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Framework for an Integrated Disease Report

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• **Context.**—The volume of information that must be assimilated to appropriately manage patients with complex or chronic disease can make this task difficult because of the number of data points, their variable temporal availability, and the fact that they may reside in different systems or even institutions.

Objective.—To outline a framework for building an integrated disease report (IDR) that takes advantage of the capabilities of electronic reporting to create a single, succinct, interpretative report comprising all disease pertinent data.

Design.—Disease pertinent data of an IDR include pathology results, laboratory and radiology data, pathologic correlations, risk profiles, and therapeutic implications. We used cancer herein as a representative process for proposing what is, to our knowledge, the first example of standardized guidelines for such a report. The IDR was defined as a modular, dynamic, electronic summary of the most current state of a patient in regard to a particular

illness such as lung cancer or diabetes, which includes all information relevant for patient management.

Results.—We propose the following 11 core data concepts that an IDR should include: patient identification; patient demographics; disease, diagnosis, and prognosis; tumor board dispositions and decisions; graphic timeline; preresection workup and therapy; resection workup; interpretative comment summarizing pertinent findings; biobanking data; postresection workup; and disease and patient status at follow-up.

Conclusions.—A well-executed IDR should improve patient care and efficiency for health care team members. It would demonstrate the added value of pathology interpretation and likely contribute to a reduction in errors and improved patient safety by decreasing the risk that important data will be overlooked.

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The complexity of the data used to manage patients with chronic diseases such as cancer has grown during the past decades. Consequently, the task of the clinician has become increasingly difficult and time-consuming; for each patient, clinicians need multiple reports, which reach them in a discontinuous, often illogical, time frame. Furthermore, these reports must be monitored, reviewed, and integrated

with other reports and results. What did the chest radiography show? What did the computed tomography show? Do those findings correlate? What did the positron emission tomography–computed tomography show? Did the pathology and radiology findings correlate? Did they correlate with the fine-needle aspiration, with the biopsy results, or with both? Is this pathology report finalized? Is this a preliminary report? Were the appropriate special studies performed to determine therapy? Is information still outstanding? When is it expected? What information is outstanding for clinical trial enrollment? When can we expect those data?

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At its worst, patient safety can be compromised,¹ or the delivery of care may be delayed because of the difficulty in retrieving all of the necessary data elements needed for treatment. Contributing to this situation is the need to retrieve test results from various departmental information systems such as different areas of the electronic medical record (EMR), the radiology picture archiving and communications systems, and the laboratory information system² or the anatomic pathology laboratory information system,^{3,4} as well as systems outside of the treating facility or hospital system. In addition, for each of these retrieval locations, there may be multiple pertinent tests or results. For diseases such as cancer, several laboratory findings may result from a single specimen, which are added to the record over time⁵; this phenomenon is not restricted to laboratory results

(Figure 1). In this article, we outline a framework that takes advantage of the capabilities of electronic reporting to create an integrated disease report (IDR), a single, succinct, integrated, interpretative report comprising all data pertinent to the disease, including pathology results, laboratory and radiology data, imaging findings and pathologic correlations, risk profiles, and therapeutic implications. In this initial iteration of an IDR, we have not attempted a detailed delineation of the clinical work flow of the various subspecialties and ancillary services that would likely be involved in the care of a patient. We recognize the importance of such an exercise in the implementation of a fully functional IDR, but this should be the subject of subsequent work. In the present work, we demonstrate at a conceptual level the potential benefits of an IDR. A simple example might be a decreased likelihood of time being wasted or of significant information being missed because of important data being posted in an unexpected location or in an inconsistent fashion in the medical record.

Although a similar concept has been previously suggested⁸¹ and individual institutions may have developed conceptually similar solutions, standardized guidelines for the creation of an IDR have not, to our knowledge, been proposed. Because guidelines for IDRs will vary by the disease process and to keep our task manageable in this first iteration of an IDR, we have limited our scope to the single disease process of cancer.

MATERIALS AND METHODS

To determine guidelines for an IDR, we first developed a use case built around the common cancer disease scenario of a patient with non-small cell lung cancer. We reviewed the pathology reporting literature,⁶⁻⁶⁴ the radiology reporting literature,⁶⁵⁻⁷¹ and the surgical and clinical reporting literature,⁷²⁻⁷⁴ as well as diagnostic guidelines (National Comprehensive Cancer Network [<http://www.nccn.org>] and College of American Pathologists [CAP] cancer protocols [<http://www.cap.org>]). From this review, we created an initial criteria set that we vetted with other pathologists, radiologists, internists, and oncologists. From those results, we created a timeline of the disease marked by milestones that include 1 or more instances of the core elements listed in the Table.

