

HEALTHCARE DOCUMENTATION: A REPORT ON INFORMATION CAPTURE AND REPORT GENERATION

**Consensus Workgroup on
Health Information Capture and Report Generation**

C. Peter Waegemann, Claudia Tessier, Andrew Barbash, Barry H. Blumenfeld, Jonathan Borden,
Robert M. Brinson Jr, Todd Cooper, Peter L. Elkin, J. Michael Fitzmaurice, Susan Helbig,
Kathleen Milholland Hunter, Brenda Hurley, Brian Jackson, James M. Maisel, David Mohr,
Kathy Rockel, Joseph H. Schneider, Thomas Sullivan, Joe Weber

June 2002

Copyright C. Peter Waegemann, Claudia Tessier, et al., Newton, MA, 2002. Permission to quote portions of this document is granted provided this source document and copyright are acknowledged and a copy of the material in which the quote is used is provided to C. Peter Waegemann, c/o Medical Records Institute, PO Box 600770, Newton, MA 02460.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	2
<i>Recommendations</i>	3
INTRODUCTION	5
<i>Mission Statement</i>	5
<i>Objectives of This Report</i>	5
<i>What Is Healthcare Documentation?</i>	5
CHAPTER 1: ESSENTIAL PRINCIPLES OF HEALTHCARE DOCUMENTATION	9
CHAPTER 2: EFFECTS OF PATIENT DOCUMENTATION ON HEALTH CARE	11
<i>Patient Safety</i>	11
<i>Public Safety</i>	11
<i>Continuity of Patient Care</i>	12
<i>Healthcare Economics</i>	13
<i>Clinical Research and Outcomes Analysis</i>	14
<i>Summary</i>	14
CHAPTER 3: ANALYZING THE HEALTHCARE DOCUMENTATION PROCESS	16
<i>Free (Unstructured), Structured, and Interactive Text</i>	16
<i>Practitioner Documentation Preferences</i>	18
<i>Impact of Technology on Information Capture and Report Generation</i>	19
<i>Report Generation for Decision Support</i>	19
<i>Compliance with Legal, Regulatory, and Professional Requirements</i>	19
<i>Documentation Standards Needs</i>	20
CHAPTER 4: INFORMATION CAPTURE METHODS	21
1. <i>Handwriting (Traditional, on Paper)</i>	21
2. <i>Speech</i>	24
3. <i>Direct Input</i>	32
4. <i>Document Imaging and Analog X-rays</i>	36
5. <i>Device Capture</i>	37
6. <i>Clinical Imaging</i>	42
CHAPTER 5: ACCOUNTABILITY, AUTHENTICATION, AND AUDITS	44
<i>Accountability</i>	44
<i>Authentication</i>	44
<i>Audits</i>	45
CHAPTER 6: CONCLUSION	46
REFERENCES	47
APPENDICES	50
<i>Appendix 1: Authors and Participants</i>	50
<i>Appendix 2: Glossary of Terminology and Abbreviations</i>	52
<i>Appendix 3: Comparison of Information Capture Styles</i>	56

Healthcare Documentation: A Report on Information Capture and Report Generation

Executive Summary¹

Accurate, accessible, and shareable health information is a well-accepted prerequisite of good health care. Yet, the healthcare system in the United States continues to accept illegible handwriting and other documentation practices that diminish the quality of healthcare documentation through reduced accuracy, accessibility, and shareability. This reduced quality influences five major areas in the healthcare system.

- **Patient safety** is affected by inadequate information, illegible entries, misinterpretations, and insufficient interoperability.
- **Public safety**, a major component of public health, is diminished by the inability to collect information in a coordinated, timely manner at the provider level in response to epidemics and the threat of terrorism.
- **Continuity of patient care** is adversely affected by the lack of shareable information among patient care providers.
- **Healthcare economics** are adversely affected, with information capture and report generation costs currently estimated to be well over \$50 billion annually.
- **Clinical research and outcomes analysis** are adversely affected by a lack of uniform information capture that is needed to facilitate the derivation of data from routine patient care documentation.

Healthcare documentation has two parts: information capture and report generation. *Information capture* is the process of recording representations of human thought, perceptions, or actions in documenting patient care, as well as device-generated information that is gathered and/or computed about a patient as part of health care. Typical means for information capture are handwriting, speaking, typing, touching a screen, or pointing and clicking on words, phrases, etc. Other means include videotaping, audio recordings, and image generation through x-rays, etc. *Report generation*, i.e., the construction of a healthcare document (paper or digital), consists of the formatting and/or structuring of captured information. It is the process of analyzing, organizing, and presenting recorded patient information for authentication and inclusion in the patient's healthcare record.

This Report focuses on six documentation methods, i.e., handwriting, speech, direct computer input, document imaging, device capture, and clinical imaging, as well as their hybrids. The evolution from handwriting to electronic healthcare documentation is concurrent with a transition from free (i.e., unstructured and typically unsearchable) text to structured and interactive text. To better understand this transition, this Report addresses the characteristics of unstructured, structured, and interactive data capture styles.

The challenge of attempting to standardize *information capture*, given today's varied, proprietary, vendor-related, and often innovative approaches, is an almost overwhelming task. Although it merits continued attention and work, the more fruitful, near-term, pragmatic goal should be the standardization of *report generation*, thus facilitating the exchange of information.

¹ The Consensus Workgroup on Health Information Capture and Report Generation studied these issues extensively. We seek input and responses to our findings. Contact the co-chairs and primary authors, Peter Waegemann at peterw@medrecinst.com and Claudia Tessier at cteissi@attglobal.net. Appendix 1 provides a full list of authors and participants.

The need for sharing health information among authorized health practitioners is hindered by inadequate documentation methods. Handwriting is often illegible, and varying terminologies represent different meanings to different practitioners. Lack of a universal structure of patient information makes it difficult to find relevant information in a record created with free text or from another organization. Also of note are legal and professional barriers related to nonstandardization, data integrity, signatures, etc.

Many steps must be taken to create systems and policies that make healthcare documentation more effective for quality health care. The Workgroup has developed a set of “Essential Principles of Healthcare Documentation”² and has assessed how they are met by the healthcare documentation methods addressed in this Report. The key principles are that:

- Unique patient identification must be assured within and across healthcare documentation systems.
- Healthcare documentation must be:
 - Accurate and consistent.
 - Complete.
 - Timely.
 - Interoperable across types of documentation systems.
 - Accessible at any time and at any place where patient care is needed.
 - Auditable.
- Confidential and secure authentication and accountability must be provided.

The practitioner who effectively interacts with electronic resources for patient care, rather than relying on memory, gains more complete and timely access to information. Rapid access to databases such as formularies, drug references, and other decision-making support tools, improves the quality of care. When this is accompanied by practices that support the “Essential Principles of Healthcare Documentation” noted above, quality of care is further enhanced.

In the interest of improving the quality of healthcare documentation, this Report makes the following recommendations to the healthcare community.

RECOMMENDATIONS

RECOMMENDATION #1: Fund, create, and promote a practical implementation guide for the dissemination, teaching, and adoption of the “Essential Principles of Healthcare Documentation” by practitioners, providers, vendors, and healthcare organizations, as well as regulatory bodies and medical schools. (Chapter 1)

RECOMMENDATION #2: Develop and fund a national rapid response system at the practitioner/provider level for data collection and shareable reports to deal with incidents of epidemic outbreaks and bioterrorism. (Chapter 2)

RECOMMENDATION #3: Create, mandate, and fund a standardized Discharge Care Plan for ambulatory and inpatient care, providing a uniform summary of care given to a patient in a specific provider setting, and a recommended care plan that can be easily accessed when the patient is seen by a new provider.³ (Chapter 2)

RECOMMENDATION #4: Develop and fund a model study of the costs and benefits of uniform healthcare documentation using the “Essential Principles of Healthcare Documentation” and the Discharge Care Plan. (Chapter 2)

² See Chapter 1 for more details regarding the “Essential Principles of Healthcare Documentation.”

³ Standards organization ASTM E31 Committee on Health Informatics is currently working on a national standard “Discharge Care Plan.”

RECOMMENDATION #5: Develop a coordinated 5- to 10-year national plan to minimize the use of both unsearchable free text and handwriting in healthcare documentation. (Chapter 3)

RECOMMENDATION #6: Develop and adopt standardized templates to enhance data integrity at the point of care. (Chapter 3)

RECOMMENDATION #7: Provide more information to practitioners/providers related to the impact of handwriting on a healthcare system's effectiveness and efficiency in handling information. (Chapter 4)

RECOMMENDATION #8: Develop standards and guidelines for the editorial process related to report generation, with emphasis on standardized, exchangeable reports. (Chapter 4)

RECOMMENDATION #9: Create a cost-benefit model of uniform healthcare documentation methods with emphasis on standard reports. (Chapter 4)

RECOMMENDATION #10: Conduct a risk assessment of authentication in order to provide guidelines for electronic and digital signature types. (Chapter 5)

RECOMMENDATION #11: Develop guidelines for security, including nonrepudiation, data integrity, and auditing of healthcare documentation. (Chapter 5)

RECOMMENDATION #12: Create and fund an institute for healthcare documentation to (1) conduct further research and create practical implementation guides for uniform adoption of the "Essential Principles of Healthcare Documentation," (2) advance the recommendations of this Report, and (3) develop and administer education and certification programs in (a) healthcare documentation based on the "Essential Principles of Healthcare Documentation" and (b) security/authentication of healthcare documentation. (Chapter 6)

INTRODUCTION⁴

This document, *Healthcare Documentation: A Report on Information Capture and Report Generation*, describes healthcare documentation practices and their effects on the healthcare system. It also presents a set of “Essential Principles of Healthcare Documentation” to enhance quality of care, reduce medical errors, and diminish documentation costs. The Report was developed by the Consensus Workgroup on Health Information Capture and Report Generation, a diverse, voluntary group of physicians, nurses, health information managers, medical transcriptionists, healthcare documentation-related vendors, and health informatics specialists, as well as representatives from government, regulatory, standards development, and professional organizations. During development, the draft document was circulated repeatedly to 93 persons, of whom 41 contributed directly as authors and participants (see Appendix 1); many of the remainder provided informal comments. Input from the e-Health Committee of the American Health Information Management Association (AHIMA) has also been incorporated into the Report.

MISSION STATEMENT

The Workgroup’s mission is to describe and assess the state of current healthcare documentation practices and to recommend steps toward improvements that benefit patients, practitioners, healthcare organizations, and the community at large.

OBJECTIVES OF THIS REPORT

The Report’s goal is to contribute to the improved quality of patient records, to the reduction of medical errors, and to the reduction of associated costs by:

- Establishing essential principles to be applied to healthcare documentation.
- Presenting and analyzing issues related to the methods of healthcare documentation.
- Making recommendations to accreditation bodies, government agencies, standards development organizations, and other entities for further action toward improving the quality and cost effectiveness of healthcare documentation.
- Encouraging cooperative adoption and fulfillment of the recommendations proposed in this Report.

WHAT IS HEALTHCARE DOCUMENTATION?

Healthcare documentation is the recording of healthcare processes within the regulatory and legal requirements, typically including descriptions of patient’s past history, clinical observations, diagnostic studies, healthcare interventions, medication history, clinical course, outcome, and care-related documents. It includes information capture and report generation.

Information capture is the process of recording representations of human thought, perceptions, or actions as well as device-generated information that is gathered and/or computed about a patient as part of a healthcare encounter. It comes in many forms, including:

- Speech.
- Free text.
- Document imaging.
- Clinical imaging, including both static (e.g., x-rays, MRI, PET scans) and dynamic.
- Full or partial motion video (e.g., in mental health settings).
- Binary electronic data representing laboratory values, device settings, operational status, and measurements.
- Waveforms (e.g., electrocardiograms).
- Graphical codes, drawings, and notations (digital ink, graphs).
- Indexing/clinical encoding (e.g., XML tagging, ICD, SNOMED, nursing codes).

⁴ Direct questions and comments to the Workgroup co-chairs and primary authors, Peter Waegemann at peterw@medrecinst and Claudia Tessier at cteffi@attglobal.net.

Report generation, i.e., the construction of a healthcare document (paper or digital), consists of formatting and/or structuring the captured information. It is the process of analyzing, organizing, and presenting recorded patient information for authentication and inclusion in the patient's healthcare record. The information presented in reports is used for continuity of patient care over time as well as for myriad other purposes. Improved methods of report generation offer the potential to enable both proprietary and nonproprietary information to be shareable and interoperable.

Health information is most often generated in conjunction with some aspect of patient care. However, information capture and report generation may or may not be simultaneous acts, depending on the healthcare context, including the acuity of the clinical situation, the preferences of the recorder, and organizational systems and policies.

Much emphasis is placed on ease of use for the author of health information, who does not always consider the differing needs of other users of health information. These other users often differ in their knowledge of the clinical topic, need for content, ability to locate the needed content, time available to read, and the motivation to understand health information at any given time. For example, a common problem confronting architects of electronic healthcare record systems is how to present the detail that is required by some users while at the same time permitting the experienced users to easily find the information they need.

More research and study is warranted on how individual practitioners (e.g., physicians, nurses, social workers, physical therapists) can easily and efficiently access information needed for patient care as well as how they can create truly integrated information from multiple disciplines.

