowered with this functionality. We hope that the imaging informatics community will take ownership of this definition format and use it to express the kinds of content that will further enrich our radiology reports.

Using this CAR/DS format, expert groups such as the ACR will be able to create and adapt guidelines definitions. Specifically, we hope that the ACR and many other groups will include encoding guidelines into this new format as part of their ongoing radiology clinical guideline development process. White papers remain an important method for communicating clinical guidelines and the evidence basis behind them, but CAR/DS takes that guideline off the paper and brings it to the point of care. To this end, the ACR Assist initiative is intended to make some of the College's clinical content, including the Incidental Findings Committee White Papers, available to vendors for decision support tool creation using this open CAR/DS framework.

Vendors of VRS, as well as other vendors in the radiology workflow, can implement CAR/DS content to extend the functionality of commercial tools currently in use. Importantly, the CAR/DS definition format serves to separate the content of the guideline from the vendor functionality that is implementing the clinical decision support for the said guideline. Thus, individual software vendors are able to decide how best to implement the CAR/DS interaction for their specific use case. As a result, we hope that different vendors will experiment with different ways to implement subsets of the CAR/DS functionality, creating a healthy competition to provide the richest CAR/DS implementation.

TAKE HOME POINTS

- Traditional open-ended reporting practices in radiology have resulted in undesirable clinical variability between radiologists that can frustrate referring physicians and complicate patient care.
- Studies suggest that point-of-care integration of clinical guidelines into the radiologist workflow could decrease unnecessary reporting variation and improve guidelines-based care.
- The CAR/DS framework, described herein, provides a robust authoring environment for developing workflow-integrated CAR/DS reporting tools and testing those tools before clinical implementation.
- The imaging informatics and radiology vendor communities can use the CAR/DS framework as a starting point to build a suite of radiology clinical decision support content that will further enrich our radiology reports and bring additional value to radiology services.

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ADDITIONAL RESOURCES

Additional resources can be found online at: http://dx. doi.org/10.1016/j.jacr.2017.04.031.

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