RESULTS

Definition of an IDR

Based on our analysis and extrapolation from the cancer use case, as well as other disease states and their management, a series of characteristics became apparent that applied across multiple diseases. We categorized the characteristics into several higher overarching levels and reviewed these components with members of the CAP Diagnostic Intelligence and Health Information Technology Committee and the Pathology Electronic Reporting Committee. We further fine-tuned the attributes to create a definition of an IDR. We define the IDR as a modular, dynamic, and current electronic summary of the state of a patient in regard to a particular illness (eg, lung cancer or diabetes), which includes all relevant clinical information, historical data, and relevant pathology interpretations and data. Pathology reports and laboratory data are appended as new information is obtained; interpretations are appended as needed. Clinical information includes pertinent imaging (radiographs, computed tomography, magnetic resonance, ultrasonography, etc) interpretations with links to images and full interpretative reports (imaging, oncology, radiation oncology, etc), as well as treatments and outcomes. Historical

data include the clinical history pertinent to the diagnosis and treatment of the patient. If sequential laboratory values are pertinent to the current presentation, the parameter values during the relevant time range are presented contiguously or graphically as appropriate. A specific completion point may be defined depending on the specific disease process. The IDR and the source documents must always be synchronized, ensuring that addenda and corrections to the source documents are clearly reflected therein. A portion of the IDR may be assembled through an automated or rule-based process; however, there is also an interpretative component in which important summary clinical aspects such as prognostic categorization, indications, or contraindications for specific therapies are discussed. Some sections of the IDR may be designated as not to be subdivided to prevent potentially misleading fragmentation of information if excerpted. Data elements are searchable with coded data elements, discrete electronic queries, and natural language processing methods. Given the complexity of the full IDR, customized report views and displays are available depending on the end user preferences. Ideally, the IDR links to the source documents in a fashion that allows direct editing of them if appropriate security and identity requirements are met. A stringent version history (with a record of author changes and comments) and an audit trail are maintained and available; all changes and comments are transmitted to the report recipient group.

Even with the simplified example use case presented above, we believe that a well-designed and executed IDR would benefit patient care. It would increase the efficiency of health care team members by presenting the key primary data elements about a patient's disease process in a contiguous and succinct fashion. An IDR could potentially reduce errors^{7,75,76} and improve patient safety by decreasing the risk that important data may inadvertently fail to come to the attention of caregivers.⁷⁷

Determination of the Core Elements and Recommended Definitions

The list of the core elements described is not the result of an isolated effort of the Diagnostic Intelligence and Health Information Technology Committee and Pathology Electronic Reporting Committee working groups, which comprise practicing pathologists with sign-out duties and informatics interests. Rather, the development of the core elements is the result of years of conversations with surgery and oncology colleagues from our own institutions, to whom we owe a debt of gratitude. In addition, the conversation included collaborative effort with members of the American Society of Clinical Oncology, the Radiological Society of North America, and the Society of Surgical Oncology, among others, who are equally engaged in developing creative ways to present large amounts of information in a synthesized and manageable way. An extensive review of the literature for articles addressing reporting, including synoptic reporting, integrated reporting, and the use of templates in reporting, was performed to further inform this project (see the References).

Core Data Elements of the IDR

To continue with our use case, we propose core data elements for a cancer IDR. The level of detail that would be provided for each core data element might vary depending on the needs of the end user, and it could range from the