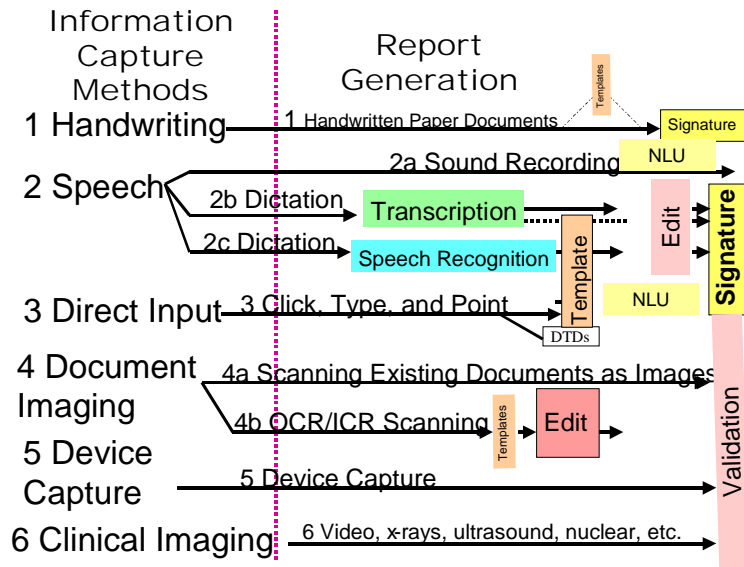
The distinction between *information capture* and *report generation*, though often blurred in a real-world scenario, offers an opportunity for progress toward our goal of improving healthcare documentation and sharing accurate and appropriate information. The continuum of documentation starts with a variety of *information capture* methods. Each is accompanied by strengths and weaknesses, and in the newer electronic world, each is often associated with true innovation, protected by proprietary rights. The subsequent difficulty of reproducing or acquiring the information capture technology for widespread use is hampered by cost considerations and the lack of standardization.

Report generation methods, tools, and formats are much more widely distributed and recognized than information capture methods, and they are also more likely to have low cost. Examples of widely recognized or standardized reporting tools and formats are some of the electronic files represented by 3-letter extension names, such as txt, doc, rtf, pdf, dif, htm, and more recently, xml. Each one also has strengths and weaknesses, but the most important property of all is that these document-centric files are usually easy to share or exchange over electronic networks, particularly the public Internet and private intranets that are rapidly becoming the dominant transmission protocols throughout the world. Data converters and interface engines play an important role in both receiving and generating reports using these de facto standards until better interoperability is achieved through web-based interoperability. HL7 is currently developing the Clinical Documentation Architecture as a method for standardizing and integrating messages into a healthcare information system.

Everyone involved with healthcare documentation, particularly report generation, should make efforts to ensure that all pertinent information conforms to these and other widely distributed and low-cost file formats. These standardized reporting tools should be included as an option in every electronic health record (EHR) where the information may have to be shared. The benefit is that whenever the report is accessed from a data repository, transmitted to another provider, sent to a payer for claims adjudication, or needed for research, the output can easily be interpreted.

The information capture and report generation methods addressed in this Report include handwriting, speech, direct input, document imaging, device capture, and clinical imaging. Figure 1 shows these methods and outlines some of the characteristics of each method that are discussed later in this Report.

FIGURE 1: INFORMATION CAPTURE AND REPORT GENERATION METHODS ADDRESSED IN THIS REPORT



Legend

Note that handwriting, speech, and direct input usually require author signatures as means of authentication, while document imaging, device capture, and clinical imaging are validated by other persons and devices.

1. *Handwriting* is usually in free text, but templates are increasingly used. The handwritten note is usually signed by the author when recorded.
2. *Speech* handling varies by type of process:
 - 2.a. A stored sound recording is usually not edited or signed.
 - 2.b. In dictation and transcription, the recorded speech is transcribed, edited, and formatted by a medical transcriptionist. It is then ready for editing and signature by the author. Templates or macros may be used.
 - 2.c. In dictation and speech recognition, information recorded by the automated speech recognition process is edited by the author or an editor and reviewed and signed by the author. A template is routinely involved in the report generation process.
3. *Direct input* is captured in a computer or mobile computing device by keyboarding, clicking a mouse, or touching a screen. Information may be formatted with a template or through coding, such as document type definitions (DTDs) in XML (extensible markup language). The information is then ready to be edited, signed, and/or validated.
4. *Document imaging* requires the scanning, validating, and indexing of an analog document, such as a paper-based document or an analog photographic film. The analog paper or film-based document may or may not be discarded.
 - 4.a. When an analog paper or film-based document is scanned as a bit-mapped image, the information cannot be used for processes such as decision support or aggregation of data. However, because an analog paper-based document has signatures and other data integrity features, it does not need additional review and

authentication. Editing is limited to the conversion process, during which data integrity must be validated.

- 4.b. When an analog, paper-based document is scanned with automatic identification software, such as optical character recognition software (OCR), intelligent character recognition software (ICR), or other, related means in which the automatic identification software is linked with artificial intelligence (AI), editing and signing by the author is necessary. In any case, the information must be validated.
5. *Device capture* includes capture and validation of health information directly from a medical device, such as an electrocardiogram (ECG), a pressure transducer/monitor, a thermometer, or a ventilator.
6. *Clinical imaging* involves digital data capture from a device such as computed radiography, ultrasound, MRI (magnetic resonance imaging), radioisotope imaging, fiber optic, and other video capture means. Prior to interpretation and report generation, information must be validated, usually by the technologist performing the study.

This Report does not address the following applications:

- Automatic identification software such as repeat-code capture (i.e., bar code capture), which may be used before, throughout, and after the encounter process.
- Capture of patient demographic information for information and administrative or financial purposes. The Workgroup did not address potential wasted efforts and opportunities for errors through duplicate capture of such information.
- Note taking, work lists, and other works in progress created solely as prompts for subsequent replacement by permanent information capture.

Chapter 1: Essential Principles of Healthcare Documentation

For optimal information capture and report generation, it is important to establish a set of documentation principles to be implemented on a national/international basis. This Report recommends that all healthcare documentation must meet the following “Essential Principles of Healthcare Documentation.”

Unique identification of patient

Systems, policies, and practices should:

- Provide unique identification of the patient at the time of recording or accessing the information.
- Provide within and across organizations:
 - Simple and easy methods to identify individuals and correct duplicate identities of the same individual.
 - Methods to distinguish among individuals, including those with similar names, birth dates, and other demographic information.
 - Linkages between different identifications of the same individual.

Accuracy

Systems, policies, and practices should:

- Promote accuracy of information throughout the information capture and report generation processes as well as during its transfer among systems.
- Require review to assure accuracy prior to integration in the patient’s record.
- Include a means to append a correction to an authenticated document, without altering the original.
- Require the use of standard terminology so as to diminish misinterpretations.

Completeness

Systems, policies, and practices should:

- Identify the minimum set of information required to completely describe an incident, observation, or intent.
- Provide means to ensure that the information recorded meets the legal, regulatory, institutional policy, or other requirements required for specific types of reports, e.g., history and physical, operative note.
- Link amendments to the original document, i.e., one should not be able to retrieve an original document without related amendments (or vice versa) or notification that such amendments exist and how to access them.
- Discourage duplication of information.
- Discourage non-relevant and excessive documentation.

Timeliness

Systems, policies, and practices should:

- Require and facilitate that healthcare documentation be done during or immediately following the event so that:
 - Memory is not diminished or distorted.
 - The information is immediately available for subsequent care and decision-making.
- Promote rapid system response time for entry as well as retrievability through:
 - Availability and accessibility of workstations.
 - User-friendly systems and policies that allow for rapid user access.
- Provide for automatic, unalterable time-, date-, and place-stamp of each:
 - Documentation entry, such as dictation, uploading, scanning (original, edits, amendments).

- Access to the documentation.
- Transmittal of the documentation.

Interoperability

Systems, policies, and practices should:

- Provide the highest level of interoperability that is realistically achievable.
- Enable authorized practitioners to capture, share, and report healthcare information from any system, whether paper- or electronic-based.
- Support ways to document healthcare information so that it can be correctly read, integrated, and supplemented within any other system in the same or another organization.

Retrievability (the capability of allowing information to be found efficiently)

Systems, policies, and practices should:

- Support achievement of a worldwide consensus on the structure of information so that the practitioner can efficiently locate relevant information. This requires the use of standardized titles, formats, templates, and macros, as well as standardized terminology, abbreviations, and coding.
- Enable authorized data searches, indexing, and mining.
- Enable searches with incomplete information, e.g., wild card searches, fuzzy logic searches.

Authentication and accountability

Systems, policies, and practices should:

- Uniquely identify persons, devices, or systems that create or generate the information and that take responsibility for its accuracy, timeliness, etc.
- Require that all information be attributable to its source (i.e., a person or device).
- Require that unsigned documents be readily recognizable as such.
- Require review of documents prior to authentication. “Signed without review” and similar statements should be discouraged.

Auditability

Systems, policies, and practices should:

- Allow users to examine basic information elements, such as data fields.
- Audit access and disclosure of protected health information.
- Alert users of errors, inappropriate changes, and potential security breaches.
- Promote use of performance metrics as part of the audit capacity.

Confidentiality and Security

Systems, policies, and practices should:

- Demonstrate adherence to related legislation, regulations, guidelines, and policies throughout the healthcare documentation process.
- Alert the user to potential confidentiality and security breaches.

RECOMMENDATION #1: Fund, create, and promote a practical implementation guide for the dissemination, teaching, and adoption of the “Essential Principles of Healthcare Documentation” by practitioners, providers, vendors, and healthcare organizations, as well as regulatory bodies and medical schools.

Chapter 2: Effects of Patient Documentation on Health Care

Traditionally, healthcare documentation's primary role was to support an individual practitioner's memory regarding a patient. In modern healthcare systems, the primary role has changed from being an "aide memoire" to a tool for sharing and interacting. The importance of high quality patient care documentation becomes increasingly evident when we consider the impact of poor quality documentation on five major areas of health care:

PATIENT SAFETY

Patient safety can be adversely affected by documentation that does not meet the "Essential Principles of Healthcare Documentation." According to the Institute of Medicine's (IOM) report *Crossing the Quality Chasm in Health Care*, data capture is a major but little understood hurdle to eliminating errors in medicine and to using information technology for the improvement of the quality of care. As a result of the IOM study, the reduction of medical errors is the concern of the public at large, state legislators, healthcare providers, and many other health professionals. Examples of how healthcare documentation practices may cause medical errors include:

- A penicillin allergy that is recorded but illegible cannot assure that future providers will avoid prescribing penicillin for that patient.
- When two patients with the same name are seen in the same institution, one may receive the other's medications if unique identification of each is not assured.
- Notes done on continuation sheets that do not include unique identification of the patient may be placed in the wrong record, creating misinformation.
- Documentation that does not record all lab tests ordered may result in duplicate tests being ordered by another practitioner.
- Documentation that is not recorded in a timely manner may result in proceeding with a treatment course other than that which the documentation would indicate.
- When documents are not reviewed and authenticated in a timely manner but are still made available to subsequent practitioners, treatment decisions may be made on inaccurate information.

In order to improve patient safety, the "Essential Principles of Healthcare Documentation" described in Chapter 1 must be adopted throughout the healthcare system.⁵

PUBLIC SAFETY

Public safety, as a component of public health issues, is diminished by the inability to collect information in a coordinated, timely manner at the provider/practitioner level in response to emerging epidemics and the threat of bioterrorism. While there are reports of public health departments and other organizations beginning to address these issues, insufficient attention is being paid to the collection of information at the emergency department and provider/practitioner level. A public safety system can only be effectively implemented when such information is captured accurately in digital format and then can be distributed to and managed by public health centers (regional, state, or national) within seconds or minutes. This requires:

- An understanding of the information capture and report generation issues described in this Report.
- A consensus on the means by which to achieve timely, point-of-care capture of relevant information that can indicate an epidemic outbreak or a bioterrorism attack.

⁵ Patient safety issues have also been addressed in *The Computer-based Patient Record: An Essential Technology for Health Care*, Committee on Improving the Patient Record, Division of Health Care Services, Institute of Medicine, Richard S. Dick, Elaine B. Steen, and Don E. Detmer, Editors, National Academy Press, Washington, D.C., 1997, and in the NCVHS Report on PMRI (Patient Medical Record Information), 2001.

- Identification of specific information sets that can alert public health authorities of a threat.
- Rapid adoption of documentation methods that allow electronic capture and dissemination of relevant information.
- Creation of an information infrastructure that:
 - Involves all emergency departments and practitioners from whom such information is to be collected.
 - Transmits such information electronically and securely to the relevant public health centers.
 - Has adequate funding, including appropriate computer systems for practitioners who will have to collect and report data.

The concern for public health in cases of epidemic outbreaks or as a response to terrorism requires use of the “Essential Principles of Healthcare Documentation” at the provider level. While appropriate considerations are under way to improve the public health infrastructure at the state and federal levels, immediate consideration should be given to the healthcare provider’s setting as well. Information must be captured and reported in a timely manner. Appropriate data sets should be identified, and means of electronic communications must be developed and implemented. Without systems in place that adhere to the “Essential Principles of Healthcare Documentation,” delays and errors in communicating information important to public safety may occur. For example:

- Without electronic methods, such information cannot be collected in a timely manner. Transmitting handwritten information via facsimile, for example, would be cumbersome and ineffective.
- Without unique patient identification, the same patient may be reported more than once to public health authorities.
- Without interoperable systems, data cannot be readily integrated and indications of epidemic outbreaks may be delayed or missed.
- Threats to public health cannot be accurately interpreted if information is not accurate or timely.
- Time-, date-, and place-stamps are essential in reporting information to public health authorities in order to establish and evaluate patterns related to either epidemics or bioterrorism.
- Information reported to public health authorities must have the source clearly identified, must be authenticated, and must be auditable if the information is to be trusted.
- Even in cases of public health threats, a patient’s rights to confidentiality and security must remain of high concern at all levels, with exceptions, if any, properly authorized and recorded. A widespread public debate is needed about the extent to which reporting is necessary, with due consideration given to patient privacy.

It must be recognized that providers have few incentives to spend resources for public health information. National legislation or regulations must be established that will mandate (with funding) that information for public safety be electronically captured at the practitioner/provider level and communicated to the appropriate public health database(s).

CONTINUITY OF PATIENT CARE

Continuity of patient care, a highly desirable objective for quality health care from all perspectives, can be compromised because of the inability of providers to obtain timely and shareable patient information.

Traditionally, providers have relied primarily upon the documentation they create for their own patients. To achieve continuity of care, the patient’s health information must be shared among various authorized practitioners within the same organization and across healthcare

systems. However, current systems lack the secure interoperability necessary for sharing this information.

This is due to many factors, including poor information capture and report generation methods, technical incompatibility, and differences in terminology. The goal must be to create full interoperability that facilitates the integration of information across systems. Examples of how poor healthcare documentation affects continuity of care include:

- Multiple providers may order the same tests if they do not know what has already been done.
- Physicians may prescribe medications that cause adverse reactions with other medications that the patient has neglected to mention or doesn't think are important to report to the second physician.
- If the practitioner does not complete transcribed documents in which the transcriptionist left blanks, the report may lack important information for subsequent users.
- When information is not recorded in a timely manner, it is not available for subsequent users.
- When unauthenticated information is read, the provider may inappropriately rely on it—or not rely on it—to the patient's detriment.
- If patient confidentiality is violated, the patient may be harmed and/or may subsequently withhold information that is crucial to future diagnosis and treatment decisions.

The IOM has described a vision of the computer-based patient record (CPR) that would capture information related to all medical care provided to a patient. While interoperability problems prohibit realistic implementation of this vision in the near future, the goal of continuity remains a key element for better quality health care, higher efficiency, and improved economics. Uniform documentation is one of the milestones toward achieving interoperability among healthcare information systems.

To improve continuity of care, there must be:

- Universal guidelines and standards for healthcare documentation that enable interoperability.
- The creation and mandated adoption of a Discharge Care Plan for ambulatory and acute care, providing a summary of care given to a patient in a specific provider setting and combining it with a recommended care plan that can be easily accessed when the patient is seen by a new provider.
- Development of positive incentives, legislation, or other mandates to effect these changes.

HEALTHCARE ECONOMICS

Healthcare economics are adversely affected by poor documentation quality. In the United States alone, the cost of information capture and report generation is estimated to be over \$50 billion annually. A significant portion of this cost is likely due to inefficiencies. In the United States, reimbursement requirements have influenced what is documented and how it is documented. Poor documentation and administrative inefficiencies can result as payers and providers spend excessive time communicating what is needed to justify reimbursements.

It should be emphasized that decisions based on the cost at the point of care (POC) may stimulate increased overall cost. For example, what may seem to be economical to a practitioner, such as handwriting, can result in substantial costs because information cannot be shared or integrated into a system, potentially resulting in medical errors or in additional costs for repeated tests.

Other examples of how costs can increase when documentation methods do not adequately meet the "Essential Principles of Healthcare Documentation" are:

- *Accuracy*: High costs may occur in remedying situations where incorrect data leads to incorrect treatment with adverse effects (e.g., writing 1.0 mg of a medication and having it interpreted as 10 mg).
- *Completeness*: Missing information due to incomplete recording (e.g., not recording a patient's blood pressure) or insufficient data availability can result in higher costs if inappropriate treatment is given as a result.
- *Timeliness*: When information is not recorded in a timely manner, tests and procedures may be repeated, resulting in duplicate costs. Additionally, valuable time may be lost, delaying treatment.
- *Interoperability*: Patients receiving care at emergency departments and specialists' offices often receive duplicative tests (e.g., x-rays for fractures) that could be avoided if test results from other locations were made available.
- *Retrievability*: When free text is used and there is excessive documentation, practitioners often cannot find the relevant information within the reams of paper or the many screens of data available to them. In such cases, the cost of excessive free-text recording can be substantial.
- *Authentication and accountability*: When information is not authenticated, its source may be questioned, leading the next provider to duplicate processes, tests, and procedures, resulting in duplicate costs as well.
- *Confidentiality and security*: Breaches of confidentiality and security can be costly to the caregiver as well as to the healthcare institution in the form of legal costs and monetary penalties as well as the public's loss of confidence in them.

Economic considerations of healthcare documentation include the following:

- Resources needed for documentation: Different information capture methods require varying degrees of practitioner time, support costs (e.g., transcription costs), and systems/management costs (e.g., editing and additional handling and processing).
- Impact of an information capture method on information handling throughout the care process. Different information capture methods allow more efficient access to data after the completion of an encounter. For example, digital x-rays can be reviewed remotely from the film, thereby speeding interpretation and patient management. Identifying the ancillary effects of information capture methods, such as faster processing, can provide a very different perspective and have an impact on how to make better and more informed decisions.
- Effect of quality documentation of the care process on reimbursement, patient safety, and quality of care: Practitioners who document excessive irrelevant information inflate healthcare documentation costs and diminish the value of the documentation by making it difficult to find relevant information within the massive amount of documentation generated. This practice of "excessive documentation" has been driven partly by professional liability concerns and partly by documentation guidelines for reimbursement, particularly federal "fraud and abuse" cases.

CLINICAL RESEARCH AND OUTCOMES ANALYSIS

Clinical research and outcomes analysis are also dependent on healthcare data. We are at the beginning of a transition to an era where such data will be directly derived from routine patient care documentation. This will require that uniform documentation be implemented. Additionally, standards and systems should be created and implemented to enable better data collection. Encouraging uniform documentation for clinical research purposes, including the use and analysis of structured/codified data, will enhance the science of medicine.

SUMMARY

As described above, the quality of health information capture and report generation can have serious impacts on several areas within the healthcare system. The first step to improving these practices is the adoption and implementation of a set of "Essential Principles of Healthcare Documentation," as proposed in Chapter 1. Such principles should be used as a checklist for

providers, vendors of health information systems (HIS), and information professionals. In Chapter 4, these principles are addressed as they relate to each documentation method.

RECOMMENDATION #2: Develop and fund a national rapid response system at the practitioner/provider level for data collection and shareable reports to deal with incidents of epidemic outbreaks and bioterrorism.

RECOMMENDATION #3: Create, mandate, and fund a standardized Discharge Care Plan for ambulatory and inpatient care, providing a uniform summary of care given to a patient in a specific provider setting, and a recommended care plan that can be easily accessed when the patient is seen by a new provider.

RECOMMENDATION #4: Develop and fund a model study of the costs and benefits of uniform healthcare documentation using the “Essential Principles of Healthcare Documentation” and the Discharge Care Plan.

Chapter 3: Analyzing the Healthcare Documentation Process

As shown previously in Figure 1 (page 7), information capture and report generation are related and overlapping processes. In these processes, both information representation (structure, context, and format) and concept representation (abbreviations, synonymy, hierarchical representations, meaning of concepts with both formal and systematic [dictionary-like] definitions) are important, but their exact roles need further analysis.

All documentation, whether an image or a recordable code, whether generated by a device or entered by a person, involves translation of information into a recordable format. All information regardless of the information capture method should be indexed to facilitate both clinical and administrative retrieval. This is not routinely or easily done in handwriting and other forms of free text.

This chapter focuses on several aspects of the documentation process including:

- Free (unstructured), structured and interactive text.
- Impact of technology on information capture and report generation.
- Report generation for decision support.
- Compliance with legal, regulatory, and professional requirements.

FREE (UNSTRUCTURED), STRUCTURED, AND INTERACTIVE TEXT

As noted previously, information may be captured by several methods. It is also important to understand that textual information may be recorded by a clinician in one or more styles. These are free text (i.e., unstructured), structured text, and interactive recording. These styles are summarized, along with several information capture methods, in Table 1, below.

TABLE 1: DOCUMENTATION STYLES AND MAJOR INFORMATION CAPTURE METHODS

	Free Text	Structured Text	Interactive Text
Handwriting	Mostly free text	Paper forms	N/A
Transcription	Mostly free text	Macros and normals	N/A
Speech Recognition	Free text	Templates	Interactive templates
Direct Input	Free text	Mostly structured text	More interactive

Free text is the unguided, free-flowing recording of a practitioner's thoughts and observations. It is found predominantly in handwriting and dictation, and partly in speech recognition. It may also be in sections of direct input systems. Some practitioners regard free text as a symbol for "medicine as an art" in contrast to structured text and interactive recording, which they may regard as "scientific healthcare processes".

In recent years, practitioners, patients, and other healthcare participants are increasingly using email as a method of communication. It must be noted that some practitioners who have typically shunned the keyboard are now typing email messages. As a direct input method, email is created by using the keyboard to record free-flowing text for electronic transmission. Any email concerning the care of a specific patient, or with a patient, is part of that patient's health record documentation. Therefore, the challenge of electronic medical record (EMR) systems consists of integrating such free-text messages in a way that they are retrievable in context.

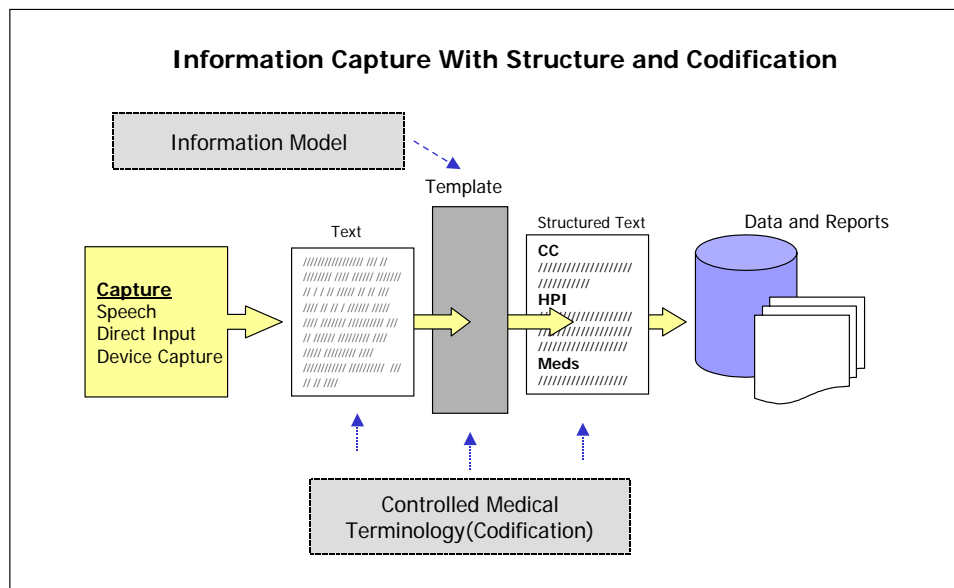
In *structured text* the documentation process is guided through the use of titles and templates. Templates are guides used to create standardized health information documentation. The purpose is to produce data of more consistent quality, make information more usable for decision support, make information more complete and more easily retrievable, and save

documentation time. Templates are usually “attached” to a document title in both paper and electronic media, making it easy to find the document. In paper form, templates are often referred to as “printed forms”. In electronic media, they are also called “macros”.

Templates typically consist of hierarchically arranged sections and subsections that impose structure on the data collected according to some external information model. Templates may also contain data representing the values for information collected. In transcription, such usual values are often called “macros” and are computer-stored. They are also called “normals” as they represent the “normal” or usual description of an observation. Templates may also present data for the physician to choose from menus, lists, or forms. Data elements and fields are filled in and recorded according to the template’s logic and requirements.

Figure 2 demonstrates how captured text is structured and codified through the use of templates and codes to identify medical concepts.

FIGURE 2: INFORMATION CAPTURE WITH STRUCTURE AND CODIFICATION



Processing of the free text contained within the record can also include the codification of textual material. When text is codified, an externally controlled medical terminology (CMT) is used as a source of codes to clearly and unambiguously identify the concepts contained in the text. The codes may be applied to the captured text or the template itself to identify the “meaning” of the sections and data contained in the template. For example, text in the history of present illness that discusses the patient’s “Family History of Coronary Artery Disease” can lead to instantiation of the concept “Coronary Artery Disease” in the “Family History” section of a template.

Interactive recording is a more complex version of structured recording as it interactively prompts and provides feedback to the person using it. Typically, it uses a higher level of computer intelligence that interacts with the person who records information.

A detailed comparison of free text, structured, and interactive recording, describing ease of use and interoperability, can be found in Appendix 3.

PRACTITIONER DOCUMENTATION PREFERENCES

A practitioner's choice among these documentation methods may have to do with habit, style of practicing medicine, and computer familiarity. Where documentation methods are not policy-based, practitioners use methods according to convenience, custom, access, and perceived cost. The adoption of standardized documentation techniques that reduce medical errors and benefit a system may require incentives (payment, time, benefits, etc.) to induce practitioners to switch from traditional information capture methods to methods that are more interoperable, economic, and provide a basis for better care.

Historically, one can identify a cycle in healthcare documentation. Originally, the practitioner recorded the medical history himself in the paper medical record. Due to instances of illegibility, it became desirable to record such information in a legible way, i.e., in typed format. The process of dictation was born as doctors dictated to secretaries or other assistants, and ultimately to medical transcriptionists, who captured the spoken text with shorthand to be transcribed later. In the second half of the 20th century, dictation devices were introduced, thus replacing the human interface in the dictation process. This became prevalent when DRGs (diagnostic related groups) were introduced for charge capture and payment depended on appropriate, legible documentation. Dictation and medical transcription were increasingly the answer to reimbursement demands. At the beginning of the 21st century in the United States, advanced medical transcription (as described below) uses speech recognition, macros, and XML. There are indications that the documentation cycle will close as practitioners themselves record on mobile healthcare computing devices (MHCDs) when such systems become easier and faster than dictation and provide the benefits of structured and/or interactive recording.