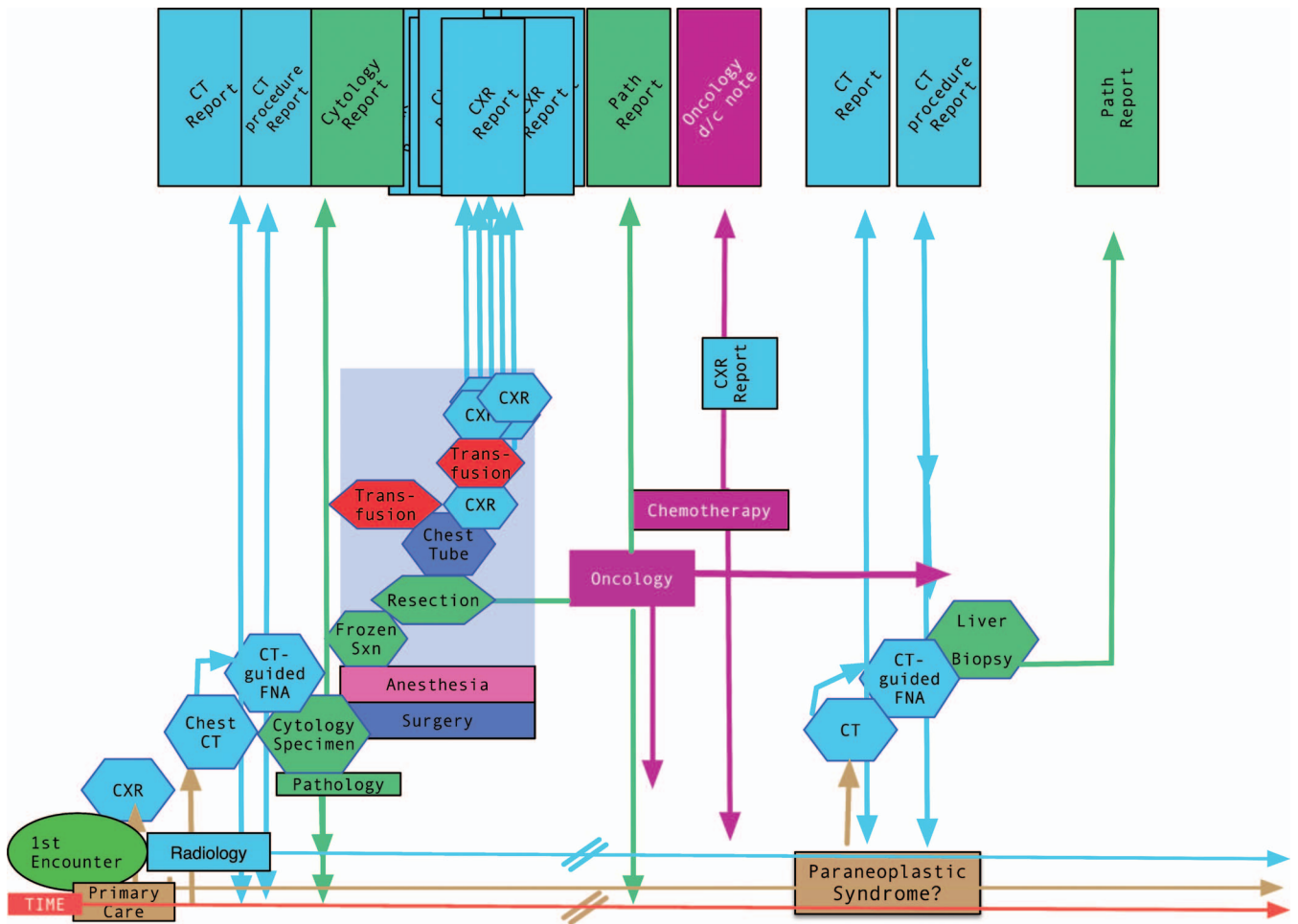


Figure 1. Graphic representation of a disease timeline demonstrating the complexity of reporting in even a simple scenario. Patient events and encounters are shown from initial presentation through recurrence in this simulated cancer use case. Abbreviations: CT, computed tomography; CXR, chest radiograph; d/c, discharge; FNA, fine-needle aspiration; Sxn, section.

provision of all of the pathologic detail needed to stage cancer in a patient to as little as a hyperlink to a different report in another area of the EMR. The core data concepts we propose are listed in the Table. A short description of each of the elements follows and provides a core of the requirements to build an IDR.

Patient Identification.—The first function of the report is to identify the patient. Conventional approaches (name, driver’s license number, date of birth, or master patient index) have been less than optimal, despite identification requirements by authorities such as the Clinical Laboratory Improvement Act. Positive identification is basic but of vital importance; without it, our practices run the risk of linking a devastating diagnosis to the wrong patient or failing to make such a link when appropriate. This issue is exacerbated when relevant patient data are housed in multiple systems that are not linked to each other or if the patient’s name or other identifiers change over time. While full discussion of the topic is outside the scope of this document, we agree along with our collaborators that, moving forward, the field of medicine should adopt biometric authentication (eg, fingerprint, palm vein pattern, iris pattern, or DNA profile) as part of the implementation of electronic health care records. Such technology offers greater identification fidelity and exists currently. Fingerprint authentication has

been recently introduced in the latest version of a smartphone (iPhone; Apple Inc, Cupertino, California).