New methods for information capture and interoperability must overcome the challenges of workflow change, which are influenced by cost, technology, and behavior, as well as payer pressures regarding reimbursement. User acceptance requires not only an appropriate tool but also appropriate integration of the data entry application with other applications that are used for patient identification, user identification, context identification, and patient care. It also requires the appropriate format and content to allow information display that supports both efficient patient care and optimal clinician workflow. Context information about users and their particular roles and locations can be used to personalize applications to facilitate data entry.

Ease of use refers to a device's, system's, or application's high degree of intuitiveness, reducing the learning time needed to use the application proficiently and avoiding repetitive entry of the same data by the user. It also relates to the size of the screen that displays information and to the ease of interacting with information. Security mechanisms must be fast and undemanding for the user, and they must require appropriate identification and authorization mechanisms. Hardware and software efficiencies permit the provider to log in and begin documentation for a particular patient in a setting that is tailored to his or her desires. For instance, when a practitioner logs in, the application should be up and running. When the provider logs off and then back on again, delays in the ability to begin documenting patient care should be minimal—the provider's applications should be running, and the look and feel of the system should be comfortable and promote efficiency. Also, the documentation system should remember the provider's preference for data entry (keyboard, voice recognition, personal digital assistant, light pen, other), the look of the screen, and which of the provider's patients are scheduled for a visit that day, as well as the most current information available concerning the status and characteristics of each patient.

Reduced resistance to change also requires that application launch times, hardware availability, infrastructure, and security requirements allow rapid access to information entry and review without disruption of the patient care process. New wireless applications of information capture (e.g., mobile health computing devices [MHCDs]) create new issues regarding user acceptance, integration, and system design, as well as patient confidentiality and security.

IMPACT OF TECHNOLOGY ON INFORMATION CAPTURE AND REPORT GENERATION

Innovations resulting in new and advancing technologies, application development tools, and telecommunications advancements offer promising benefits to the processes of information capture and report generation, in turn enhancing patient safety and facilitating the communication of public health information. The economics are complex, but many of these innovations are expected to increase efficiency, cut costs, or even increase revenues to providers. These new systems could revolutionize information capture and report generation. However, a large number of healthcare and other supporting organizations cannot take advantage of these innovations because they are negatively affected by lack of community infrastructure, lack of organizational infrastructure, obsolete hardware and software, inadequate networking bandwidth and/or proprietary hardware and software, and most of all, declining reimbursements and cost constraints.

A wide range of new information capture technologies is about to make an impact on the healthcare system. Examples of expanding and innovative technology include:

- Mobile health computing devices (MHCDs), i.e., enhanced PDAs (personal digital assistants) or handheld units.
- Digital dictation devices.
- Wireless communications.
- Increased bandwidth.
- JAVA.
- Advanced Internet applications.
- XML (extensible markup language).
- WML (wireless markup language).
- Improved speech recognition.
- Improved point and click technologies.
- Newer imaging technologies, e.g., 3-D and graphing modalities.

MHCDs will combine the functions of a PDA (mainly calendar, addresses, appointments, and scheduling) with communication and application functions, leading providers to make a major shift to these units. Devices will be in the form of handheld units, tablets, digital pens, and digital paper applications. While the benefits of such units seem promising, it is important that guidelines for authentication, safe transmission, and system integration be observed.

REPORT GENERATION FOR DECISION SUPPORT

Decision-support techniques are specifically identified by the IOM as key elements in efforts to improve patient safety. The most widely used decision support applications include:

- Clinical order entry, including drug management and e-prescribing functions.
- Diagnostic decision support.
- Results reporting of normal and abnormal values.
- Admission and registration decision support.
- Patient-provided, computer-based history entry and guidance.
- Care plan management decision support.

Guidelines and protocols (i.e., disease management decision support) and symptom- or problem-driven workup decision support systems can offer general guidelines (e.g., articles, advice, and practical steps within a care plan) or distinct interactive advice and documentation (e.g., expert systems for the management of skin cancer). Decision support applets are computational modules that are dependent on accurate information capture and report generation.

COMPLIANCE WITH LEGAL, REGULATORY, AND PROFESSIONAL REQUIREMENTS

State laws, regulatory requirements, federal legislation, professional organizations' guidelines and requirements, reimbursement policies, codes of ethics, and guides that describe minimum requirements for information capture methods must be complied with. Most of these

requirements are for traditional documentation methods such as ink on paper and require specific authentication methods or media such as signatures in black ink. The principles of such requirements must be transferred to the computer world. This also applies to authentication, what documentation is acceptable to whom, and the relationship between state legislation and practice in the computerized world.

The American Health Information Management Association (AHIMA) published a list of authentication requirements by state, as of 1998.⁶ To date, we have not found a more current and comprehensive list of state laws regarding documentation requirements. Such state legislation is usually for a specific provider type and often covers one or more specific medical record documents. Requirements cover the need to document, the content to be documented, and the method or medium (e.g., only black ink is allowed).

In the real world of medicine and surgery, professional liability concerns also influence documentation. Also, malpractice insurance carriers are beginning to have a greater presence in the educational forums for providers and in the development of specific documentation guidelines, including patient-physician email captured in the patient medical record.

DOCUMENTATION STANDARDS NEEDS

Standards are lacking in regards to documentation. Areas of need include identification of key pieces of data to be included in documentation, editing, data quality, amendments/corrections, interoperability, accountability, data integrity, decision support, and integrating historical information into current records. AHIMA has developed guidelines for medical documentation, and various medical specialties have created recommendations for specific data sets that apply to documentation within their specialty. ASTM E31 has several standards on transcription, the content and structure of electronic medical records, and XML DTDs (document type definitions). The standards organization Health Level Seven (HL7) has developed the HL7 Clinical Document Architecture (CDA), a document markup standard that specifies the structure and semantics of “clinical documents” for the purpose of exchange.

The main consideration is in regard to standards for data integrity. Data integrity requires that recorded and authenticated information not be altered or lost while being processed, transmitted, and stored. No standards exist to define the minimum threshold of changes allowed in health documentation when exchanged among disparate systems. Also, standards are needed to define the permanence requirements of health information stored on computer media. Because of the lack of these standards and the lack of consensus on commercial solutions, the vast majority of providers keep paper-based information systems as backup.

RECOMMENDATION #5: Develop a coordinated 5- to 10-year national plan to minimize the use of both unsearchable free text and handwriting in healthcare documentation.

RECOMMENDATION #6: Develop and adopt standardized templates to enhance data integrity at the point of care.

⁶ See www.ahima.org for practice briefs on authentication and a list of related state legislation (updated 1998).

Chapter 4: Information Capture Methods

In most cases, information is captured in one of six forms, or a combination of these:

- Handwriting.
- Speech.
- Direct user input (often called “type, click, or touch”) and direct patient input.
- Document imaging.
- Device capture.
- Clinical imaging.

The value of a documentation method may be defined as the benefits it provides the authors, the recipients, and the patients, and it includes far more than the direct costs of a method. Each method is described below, including its features such as ease of use, cost, and shareability. Each is also addressed in relationship to the “Essential Principles of Healthcare Documentation.”

1. HANDWRITING (TRADITIONAL, ON PAPER)^{7, 8}

Description

Handwriting has been the primary information capture method for thousands of years and continues to be the method of choice for many practitioners. They are familiar with and accustomed to handwriting, and they find the transition to electronic means of information capture cumbersome because it requires a major change in workflow, habits, and skills. Also, at least initially, they find electronic entry slower than handwriting, and they may also perceive the use of computing devices as more costly, not recognizing the hidden costs of handwritten notes and other problems associated with handwriting.

Three factors make handwriting so popular. First, because of its history and the habits of practitioners, it boasts the greatest “ease of use.” Second, in many cases, particularly with short notes, it is perceived as the most cost-effective recording method. And third, it offers a high degree of timeliness, which is not currently found with dictation and some applications of desktop computing. Handwritten notes are routinely done during or immediately following an encounter so they are likely to be more contemporaneous than other forms of information capture.

Information is the currency of health care. While some practitioners claim that a short, handwritten note is the most economical of all entries, consideration must be given to the impact of handwritten notes on information handling throughout the care process. Unless scanned and indexed, handwritten notes cannot be integrated into health information systems and cannot be accessed and integrated into various parts of the record; even then, the integration is only partial. Therefore, practitioners may have to spend time and resources on repeated tests and information gathering that would not be necessary if more efficient and effective information capture methods were used.

Handwriting is the most problematic information capture method in regards to legibility. Attention to handwriting and the effect of its illegibility has heightened since the Institute of Medicine’s reports *To Err Is Human: Building a Safer Health System* (2000) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001). These reports link medical errors to handwritten prescriptions and call for the elimination of handwriting in clinical

⁷ Note: Many practitioners handwrite notes during patient encounters. These notes do not themselves become a part of the patient record but rather are used to organize and prompt information entry at a later time via dictation or other means. It is not the intent of this Report to discourage this type of temporary note taking by hand. Nor does this Report analyze such note taking.

⁸ Here we address handwriting without recognition, or in other words, handwriting onto paper. It is acknowledged that future technologies may offer new information capture methods that will include handwriting for digital capturing of information. These are not discussed in this Report.

documentation within this decade. JCAHO has two standards addressing legibility (IM.7.10, 7.10.1 and MS.8.2.3.), and their surveyors include legibility among factors checked in regards to Type I recommendations.

Definitions of “legible” range from “it is or isn’t legible” (“somewhat legible” not being allowed) to policies requiring two or more professionals to find it very difficult or impossible to read the handwriting in question. Some institutions designate legibility as an indicator during medical record review, some offer handwriting seminars to physicians, and some specify readable writing as a condition of employment or medical staff membership.⁹

The potential for medical errors, the negative influence on continuity of care, and the very fact that public safety cannot be assured should be sufficient reasons for the healthcare community to develop policies and practices that reduce handwriting over time. During this transition to alternative recording methods, every provider should have systems and policies in place that encourage application of the “Essential Principles of Healthcare Documentation” for handwritten documentation.

Strengths of handwritten documentation

- Easy to use.
- Perceived as most cost effective; low direct cost.
- More timely than many alternative documentation methods.
- Quick when brief/abbreviated.
- Allows free expression.
- Technology independent.

Weaknesses of handwritten documentation

- Often difficult to read/decipher.
- Lacks standardized structure.
- Typically lacks detail.
- Difficult to recognize misplaced or lost entries.
- Difficult to reproduce when lost.
- Does not allow electronic analysis.
- Does not support defense litigation well.
- Poorly supports documentation requirements for reimbursement.
- Does not efficiently support either real-time or subsequent information sharing, other than through photocopied or faxed images of handwriting.

Risks associated with handwritten documentation

- Generates potentially high associated costs with regards to:
 - Medical errors.
 - Administration.
 - Malpractice insurance.
 - Malpractice litigation.
- Illegibility can result in misdiagnosis, adverse reactions, or death.

Relating Handwriting to the “Essential Principles of Healthcare Documentation”

Unique identification of patient

- In handwritten notes, the patient’s identification should be inserted on each side of each sheet. Risks of mis-identification occur if continuation sheets are added without their being pre-stamped.
- Handwritten notes should be routinely linked between systems through indexing, photocopying, or scanning, the latter being preferred.

⁹ *Reading between the lines: Improving legibility to reduce medical errors*, Opus Communications, Marblehead MA, 2001.

Accuracy

- Handwritten notes are more susceptible to the limitations of any documentation process that is not the result of interactive validation. If inaccurate information is recorded, handwriting offers less practical opportunity for correction and validation.
- With handwritten notes, authors commonly use their own preferred terms, abbreviations, and symbols. In the absence of national standards, each health organization should implement policies and systems to ensure that at least throughout an enterprise, discrepancies in the use of terminology are identified, reduced, and eliminated. It is also important to identify other organizations with which patient information is regularly shared or exchanged and to reduce inconsistent or misleading vocabulary use.
- Authors whose handwriting is causing problems with legibility should be identified. Courses for more legible handwriting may help, but an organization should consider whether it is more efficient to mandate that individuals with illegible handwriting use alternative means that support legibility for recording purposes.
- Amendments and addenda are easily made to handwritten notes, but these are unlikely to be circulated to all those who have read or used the original note, so there is potential for error if treatment is based on original data without awareness of or access to its subsequent amendment or addendum.

Completeness

- Free-text handwritten notes may be truncated to such a degree that complete information may not be recorded.

Timeliness

- Handwritten notes are usually hand-dated by the author, which allows backdating if the note is not done during or immediately following an event.
- Practices for including the time of encounter and entry vary among providers.
- The place of care is usually inferred from the patient ID (identifier) stamp on the sheet.

Interoperability

- Handwritten notes are difficult to share among providers both because they are often illegible and because they are not routinely or readily integrated into other systems except through document imaging. Most importantly, multiple practitioners cannot simultaneously use paper charts because of the very nature of non-digital information.

Retrievability

- The structure and formats of handwritten notes generally reflect the preferences of the author, except for SOAP notes.
- The terminology and abbreviations within handwritten notes usually reflect the author's preferences.
- Handwritten notes are not readily or usually indexed to support easy retrieval of information.
- Handwritten notes do not support data searches.

Authentication

- There are no controls over the authenticity of handwritten signatures.
- Amendments must be signed, along with date and time of amendment.

Auditability

- Handwritten notes provide no automatic alerts for errors, inappropriate changes, or security breaches.

Confidentiality and security

- Policies should be implemented to manage confidentiality and security of paper records with handwritten notes since they can be accessed and copied without leaving an audit trail.

Variations of handwritten notes

Pre-printed forms have long been used in health care. They constitute an easy way to structure information, enhancing retrievability and sometimes readability.

Future handwriting opportunities

In the future, recognition systems such as “digital pens” or “digital paper” will combine the ease of use of handwriting with capabilities to structure information and to capture it digitally. They have the potential of becoming popular direct input methods. Also on the horizon are computer devices that interpret handwriting and convert it to digital text in a more reliable way than currently possible.