Patient Demographics.—This section needs little explanation. In addition to the fundamental demographic information, it is obviously important that any social issues that might affect the therapeutic approach or care of the patient should be stated in this section.

Disease, Diagnosis, and Prognosis.—The primary information in this section is the pathologic diagnosis, with sufficient detail to establish the pathologic stage of the

Proposed Core Elements of the Integrated Disease Report	
Core Element	
Patient identification	
Patient demographics	
Disease, diagnosis, and prognosis	
Tumor board dispositions and decisions	
Graphic timeline	
Preresection workup and therapy	
Resection workup	
Interpretative comment summarizing pertinent findings	
Biobanking data	
Postresection workup	
Disease and patient status at follow-up	

patient's disease and any ancillary results available at the time the report is created. If information with prognostic significance has been acquired, it should be included in this section. Subsequent ancillary study results, reported after the initial creation of the report, are added to this section. Also included are the initial presentation, comorbidities, and the dynamic clinical team members (primary care physician, surgeon, pathologist, oncologist, radiation oncologist, etc). Links to pertinent imaging studies are provided in this section, and the bottom-line imaging interpretation can be linked to or included in the IDR if appropriate. The dates of all studies and the names of all signing physicians are included.

Tumor Board Dispositions and Decisions.—This section documents dispositions made at tumor board meetings if indicated. End users may wish to know explicitly which services were in attendance (or alternatively note the absence of specific services).

Graphic Timeline.—The graphic timeline displays the course of the patient's diagnostic workup and treatment. Its presentation may be a simple timeline or a flow diagram with multiple nodes that can be opened or expanded to reveal subprocesses. The most important characteristic of the graphic timeline is its readily comprehensible appearance (Figure 2).

Preresection Workup and Therapy.—This section contains the pertinent studies performed before the definitive resection procedure. This may include imaging studies, clinical laboratory tests, biopsy and cytology specimens, neoadjuvant therapy, and so forth. Among clinical laboratory tests, liver and renal function tests will be pertinent if the choice of chemotherapy might be affected. Comorbidities that might affect therapeutic decisions are discussed here.

Resection Workup.—This section is a synopsis of the findings derived from the tumor resection. Much of this will be obtained from the surgical pathology cancer case summary and may include primary pathologic staging parameters, histologic findings, and molecular pathology data. The specific data elements will depend on the tumor type and other relevant clinical parameters. Different medical specialties and other authorized users will likely emphasize different sections of the cancer case summary. For example, surgeons may have a more keen interest in the tumor size and margin status, while medical oncologists may be more interested in emphasizing immunohistochemistry, molecular markers, and omics studies. Both of these specialties are likely interested in all of the parameters mentioned above to some degree, but they may be prioritized differently. Some of the data elements in the cancer case summary may be omitted altogether in the IDR. The full cancer case summary should be available via a link.

Interpretative Comment Summarizing Pertinent Findings.—The interpretative comment summarizes all of the available pertinent laboratory data and contains links to pertinent imaging and other clinical findings. Risk assessment, prognostic and therapeutic indications, and contraindications will be discussed as appropriate. Interpretative comments from other specialties should be included here as well.

Biobanking Data.—Biobanking data delineate the tissue collection and preservation parameters that are pertinent for current and possible future molecular studies or for research.⁷⁸ In either case, documentation of parameters such as cold ischemic time, fixatives used, fixation time (for paraffin-embedded tissue), and disposition of tissue pre-

served by alternative methods (ie, frozen or nonstandard fixation for better preservation of DNA, RNA, etc) provides important information regarding the types of analyses that may be performed to anyone needing to analyze the tissue. While capture of biobanking data is of utmost importance, it may not be presented in full in many versions of the IDR; a link to this data is all that will be needed in such versions.

Postresection Workup.—The postresection portion of the IDR lists subsequent surgical procedures in the short term following definitive resections (eg, margin reexcisions), adjuvant therapy, and complications of the primary disease or of prior therapies. Additional workup and therapy attributable to metastatic disease discovered during the resection workup are documented here.