2. SPEECH

Description

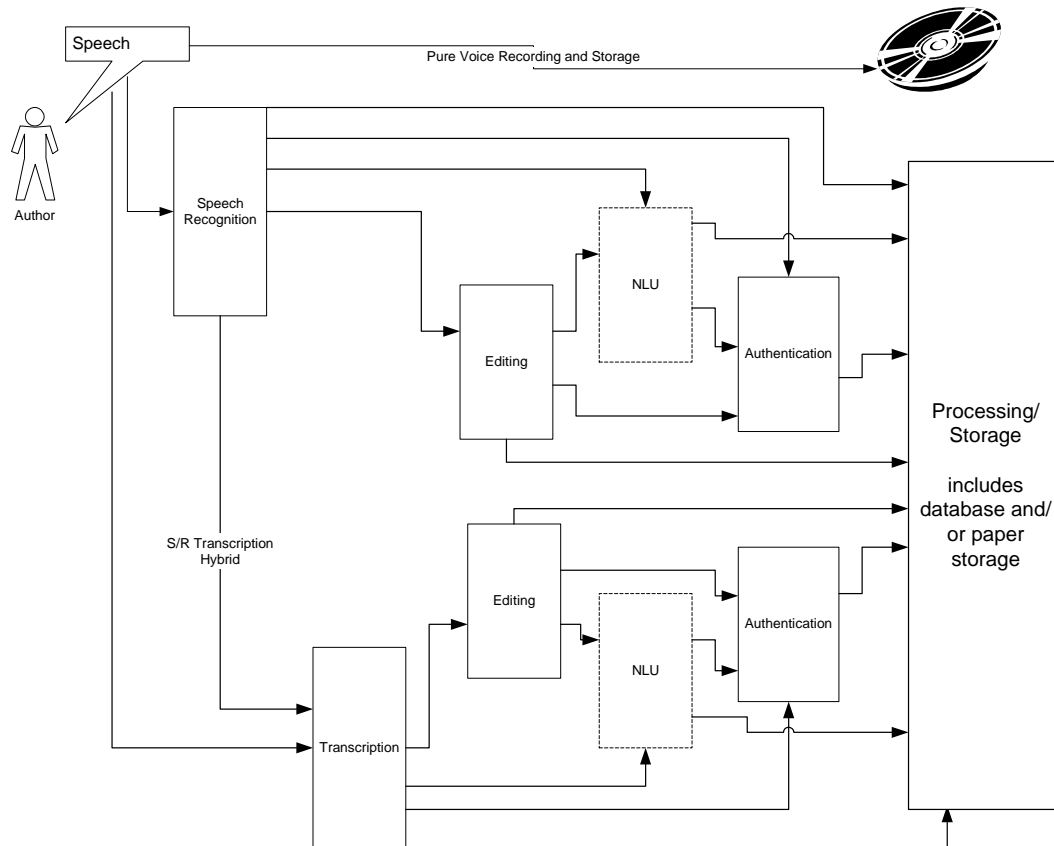
The second most prevalent information capture method is speech. Speech is a highly used, preferred, efficient method of human communication, yet free-form dictation may offer little advantage over handwritten notes, and poor pronunciation is the surrogate for illegibility.

Dictated speech is used in four modes: (a) captured and stored unedited, (b) transcribed, (c) automatically transferred into text through speech recognition (SR), and (d) processed through natural language understanding. Figure 3 below illustrates these four methods.

The quality of all speech capture and translation methods depends largely on the editing process to improve the accuracy, clarity, consistency, and completeness of dictation. It is thus an essential component of converting speech (dictation) to text. Typically, the traditional transcription process begins with a blank screen or a template with format headings, then a medical transcriptionist (MT) transcribes the dictation and inserts the information under the appropriate format headings, editing simultaneously with transcribing.

With SR, the text is first generated by the SR system and then the author or editor completes the transcript through editing, revision, and/or transcription as needed. This merger of the SR system and transcription is a hybrid system of speech to text conversion and is discussed further below. In any of these instances, the quality (and therefore value) of the final document relates both to the ability of the editor to recognize what requires editing and to make the appropriate changes. The transcribed document should then be subject to the author’s review and further editing as necessary, prior to its authentication.

FIGURE 3: CURRENT STATUS OF THE FOUR METHODS OF PROCESSING SPEECH FOR HEALTHCARE DOCUMENTATION



A. Speech recording and storage only

Description

Speech may be recorded and stored, in raw, unedited form, without transcription or recognition, or as a resource while being transcribed or recognized.

Strengths of stored speech

- Counters the potential of handwritten notes being illegible.
- Ease of recording.
- Immediate availability.
- Provides backup.
- Assists in quality control.

Weaknesses of stored speech

- While the speech itself can be authenticated as to its source, its content cannot be authenticated in a manner that assures its common interpretation.
- Corrections by the author to the original speech create a new or altered document, and it is difficult to retain the original and the amendment in a manner that allows both their identification and integrated access.
- Each listener may interpret the stored speech differently, so that without access to its authenticated translation, there is no “common” knowledge of the stored speech.
- To retain the information spoken, the listener must document it in some manner, which raises issues such as whether the documentation should be integrated into the record, whether others should depend on that listener’s interpretation and selection of excerpts for future care, and how different interpretations of the same stored speech by different listeners should be handled.
- It may be difficult to alert subsequent users to the stored speech and provide information on how to access it.
- Discrepancies between stored speech and its subsequent transcription are difficult to resolve, particularly if the issue comes up in court.

B. Speech dictation with medical transcription

Description

Transcription generally follows the dictation process that captures the information, although it occasionally is done from handwritten notes. The information is captured through listening to and interpreting speech, editing as necessary for clarity, consistency, accuracy, and completeness, and generating a report by recording that information either electronically or on paper. While most of the transcription output continues to be printed onto paper, there is increasing use of the transcribed text in electronic form.

The quality of reports generated through the dictation/transcription process is influenced by many factors. These include the clarity and accuracy of the dictation itself, the technology used, the qualifications of the medical transcriptionist, the degree to which standardization of structure and content is encouraged as well as adopted, management factors (e.g., quality assurance, turnaround time, volume of work), and budgetary considerations.

Over the last 20 years, transcription in the United States has become the most prevalent health information capture method, after handwriting. It represents an estimated \$18 billion to \$24 billion industry and approximately 400,000 MTs. This growth has arisen from its ease of use, from reimbursement demands, and from its advantages over handwriting, i.e., medical transcription in general provides more complete documentation, improved legibility, greater granularity, and more interoperability than handwriting.

Strengths of medical transcription

- Legible.
- Relatively easy to use.
- Proportionately quick relative to detail that can be captured.
- Does not require significant infrastructure or systems.
- Technology expertise required is low to moderate (quick learning curve).
- Allows free expression.
- Has some degree of standardization and readily allows more.

Weaknesses of medical transcription

- Dependence on transcriptionist’s qualifications, which vary greatly.
- Shortage of adequately qualified medical transcriptionists.
- Relies primarily on free text, so electronic data analysis and integration is difficult.
- Lacks significant content and format structure so the detail of documentation varies.
- Difficult to reproduce if lost unless electronic version is maintained.

- Delayed turnaround times (time from dictation until report is available for care and integrated into patient's record) may result in caregivers not having access to critical information.
- Real-time information sharing generally difficult or impossible.
- Security weaknesses in moving healthcare information to the site of transcription and involving another person having access to the patient's information.
- Many proprietary dictation and transcription systems do not support interoperability.
- Common practice for dictation to be transcribed on computers and a print copy to be made for the record without retaining its electronic form, thereby replacing the benefits of electronic text with the problems of paper-based text.

Future transcription opportunities

- Potential for standardization.
- Supports rapid adoption by practitioners.
- Integration with SR, XML, and NLU.

Relating Medical Transcription to the “Essential Principles of Healthcare Documentation”

Unique identification of patient

- Practices vary regarding patient identification at the time of dictation. Unless the system will not allow dictation without first giving patient identification, that step can be easily skipped. Even when included, mis-identification potential exists if insufficient identification is given to make it unique.
- Systems may be linked to the master person index (MPI) or admission records.
- Healthcare organizations should implement policies to ensure accurate patient identification in healthcare documentation.

Accuracy

- Errors, mispronunciations, and inaudible dictation are common (due to background noises, technical difficulties, speech patterns, etc.).
- Errors may occur due to transcriptionist's inexperience or limited qualifications.
- Quality assurance reviews are not always provided by the transcription department or contracted service.
- Inconsistencies can readily occur.
- Not unusual for an author to sign a transcribed document without reviewing or editing it.
- Common practice to release or allow access to transcripts prior to authentication.
- Few requirements for and certainly not routine use of standard terminology within dictated/transcribed reports.
- Policies for accuracy should include a means to identify and locate amendments or addenda done after authentication.

Completeness

- No widely adopted minimum set of information is required for dictated/transcribed documents, but some institutions have guides or preferred formats that they urge or require be used; however, enforcement is weak and often non-existent. Regarding formats, it often falls to the transcriptionist to impose the institution's (or practitioner's) preferences.
- As with other information capture methods, meeting legal, regulatory, and policy requirements may be addressed only upon random audit, in preparation for or during an accreditation visit, when being reviewed for renewal of privileges, or when in court.
- Amendments are readily made or appended to the original copy of the transcribed document, but copies without such amendments are likely to have already been circulated and used for care.

Timeliness

- Little or no control over when dictation is done relevant to the event. The longer the time between the event and its recording, the more likely that information will be incomplete, inconsistent, or even inaccurate.
- Some authors request that the dictation date be “adjusted” to make it appear the documentation was done in a timelier manner; acceptability of this practice varies from institution to institution.
- Turnaround times likewise vary from minutes to weeks or even months. During the interim, the dictation may be available as a speech file, or the information dictated may not be available at all, potentially influencing patient care decisions.
- Date of dictation and transcription commonly recorded, but not the time and place of either dictation or transcription.
- Systems should routinely record the date, time, and place of signature, but this is not common practice.

Interoperability

- Transcribed documents have two ways of being output. The information can be printed onto paper or kept in digital format, sometimes both. When paper documents are created, some of the same limitations for interoperability exist as with handwritten documents. However, when information is edited, signed, and shared in digital format, the transcripts are readily available for access by other providers and can be read, integrated, and supplemented within compatible systems.
- An interoperability problem exists during the time of transcription. Turnaround time should be reduced to a minimum. Systems may allow access to such information during the transcription process; however, access and use of dictation prior to its transcription has potentially the same risks as identified above for stored speech.

Retrievability

- Transcribed reports generally reflect the structure and format designated by the provider organization or individual practitioner. Thus, there is little if any consistency between providers and clinicians, making it difficult to share information between practitioners, departments, and enterprises.

Authentication and accountability

- Unique identification of the author is not common unless an electronic signature system is in place.
- While the absence of a signature is obvious, care based on the document is likely to proceed even without the signature.
- “Signed without review” or similar statements continue to be used by some authors; policies prohibiting this practice are not always enforced.
- Compliance with national standards for authentication is recommended.¹⁰

Auditability

- Most dictation/transcription systems do not have auto alerts for errors, inappropriate changes, or security breaches.
- Medical transcriptionists may serve as editors, flagging reports for author review if they encounter unfamiliar terminology, indecipherable dictation, or inconsistent data within dictation. However, authors do not always address these flags.

Confidentiality and security

- Policies are generally in place to control confidentiality and security, and there are movements toward enhancing their enforcement through audit trails.

¹⁰ These include ASTM E1762 Standard Guide for Electronic Authentication of Health Care Information; E1985 Standard Guide for User Authentication and Authorization; E2017 Standard Guide for Amendments to Health Information; E2084 Standard Specification for Authentication of Healthcare Information Using Digital Signatures.

- Implementation of controls that comply with national standards, as well as state and federal legal and regulatory requirements for confidentiality and security, is recommended.¹¹

Variation on medical transcription

Transcription and XML

Medical errors can occur when the dictated information cannot be recognized appropriately and either is not flagged for review by the author or the author does not address the flag. XML, combined with ontologies and inferencing engines for automatic reasoning systems that operate on such ontologies, points the way toward new ways to use healthcare records to reduce medical errors and guide therapies. These technologies hold great promise for both reducing the number of blanks and, where blanks occur, stimulating their being flagged and resolved.

Systems that are evolving to the use of XML in medical transcription stand to increase the ease of creating medical documents, particularly in an outsourced environment where medical transcriptionists (MTs) work on multiple accounts. This system will also enhance the ability to do data aggregation and provide valuable information related to healthcare operations. The system automates not only formatting as we commonly think of it, i.e., whether something is bolded, underlined, all CAPS, etc., but also placement of information within the report.

C. Speech dictation with speech recognition

Description

Most clinicians continue to prefer dictation as a means of information capture and report generation. But transcription is expensive and can delay the availability of the data for other uses. Speech recognition (SR) systems provide computer-generated voice to text translation. It must be emphasized that the pure recording, storage, and retrieval of unedited speech through SR are not acceptable means of information capture in healthcare applications. As with traditional transcription, SR must include an editing component.

Other critical factors for success include proper training and dictation style, proper software settings, system maintenance, recording environment (background noise), workflow patterns including paradigms for naming and storing the word processing files, and compliance with legislative and regulatory requirements. Adding customized macros and templates can substantially increase productivity and generate professionally appearing documents of high quality, but these also leave room for inaccuracies due to incorrect or unedited text as a result of time or usability constraints. Other important considerations to be addressed when considering adoption of this method include the cost of training and of using these systems.

When the physician uses speech recognition with high accuracy, the possibility exists for live documentation during or immediately following the encounter. The physician must have access to a computing device and be able to dictate and save the immediately generated transcript. That transcript, in turn, should be reviewed and edited prior to signature.