Disease and Patient Status at Follow-up.—This section is a patient status update that will be added at the conclusion of primary therapy, whatever the modalities. Pertinent data include the time that the patient is seen and relevant laboratory tests (including omics studies). Recurrent or metastatic disease discovered after the initial workup and resection is documented in this section. In some scenarios, this may be the end of the report; in others, it may be a repeating section.

COMMENT

Over time, pathology reports have become more complex but remain specimen centric. Until recently, they have also been paper based, which ensured that the report was delivered without further modification. In a digital age, however, one cannot assume that the receiving system (eg, an EMR) is capable of rendering raw data (eg, a typical fielded Health Level Seven transaction [<http://www.hl7.org>]) in an understandable form when a complex report such as an IDR is sent to it. The received version may not completely recapitulate in content or form the legal document signed by the pathologist.

To ensure reporting content fidelity, we advocate that any complex report should be sent to receiving EMRs in the following 2 forms: (1) in a fielded, standard Health Level Seven format and (2) as a reference display report, which is a pregenerated visual rendering of the text, images, and other information. Many surgical pathology systems use the PDF format, some genetics systems send JPG (<http://www.jpeg.org>) or PNG (<http://www.libpng.org/pub/png>) format, and the EPUB format (<http://idpf.org/epub>) may be considered in the future, while the PDF/A-3 format (<http://www.pdfa.org/tag/pdfa-3/>) has been suggested as most suitable.

The reference display report can be embedded within the Health Level Seven message. Not only must the laboratory information system be able to produce and send these reference display reports, but the EMR must be able to receive and display them (or otherwise make them accessible) unaltered. While single values coming from fielded data elements of noncomplex reports such as the white blood cell count may be visually collated by the EMR from across multiple reports for improved readability or trending, the EMR's presentation of complex reports such as the IDR should be based on the received reference display reports, not the fielded data, to preserve the meaning communicated by the formatting at the time of report completion. The fielded discrete data elements are enclosed only to enable clinical decision support based on the atomic data they contain.

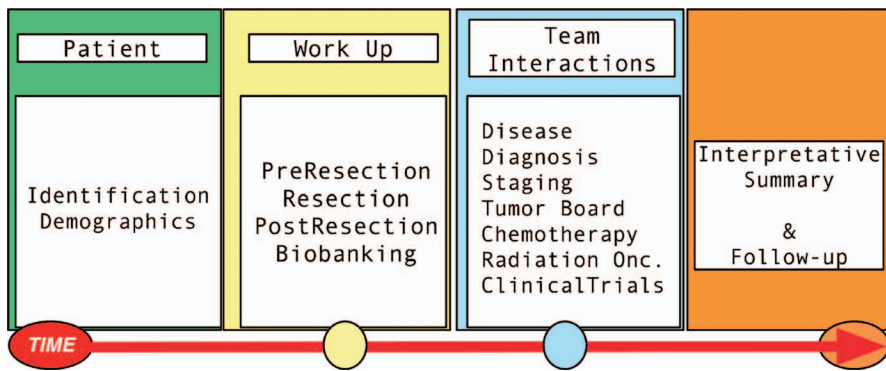


Figure 2. Timeline representation of an integrated disease report (IDR). Abbreviation: Onc, oncology.

CONCLUSIONS

Improving patient care requires integration of clinical data from across specialties. The importance of improving patient care by increased integration of diagnostic information has been the subject of study by the Assistant Secretary for Planning and Evaluation of the US Department of Health and Human Services.^{79,80} The siloed reporting that prevails in medicine today works against this goal. Integrated care requires an integrated report, the IDR. Herein, we have put forth guidelines and considerations to govern construction of such a report. The IDR development will dovetail with related future Diagnostic Intelligence and Health Information Technology Committee initiatives regarding data interoperability and data flow. Because of the quantity and complexity of the information presented in the IDR, input from all stakeholders will be critical to its continued development. To this end, we solicit feedback from our pathologist colleagues, as well as from nonpathologist physicians, public health experts, and other health care stakeholders. This effort represents a beginning for a longer, more involved process. The present design exercise included vetting of clinical stakeholders; future work should include a more rigorous ethnographic analysis to define end users and clinical work flows more precisely, with the aim of developing the most user-driven workflow-oriented IDR possible.

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