The SR industry commonly notes that the two key benefits of SR are the saving of transcription costs and the immediate availability of information. Considering the high cost of transcription and the difficulties in finding qualified transcriptionists, speech recognition seems to be the right answer. However, SR eliminates the costs of transcription processing and

¹¹ ASTM has developed a number of confidentiality- and security-related standards: *ASTM E1869 Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Computer-Based Patient Records*; *E1902 Standard Guide for Management of the Confidentiality and Security of Dictation, Transcription, and Transcribed Health Records*; *E1986 Standard Guide for Information Access Privileges to Health Information*; *E1987 Standard Guide for Individual Rights Regarding Health Information*; *E1988 Standard Guide for Training of Persons Who Have Access to Health Information*; *E2085 Standard Guide on Security Framework for Healthcare Information*; *E2086 Standard Guide for Internet and Intranet Healthcare Security*; *E2147 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems*.

transmission only when there is no editing, meaning the dictating person does not spend extra time in reviewing and editing the information. In reality, when a physician edits a report that has been captured with SR, it may take longer to edit it than it took to dictate it, resulting in increased costs. Hybrid systems that allow a transcriptionist or medical editor to edit information within the SR system can reduce the editing costs.

Strengths of speech recognition

- Reduction of transcription costs.
- Customizing the language model, by processing each individual author's prior reports, can immediately and substantially improve recognition accuracy. A successful example is SR in radiology applications.
- Where successfully adopted, turnaround times for speech recognition are faster than and the reports are as readable as the traditional dictation-transcription reports. Additionally, they are formatted for easy inclusion in the electronic health record.
- Provides quicker access for use in computerized clinical practice guidelines.

Weaknesses of speech recognition

- Users may be resistant to required training.
- Must include an editing component—whether by the author or by a medical editor.
- The author still needs to review and authenticate the document, editing as necessary, whether the transcript is direct from the SR system or there has been intervention by a medical transcriptionist or other medical editor.

Variations on speech recognition

Speech recognition and medical transcription

Within the hybrid solution of medical transcription and speech recognition (SR), the MT assumes the role of editor. There are advantages to this solution, provided that the MTs are qualified to serve as editors. For one, turnaround time for report processing is greatly enhanced. Also, the medical transcriptionist's time is less costly than that of the author. However, the author should still review the document, further editing it as necessary, prior to authenticating it.

Hybrid solutions combining medical transcription and/or speech recognition with structured/codified input are addressed in the direct input section below.

Relating Speech Recognition to the “Essential Principles of Healthcare Documentation”

Unique identification of patient

- Practices vary regarding patient identification at the time of dictation. Unless the SR system will not allow dictation without first giving patient identification, that step can be easily skipped.
- Systems that are linked to the MPI or admission records can assist in reducing errors in patient identification.

Accuracy

- Verbatim translations of dictation have great potential for error; editing must be a component of the SR process.
- Error reduction can be addressed by having a medical editor (e.g., medical transcriptionist) review and edit the SR draft prior to its release to the author.
- It is not unusual for an author to sign an SR-transcribed document without reviewing it, and it is common practice to release or allow access to such documents prior to authentication.
- SR systems that incorporate prompts to the author may stimulate greater use of standard terminology within SR transcribed reports rather than in those done by traditional transcription. However, such “standard” terminology is likely to be unique to the proprietary system and not common across disparate systems.

Completeness

- No widely adopted minimum set of information required for SR-transcribed documents, except those unique to the proprietary system or supplemented by the institution or user.
- As with traditional transcription, meeting legal, regulatory, and policy requirements may be addressed only upon random audit, in preparation for or during an accreditation visit, when being reviewed for renewal of privileges, or in court.
- Amendments are readily made or appended to the original copy of the SR-transcribed document, but copies without such amendments are likely to have already been circulated and even used for care.

Timeliness

- As with traditional transcription systems, dictation may be done immediately following, or even during, an event, but there is no control. The longer the time between the event and its recording the more likely it is that information will be incomplete, inconsistent, or even inaccurate.
- Turnaround time for initial translation is quick, but editing may create delays.
- SR systems usually restrict the author from changing the actual date of dictation, thus providing greater assurance of the date's accuracy.

Interoperability

- SR-transcribed documents are readily copied and distributed.
- If electronic, they are also readily available for access by other providers and can be read, integrated, and supplemented within compatible systems. However, systems within and outside the institution do not commonly support such integration.
- As with traditional transcription, SR documents prepared electronically may then be printed and shared in paper form, with the electronic form discarded.

Retrievability

- SR systems' "standard" formats, templates, macros, terminology, abbreviations, and coding, or those customized for the institution or user, are not routinely compatible with other systems.

Authentication and accountability

- The SR system may allow unique identification of the author whether or not an electronic signature system is in place.
- While the absence of a signature (traditional or electronic) is obvious, care based on the document is likely to proceed even without the signature.
- "Signed without review" or similar statements continue to be used by some authors; policies prohibiting this are not always enforced.

Auditability

- SR systems may or may not have alerts for errors, inappropriate changes, or security breaches if the documents are maintained electronically.
- Once in paper form, however, the same limitations in these areas exist as for traditionally transcribed documents.

Confidentiality and security

- Policies to control confidentiality and security in SR systems vary depending on the systems' capabilities and utilization of same.

D. Natural language (NLU)

Description

Clinical documents contain an enormous amount of valuable information needed for direct clinical care, decision support, quality improvement, and research. But because most of

this information is in the form of non-machine-understandable free text, it remains largely inaccessible. Free text, in spite of its palatability to clinicians and its comprehensive flexibility, is language, not machine-readable data, and therefore it is not readily available for decision support and aggregate analysis. Structured data entry has been offered as a solution and has had some success, but it generally cannot compete with the convenience, speed, and expressivity of dictation. Over time, advances in speech recognition will raise the convenience and speed hurdles even higher, without solving the problem of structure.

NLU shows promise in being able to turn free text into structured data. As it matures, it may provide a feasible method of extracting data from commonly used methods of communication and documentation.

NLU systems vary greatly in their approaches, but generally include the following components:

- A tokenizer, to identify word, sentence and document boundaries.
- A lexicon, to look up words and certain information about them such as parts of speech.
- A grammar, to recognize word patterns and begin to assign meaning.
- A domain ontology, to match up the meanings of the words and sentences.

Much of the challenge in NLU comes from the ambiguity that creeps into human language at each of these layers, and so various components are typically added to decrease ambiguity. For example, templates can provide high-level structure such as defining different sections (family history, physical exam, etc.), without impeding efficiency or constraining expressivity. These provide unambiguous context cues, which can greatly improve the accuracy of NLU software. The NLU systems can then take the contents of individual template sections and translate them into granularly structured data for precise capture of the structured clinical information.

The question of how much text should be codified through structured data entry vs back-end processing (NLU) is one of process and practicality. In very high throughput environments, when speed is of the essence, dictation (even structured dictation) may be preferable to fully codified structured data input. In these situations NLU offers a sensible albeit less accurate mechanism for data capture so that this “expensive text” can become data. These data are key to the downstream applications, such as decision support systems.

Strengths of NLU

- Uses speech dictation, which is already widely acceptable to authors.
- Provides structured clinical information retrievable for the benefit of the care of individual patients and patient populations.
- Can be made essentially invisible to the clinician so that convenience and speed are not affected.

Weaknesses of NLU

- Not mature.
- Lacks fully specified reference terminologies.

3. DIRECT INPUT

Description

Healthcare documentation began with the practitioner in full control of the information capture and report generation process through handwriting. Since the introduction of typewriters, dictated information has increasingly been transcribed, edited, corrected, and structured by medical secretaries, assistants, and transcriptionists. Direct input is closing the cycle as responsibility is given back to the author to record, edit, and authenticate documentation. Also of significance is that this is being done in an increasingly structured and interactive way.

Direct input consists of capturing information through typing, pointing, clicking (mostly a mouse), and touching or pointing at a screen. With direct control over the recording, the practitioner has a better opportunity to edit. However, this may take up more of the practitioner's time, and some clinicians use assistants (secretaries, transcriptionists, others) to assist in this process. Thus, in assessing costs related to direct input, the cost of the practitioner's time as well as that of the recording assistant (where used) must be taken into account.

Direct input has both clinical and economic benefits. Clinical benefits come from information recorded in a structured and an increasingly interactive way, resulting in more usable and complete structured information. By its very nature, direct input improves compliance with the "Essential Principles of Healthcare Documentation." Therefore, this method is clearly preferred for patient and public safety. On the economic side, some healthcare providers show substantial savings as transcription is diminished or eliminated. While some of the return on investment (ROI) reports are impressive, savings in transcription costs need to be balanced against the extra time and efforts required by authors and their staff.

Tools used for direct input

Two direct input methods are increasingly being adopted: traditional (desktop) computing and the new, maturing mobile healthcare computing devices (MHCDs—PDA-style units, tablets, and other handheld mobile devices). The adoption of such units will accelerate shifts away from transcription and speech recognition techniques.

MHCDs are used in four ways: (1) Practitioners use MHCDs as mobile devices to look up information. It is easy to access at the point of care information that changes infrequently, such as guidelines and protocols. These may be updated as needed, for example every 30 days or 6 months, by quickly replacing a single chip. (2) The MHCD is used as an intermittently connected device that is synchronized at the beginning of the day or shift and again a few hours later. This intermittent synchronization is often done through a USB (universal serial bus), infrared connection, or other means. Applications for such use of MHCDs include schedules, which can be loaded before a shift, and up-to-date patient information related to a shift or hospital visit. (3) MHCDs can be locally and continuously connected. The trend is to have a number of sending devices (called access points) positioned throughout an institution or office, allowing practitioners with MHCDs to be connected anywhere within a building, campus, or geographic area covered by the system. Most of such systems are based on Ethernet networks or the IEEE 802.11b standard, which is limited in capacity and has some security issues. Newer systems are based on the IEEE 802.11a and 802.11g standards, which offer more security and better transmission speed. (4) The user has a cellphone-like connection to databases and Internet sites, permitting this communication to be conducted anywhere, e.g., in the car, at home, and on the golf course. Implementation of #3 and #4 above depend on system integration and the provider's policy on the use of wireless units in relationship to medical devices, due to concerns about interference with such devices.¹²

MHCDs are maturing rapidly. Many combine PDA functions (i.e., address book, scheduling, and organizing) with communications (i.e., cell phone and pager) and desktop computing functions (i.e., looking up databases, recording information, and interacting with applications). In many instances this requires a change of workflow, but it often provides the needed solution to point-of-care computing in health care. It is anticipated that this type of information capture and report generation will become dominant over the next decade as these devices become more integrated with the Internet and healthcare computing systems. Specific applications have already shown substantial advantages for early adopters.

¹² The Mobile Healthcare Alliance (MoHCA) is preparing a Guideline for the Use of Wireless Devices in Healthcare Facilities. See www.mohca.org.

Strengths of direct input devices

- Allow information to be captured at the point of care, especially with MHCDs.
- Allow the practitioner to access patient information away from the point of care and to provide care remotely, especially with MCHDs.
- Provide a high degree of timeliness, accuracy, and interoperability.
- MCHDs provide multifunctional capabilities such as alerting a practitioner about an emergency and providing scheduling information.

Weakness of direct input devices

- Interference issues with medical devices.
- Ease of use is a major hurdle to both desktop systems and MHCDs. The practitioner must become familiar with the computer systems, which may be difficult for them.
- Many practitioners object to the small screen size and/or small keyboard size of MHCDs.
- Desktop-based direct input in most cases takes more time than handwriting and/or dictation. Entry time for MHCDs may be slower than dictation.
- Integration into other healthcare applications is currently limited, particularly with MHCDs, thus reducing interoperability.
- Security, authentication and interference must be addressed, especially with MHCDs.

Variations of direct input

The Internet and extensible markup language (XML)

The Internet and XML can be used in direct input for structuring information, coding for storage of information, and integrating templates. The World Wide Web (i.e., the web) has become what seems to be a worldwide standard of computing. In its first generation, it was based on hypertext markup language (html). The world is now moving to the next level, XML, which uses the Internet protocol for communication to both create and store information. It can be used to create a comprehensive report generation system that saves time and costs, allowing clinicians to create reports in less time than by dictation.

XML is designed to encode structured documents. An XML document consists of named tags that themselves contain a list of tags and/or text. Data tags create sections or headings in a report. The resulting document provides a hierarchical structure that can be archived, transmitted between systems, and analyzed. The XML family of specifications includes XSLT, an XML transformation language that allows an XML document to be rendered to a variety of formats: print, screen, or for any number of purposes using a style sheet. By using an XSLT style sheet, an online form can be transformed into either a structured document or free text as desired.

Structured/codified input, transcription/speech recognition, and free text

Systems that provide for clinician input via point-and-click, templates, or other structured/codified approaches often do not allow the full representation of the patient's condition, the physician's assessment, and/or the management plan. Sometimes only narrative text can provide the semantic richness to completely describe the situation. This may be accomplished either by using a traditional keyboard for input or by adding the capability to generate a voice file through dictation, either at the end of the structured input or at any point during it. The resulting voice file may be appended to the clinical note and may be accessible until the transcribed and authenticated text replaces it. The option exists, of course, to utilize speech recognition in this process.

Direct input by patients

As patients carry their virtual medical records in their memory, there is the issue of how to transfer patients' thoughts, observations, and reports into the health record. Of course, the traditional way is to interactively "download" patient information through a practitioner who asks questions and records the responses in a structured way. With the use of computers, the

opportunity exists to have patients themselves record information on the computer, either through the Internet before the encounter or in the waiting room of the practitioner. This has three general advantages:

- Psychologically, it is easier to record sensitive information on the computer than having to tell such information to a person.
- Practitioners save time as they can just verify important parts of the already recorded information.
- It empowers the patients, encouraging more active participation in their health care.

When patients input symptoms and other relevant medical history data over the Internet or in the waiting room, the typical result is a more comprehensive subjective component of the clinical note. This also results in reduced documentation time and lower costs for the provider.

Concerns about patient-entered information focus on reliability, security, and interaction. As always, verifying the accuracy of a patient generated history, whether it is verbal, on paper, or on computer, is challenging, particularly if it involves sensitive information. Other factors that may contribute to unsatisfactory results include patient hesitation, computer/technology fears, lack of the personal touch and lack of patient knowledge, understanding, or patience to work with the system in a manner that will result in usable information.

Relating Direct Input to the “Essential Principles of Healthcare Documentation”

(The following applies to direct input by either practitioners or patients, independent of the computer type used.)

Unique identification of patient

- Usually automatic at the time of recording/access.
- Links between systems are variable.
- Systems can be linked to the MPI.

Accuracy

- User determined throughout process.
- System may alert author to potential errors or inconsistencies within document.
- Author may be able to sign before reviewing.
- “Standard” terminology is usually unique to proprietary system.

Completeness

- Minimum information set may be unique to proprietary system or supplemented by institution or user.
- Variable compliance with legal, regulatory, policy requirements, determined by audit.
- System may or may not facilitate amendments being linked to original document.

Timeliness

- Facilitates recording at the point of care.
- System may control/enter date and time of documentation and/or signature.
- Time and place are routinely recorded.

Interoperability

- Documents are readily copied, printed, and distributed.
- Variable ability for documents to be accessed, read, integrated, or supplemented.

Retrievability

- The system’s “standard” formats, templates, macros, terminology, abbreviations, and coding, or those customized for an institution or user, are likely to be proprietary and therefore not compatible with other systems.

Authentication and accountability

- System may allow unique identification of author or device.
- May be attributable to source depending on level of authentication.
- MHCDS must be attributable to one person only.
- A policy should outline accountability, particularly regarding how often electronic signatures are required (for fields, for data elements, or for perceived sets of information considered documents).

Auditability

- System may allow auto alert for errors, inappropriate changes, and security breaches.

Confidentiality and security

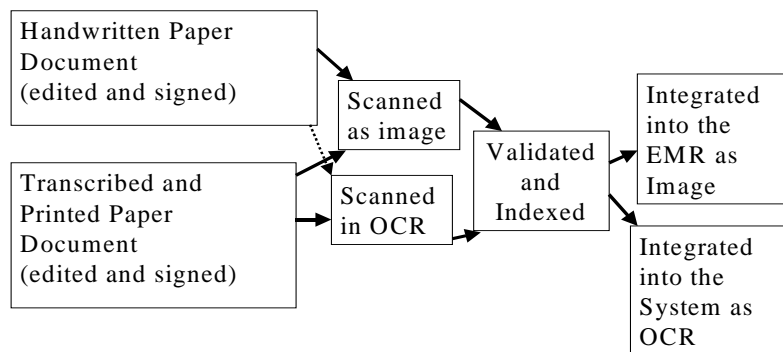
- Variable depending on systems' capabilities and utilization of same. Also variable depending on policies and enforcement of same.

4. DOCUMENT IMAGING AND ANALOG X-RAYS

Description

Document imaging and analog x-rays involve prepping, scanning/digitizing, indexing, and performing quality control of analog paper or photographic film documents into a computer system. Analog paper documents, either created through handwriting or transcription, can be transferred into digital form with image scanning, optical character recognition (OCR) scanning, or hybrid systems of these. Analog photographic film documents, created by analog cameras, can also be transferred into digital form with image scanning. Figure 4 below demonstrates the document imaging application.

FIGURE 4. DOCUMENT IMAGING APPLICATION



The acceptability of document imaging is in direct relationship to the quality control during the conversion process. It must be guaranteed that the scanned/digitized image of a document is congruent to the original version. Furthermore, the indexing must be precise, non-alterable, and accurate.

Strengths of document imaging

- Computer documents can be created where practitioners prefer handwriting and/or dictation to direct computer input or where they use analog cameras.
- Shareable across a network at point of care.

- The imaged document can guarantee a higher level of document integrity than found in many current computer systems in regard to signature, persistence in storage, and other integrity features.
- It allows documents to be electronically transferred and to be accessed by more than one user at a time.
- Depending on the system, document imaging can "improve" the legibility of the original paper document and, according to some diagnostic imaging specialists, can "improve" the resolution of the original photographic film. With additional effort, the reader is able to enlarge the handwritten image to more easily read it.

Weaknesses of document imaging

- Document imaging repeats the recording process. A document is created with handwriting, transcription, or an analog camera. In each case, the information is captured and formatted. Such information is then edited and authenticated with a signature. The only reason to convert this document again is to make it accessible to a computer system. In most cases, this is done in imaging format as a document image.
- The document image allows the reader to view the information only as a complete image.
- Optical character recognition, in which the text is scanned/digitized line by line, has recognition and authentication problems, so it is very rarely used and is costly.

Relating Document Imaging to the "Essential Principles of Healthcare Documentation"

Unique identification of patient

- Although identification is provided in the original document, extra care must be taken in the indexing and scanning process.

Accuracy

- Accuracy depends on the quality control process during conversion. That process must be strict, well documented, validated, and auditable.

Completeness

- When OCR is used, the author should explicitly read, edit, and authenticate the resulting document.

Interoperability

- Documents can be read within compatible systems but not integrated or aggregated, i.e., one can see the image but cannot aggregate the information or use it in other applications.

Retrievability

- Depends on indexing, which is limited to page views.

Authentication and accountability

- Because signed documents are scanned into the system, documents need validation that the information or image is captured correctly.

5. DEVICE CAPTURE

Description

A wide variety of devices at the point of care are capable of communicating detailed information about a patient and the care that is being delivered, including vital signs monitors (e.g., blood pressure, pulse, respiratory rate, and temperature), ECG and EEG monitors, pulse oximeters, infusion pumps, ventilators, blood gas analyzers, glucometers. Due to a lack of standardization, very little of these data are captured and if they are, the cost for the data collection infrastructure is high, so device capture is deployed only where the acuity of the

patient's condition warrants it. If this information could be captured and more widely integrated into the healthcare information infrastructure, significant benefits would be realized including increased patient safety, enhanced quality of care, and reduced healthcare costs.

Device communication interfaces vary widely, due in part to the differences in instrument complexity and the nature of the data being communicated. Some very simple devices (e.g., a medical scale, thermometer, or very basic infusion pump) report a handful of parameters every few seconds, whereas other systems report beat-to-beat or breath-to-breath information with multiple waveforms sampled every few milliseconds. Therefore, devices must employ different communications technologies to enable appropriate communications at a cost-effective price.

Once data is collected, many additional issues come into play, including how to:

- Manage data so that the practitioner doesn't suffer information overload.
- Retain data so that they aren't deleted prematurely.
- Filter, summarize, validate, and even reformat data so that they can be stored in patient records, included in reports, and processed by healthcare applications.

In order to achieve the benefits resulting from automatic capture of medical device data, international standards that address these issues and the "Essential Principles of Healthcare Documentation" must be adopted. Policies and procedures must help ensure that the medical device industry moves rapidly toward standardization of captured device data and integration of this information into data systems and applications.

Due to the lack of standardization, the cost of implementing automatic medical device data capture remains high, typically hundreds of dollars per device, with a bedside device manager or concentrator often running thousands of dollars. The primary driver in these costs is the complexity that needs to be managed with devices that have completely different proprietary communications protocols. Custom interface software and hardware must be designed to support each device, at considerable expense. Engineering staffs are required to continually update and maintain these systems to ensure compatibility with the latest versions of equipment.

Costs are expected to drop dramatically as standardization takes hold in the industry, as usage increases, and as technology costs decrease. It is hoped that companies will be able to mass-produce a single interface without having to customize it for every device and application to which it must connect. Once standardized interfaces become the norm in the industry, a significant return on investment may be realized, exceeding by far the required investment in communications infrastructure.

Strengths of device capture

- Data is highly accurate, complete, and received in a timely fashion.
- Systems can be deployed that help reduce clinical errors (e.g., medication errors).
- Paperwork required to manually record patient care data is greatly reduced.
- Patients may be more accurately assessed by real-time comparison of information from multiple devices and care adjusted more quickly.
- Quantitative data from a broad array of devices can be fed into clinical pathway and decision support systems to enhance patient care.
- Enhanced data mining applications are enabled.
- Medical device asset tracking (location, utilization, maintenance, etc.) is facilitated.

Weaknesses of device capture

- Lack of standardization results in the need to work with various proprietary networking and information management systems.
- Vast amounts of data may be captured very quickly, consuming considerable storage resources with potential information overload for the practitioner.

- Data collection networks are frequently reconfigured, with the potential for data loss or improperly attributed information.
- Data security (privacy, confidentiality, authentication, etc.) is currently limited. Very few devices directly support secure communications or the security policies and technologies used in each facility.
- With the evolution of technologies such as IEEE 802.11a, 802.11b, and 802.11g, Bluetooth, or Wireless Medical Telemetry Service (WMTS), device incompatibility may result in poor quality and even inhibited communications, with devices jamming each other's signals.

The broad penetration of mobile, biometric, and asynchronously connected devices escalates many issues associated with raw data capture and “off line” interaction with the health record, such as data integrity, definition, ownership, validation, and archiving. It also raises issues around asynchronous interaction with the patient record, since “always connected” is not how practitioners work in creating health documentation. These workflows may have the process of direct data capture “disconnected” from the health record, with real-time decision support and clinical alerts at the point of care significantly impacted by this reality.

As newer devices and improved raw data capture methods evolve, these process issues will surface as significant in the assessment of data quality and information overload. The limitations of these systems and the potential issues that might arise when new devices are added should be well understood before they are deployed.

Relating Device Capture to the “Essential Principles of Healthcare Documentation”

Unique identification of patient

- Patient-connected medical devices should internally support some means of patient identification, although this is not always possible or practicable.
- Data collection networks should be designed to ensure that patient identification information is coupled with patient data as “close” to the device as possible:
 - If patient identification can be associated with a given network access point or point of care (POC), then maintaining this location or “port” information may be sufficient, with the patient ID added later. However, this too can be error prone when patients change location.
- For devices that support internal patient identification, procedures and automated systems should be established to ensure synchronization of the patient identification in all associated equipment, including erasing the patient ID when the device is no longer needed.

Accuracy

- One of the strengths of automatically capturing data directly from devices at the POC is that the information is highly immune to standard sources of inaccuracies (e.g., transcription errors). However, any medical device data collection network and management systems must employ protocols and connections that ensure reliable, error-free communication of information along the complete path from the medical device to the repository. This includes the ability not only to detect when the data may have been corrupted but also to automatically correct and if necessary automatically re-capture the information from the device.
- This accuracy must also be ensured for data in store-and-forward systems or that are routed through a gateway. These may result in translation of the data's “native” format from the device to a format that is required by the repository system (e.g., an IEEE 1073 device that sends data through a gateway to an HL7-based system).

Completeness

- To ensure maximum utility of a device in contexts where its information is automatically captured, the device should support “full disclosure” on its

communication port—all information that is viewable from the device's front panel or user interface should also be accessible by its computer interface.

- Device manager applications should be able to either configure the device to report only the information that is needed in a particular context or to filter the information before passing it on to subsequent applications and repository systems.
- The granularity of information must be carefully considered to determine what may be summarized and what may be filtered out.
- Devices that support communication of a small subset of their information will not be able to provide “complete” data sets for the full complement of applications with which they interact.
- The alternative is to analyze proactively all the applications that might use device data and ensure that all devices that are attached to a data collection network can support these sets. However, this approach is very error prone (applications can easily be overlooked) and subject to premature obsolescence as new applications may well require additional information beyond what was indicated in the initial survey.
- Another approach would be to limit the type of applications to a small subset that is supported by basic interfaces from almost any device of a given class. This will greatly reduce the benefits that can be realized from integration of medical devices into an information system network.
- Given the vast amounts of information that can potentially be generated by multiple devices associated with a single patient (e.g., ECG, vital signs monitor, ventilator, infusion pumps), binary data formats and compression schemes should be supported.

Timeliness

- In general, information obtained from devices is captured in a “timely” manner. A problem may occur if the information is captured before other parts of the information network have “caught up” and been synchronized, including assigning the bed to a patient. Therefore, medical device data capture systems must be able to collect and store information for a period of time before it is formally associated with a patient and can be forwarded onto subsequent information processing applications.
- Standardized time and date stamps should be associated with all information that is retrieved from a device. When possible, these stamps should be assigned internally by the device when the information is first generated (e.g., when a given measurement is performed), rather than when reported or when received by a manager system. Sufficient time resolution should be provided to allow for correlating data from multiple disparate sources, potentially in real time. For example, waveforms from multiple devices may be displayed on a single patient monitor and would need to have their display synchronized.
- Devices should support standard time synchronization protocols (e.g., NTP or SNTP) to allow their internal time/date stamps to be synchronized to an external source.
- With systems that operate across wide distances (for example, telehealth applications), care must be taken to ensure that (a) policies and procedures are in place to establish what time stamp is used (i.e., one for where the device is located or one based on the central system's location); and (b) an international format is used such that if the location information associated with the stamp doesn't exist, it may still be properly interpreted.

Interoperability

- For device capture, interoperability is primarily focused on the ability to connect a device to a data collection system or network and the ability to monitor information

from the device. The level or “ease” of achieving interoperability varies greatly. Often a device needs to not only have the proper cable and connector attached, but the monitoring network also needs to be told which device is active on which port before the information can be collected.

- If data are to be automatically applied to a patient record, the communication path from the device to the device/data manager system (typically for summarization and validation/review) to the patient record system must be fully analyzed and understood. There are many interoperability issues that could easily inhibit this communication path.
- If RF-based device communications are to be used, analysis and monitoring of the spectrum used must be done to ensure useful and reliable operation.
- Device capture interoperability must be viewed from all levels of communication. Not only is the right transport technology required (e.g., Ethernet, 802.11b), but also the right application services (e.g., RPC, ROSE, SNMP, CMIP/CMIS, HTTP, XML) and the right information model and semantics (or nomenclature) must be used. The same transport may be used, but if the application services or data language differ, then only transport-level interoperability is achieved. Communicating applications interoperability requires coordination across all levels of communication.
- The highest level of interoperability is standards-based plug-and-play. This implies that standard interfaces, including physical connectors for non-wireless technologies, are used. The device only needs to be attached and powered on for the network to automatically detect its presence, discover its configuration, possibly negotiate optional parameters, and then automatically exchange and process information.
- Use of internationally standardized technologies and protocols increases interoperability between similar devices from the same or different manufacturers. For example, a ventilator from one vendor could connect to a device manager from another vendor and provide data to an information system from yet another vendor, all without operator intervention and major system integration (i.e., engineering) effort.

Retrievability

- Data captured from medical devices should conform to international standard formats in general and for the specific class of device. This will allow processing (i.e., data content scanning and retrieval) of information collected from many different device sources by standardized applications that do not need to be customized for a particular device manufacturer or model.
- The data formats should not only use standardized technologies (e.g., languages, syntax, and nomenclatures) but also data templates that are specialized for a particular type of device. For example, a data mining application may be configured to process data from sources, such as a ventilator that generates XML-encoded information; however, since the respiratory rate from a ventilator can be reported in many different ways, the processing by the data mining application may be difficult if not impossible without significant expense.
- Standardized data formats should structure the information so that applications can quickly locate specific elements of interest and skip over other irrelevant sections without having to perform a detailed search of the entire data stream. Also, mechanisms should be provided to allow systems to skip over data that they do not recognize, while searching those sections that they do.
- For systems that capture information from devices in one geographic region and process and display it in another one, formats should allow for differences in language, orthography, time and money formats, etc. With a code, the system that is displaying the information can use the regional settings appropriate for where it is being used.

Authentication and accountability

- Every device from which data is automatically captured should provide a globally unique identifier, preferably an organizationally unique identifier (OUI). This can be used to identify the specific device from which the information is captured and to ensure differentiation between multiple instances of the same device associated with one patient (e.g., infusion pumps).
- Some systems may use the communications port of the data collection network to identify the device. However, devices are often switched between ports (e.g., when they are temporarily disconnected while a patient is turned or moved to a different bed), and thus unique identification can become difficult to ensure. If the device supplies an OUI, this problem is eliminated.
- Devices using RF technologies have an even greater need to ensure unique identification, especially if they communicate while the patient is ambulatory.
- OUIs may be used to help support authentication services in a secure network (e.g., devices “signing” their reports). They can also support secondary services such as asset management, tracking, and periodic maintenance.

Auditability

- Data formats used by a medical device should support verification audits to ensure the information has been communicated error free. Devices should support standard means of detecting and reporting data errors.

Confidentiality and security

- Most medical devices communicate in a closed network, typically with a single connection between the device and its manager. In these cases, security is typically not an issue, although if RF links are utilized, it quickly becomes one. If a device communicates across a LAN/WAN that is subject to security, privacy or confidentiality policies, then either the device needs to directly support application level security or it must connect with a secondary system that provides the needed protection.
- Security must be supported at the application level and not just within a given transport (e.g., TCP/IP link), since many LAN/WAN applications support data communication across multiple links. Trusted end-to-end data flows must be supported between the device and the end points of the communication. The security technologies utilized should be those of a common infrastructure and not unique to a given device or device communications. Data collection networks must be analyzed so as to provide appropriate secure communications, allowing trusted end-to-end information flows to be achieved.

6. CLINICAL IMAGING

Description

The following is a brief summary of current trends in clinical imaging, which will ultimately have a significant impact on the economics of clinical information systems as well as data capture and report generation. A more detailed study of clinical imaging applications in information capture and report generation is needed.

The classic static images captured in a clinical setting are analog x-rays, traditionally using specialized analog photographic film and analog cameras. “Filmless” radiology is beginning to spread, using digitized media that allow more efficient management, storage, and distribution. The histopathology and cytopathology laboratory is another area where traditional processing and storage of tissue and biopsy specimens on microscope slides is yielding to newer imaging technology.

Dynamic images or video images continue to evolve and expand in many clinical diagnostic and therapeutic settings. This methodology is most suited for the capture and

presentation of “anything that moves.” Traditionally, this has been for studies involving vascular flow, the beating heart, and peristalsis or GI (gastrointestinal) motility, e.g., cine angiography, ventriculography, and GI contrast exams. Nuclear imaging, ultrasound, fluoroscopy, and the more recent practice of videotaping encounters, e.g., in behavioral health or physical therapy settings, all generate very large files when transferred from classic “cine” or videotape media to newer “digitized” media. “Minimally invasive” procedures are usually accompanied by fiberoptic endoscopy, with multiple sequential images stored on videotape, e.g., laparoscopic cholecystectomy, arthroscopy, cystoscopy, and GI endoscopy.

We see no end to the current exponential growth of this model of data capture and procedure documentation. Specialized systems, including PACS (picture archiving and communication systems), store and manipulate “objects” rather than structured data and are becoming more widespread. The combination of full motion color video, voice or other sound, with text-based data is becoming much more commonplace, e.g., Doppler echocardiography. The efficient integration of this data into a systemwide, disseminated, electronic medical record is both promising and challenging.

The introduction of multimedia formats of patient data and increasing access to them raises new challenges to the definition and interpretation of such data. A full motion video of a patient encounter records, stores, and enables later retrieval and analysis of subtleties that may not be identified as meaningful at the initial point of care. Understanding the impact of this on data integrity and accountability of the clinician at the point of care is an important consideration.

RECOMMENDATION #7: Provide more information to practitioners/providers related to the impact of handwriting on a healthcare system’s effectiveness and efficiency in handling information.

RECOMMENDATION #8: Develop standards and guidelines for the editorial process related to report generation, with emphasis on standardized, exchangeable reports.

RECOMMENDATION #9: Create a cost-benefit model of uniform healthcare documentation methods with emphasis on standard reports.

Chapter 5: Accountability, Authentication, and Audits

As continuity of care becomes increasingly essential in health care, issues of ownership, interoperability, accuracy, and authenticity become very important. Traditionally, healthcare documentation was produced and accessed by only one practitioner. More recently, this has extended to a single provider setting. In the future, healthcare documentation will consist of a patient database that can be accessed by authorized persons from many organizational entities, medical specialties, and varying provider types.

This process begins to eliminate the traditional walls of the enterprise. Issues of identifying a steward for patient information will have to be addressed. Practitioners will have to consider information without knowing its source and its degree of accuracy. As more and more information is gathered, aggregated, and disseminated, the risk increases that such information comes from a misleading source or is distorted. As healthcare enterprises become more and more blurred, accountability, authentication, and auditability are key elements of healthcare documentation.

ACCOUNTABILITY

The final step in the information capture and report generation process is responsibility taking or accountability. This involves affixing a signature to a paper-based document or creating an electronic or digital signature if it is an electronic document. The signature is needed to identify the author, to show the author's willingness to take responsibility for the correctness of the entry, and to guarantee data integrity, as a signed document should not be altered.

Accountability has four major considerations:

- The person originating the information capture (i.e., the author) takes responsibility for captured information.
- Accountability in information systems allows users of the system to identify the individual, device, facility, department, or organization that was the original source of the data. Accountability also should enable the system to retain the identity of the source of data as it is passed from system to system within an information system network.
- Standards for accountability are necessary that require appropriate levels of data source identification and retention of the source identification throughout the information network in order to enable proper auditing.
- Accountability involves nonrepudiation, i.e., the author cannot subsequently deny having created the information captured.

AUTHENTICATION

Authentication is an essential part of healthcare documentation. In general, information must be authenticated by the authoring professional at the end of the healthcare documentation process, regardless of what information capture method is utilized. Authentication provides proof that the person claiming to create the information did create it. As shown in Figure 1 (p. 7), a signature is required for handwritten and transcribed documents. Document imaging requires validation that the scanned document truly represents the original document content. Device communication and imaging require validation that no error occurred in the conversion and transmission process. A public key infrastructure (PKI) system using a central registration authority could be used for proper authentication.

Authentication has six elements, namely, identification, encryption, data integrity, signature action, document architecture, and how to bind the signature to the message. The American National Standards Institute's Health Informatics Standards Board (ANSI HISB) signature group is addressing this at a national level. Perhaps we should look at state legislation and recommend a state summit. Regulatory agencies should also be alerted.

Several kinds of authentication exist:

- Authentication of *information* is necessary for the practitioner before an opinion is formed or an observation is recorded.
- Authentication of the *person(s)* involved in the information capture process, such as the practitioner, the transcriptionist, and the medical editor, is necessary so that each individual involved in the recording process is clearly identified with his or her role.
- With device-generated information, authentication of the *device* must be clearly identified and meta information about the person who maintains or operates the device must be available. For instance, the vendor brand and version of a specific speech recognition software must be recorded.

One must remember that health care is a regulated industry. Therefore, many of the arguments for an easy signature approach like that in e-commerce do not apply. Healthcare communication consists of a mixture of applications, some bilateral (e.g., a practitioner's communication with a payer or health plan) and many multi-lateral (e.g., a practitioner's sharing of information with others, working with various provider entities, or interacting with many other stakeholders). There are easier and more economical signature solutions for the bilateral communication than for the multilateral communication.

Electronic signature

An electronic signature has five elements. For each of these, different levels of security (certainty) are possible.

- Unique identification of the signer (there are several levels of identification and verification possible).
- Intent to sign.
- A "sealing process" that allows no changes after the signature has been affixed.
- A data integrity feature that shows any changes in subsequent transmission, processing, or storage (achieved with encryption).
- A data architecture feature that binds the signature to the information and links any amendments.

At present, only the digital signature with a full PKI can satisfy these requirements entirely. Electronic signature types that partially compromise these requirements may be acceptable in some cases as long as it is understood that nonrepudiation (i.e., the guarantee that a document cannot be disputed) is not guaranteed.

AUDITS

Audits may be done for data quality or for security. The importance of audit functions to improve data quality was discussed briefly above. The security function of audit trails is a relatively new application in clinical informatics. The impact of federal and state legislation on the development of security technology to efficiently capture and produce reports or "smart audits" of access to clinical data should not be underestimated. The overhead added to clinical data and report repositories will be substantial if the audit trails are to be effective in deterring the inappropriate access to and use of protected health information. Also, the ability to easily de-identify large numbers of clinical reports, by properly designing a database at the time of capture and report generation, will greatly facilitate the use of clinical information for quality improvement and research or knowledge discovery. However, the details of security issues and de-identification are beyond the scope of this Report.

RECOMMENDATION #10: Conduct a risk assessment of authentication in order to provide guidelines for electronic and digital signature types.

RECOMMENDATION #11: Develop guidelines for security, including nonrepudiation, data integrity, and auditing of healthcare documentation.

Chapter 6: Conclusion

The work of the Consensus Workgroup on Health Information Capture and Report Generation has shown that documentation is a complex field, influencing many areas of health care, including quality of care and public safety. Clearly, the topic warrants much greater attention.

The “Essential Principles of Healthcare Documentation” presented by the Report provide the basis for systematic evaluation of healthcare documentation methods. Providers, vendors, and healthcare organizations should be encouraged to demand and use documentation systems that meet these principles. Additional research is needed to assist in this regard, as is a practical implementation guide. Ultimately, such an implementation guide should contribute significantly to the goal of achieving high quality healthcare documentation that is consistent, uniform, and interoperable throughout the world.

As the transition to electronic information systems takes place, we must recognize that these systems are more vulnerable to security breaches than traditional paper-based systems. They also require different security systems and policies. As shown in Chapter 5, authentication, auditing, and safeguarding healthcare information require new methods and new skills to assure adequate security. Thus, additional education and certification in security are needed to enable healthcare information professionals to appropriately respond to the security issues of our times.

The need for a national rapid response system in healthcare to deal with epidemic outbreaks and bioterrorism is self-evident. However, our information capture and report generation systems are still years away from enabling us to achieve this goal. Rapid action on developing systems that capture information both in the emergency department and at the practitioner level must be a national priority.

Additionally, a dialogue is needed to create a consensus for context and content comparability of health information. This topic is beyond the scope of this Report and should be addressed by the appropriate professional organizations in a manner that reflects their unique requirements yet achieves coordination and consistency.

In closing, we offer this final recommendation:

RECOMMENDATION #12: Create and fund an institute for healthcare documentation to (1) conduct further research and create practical implementation guides for uniform adoption of the “Essential Principles of Healthcare Documentation,” (2) advance the recommendations of this Report, and (3) develop and administer education and certification programs in (a) healthcare documentation based on the “Essential Principles of Healthcare Documentation” and (b) security/authentication of healthcare documentation.

References

Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996. Public Law 104-191, August 21, 1996.

The AAMT Book of Style for Medical Transcription, C. Tessier, AAMT, Modesto, CA, 1995.

ASTM E1762 Standard Guide for Electronic Authentication of Health Care Information, ASTM, West Conshohocken, PA, 1995.

ASTM E1869 Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Computer-Based Patient Records, ASTM, West Conshohocken, PA, 1997.

ASTM E1902 Standard Specification for Management of the Confidentiality and Security of Dictation, Transcription, and Transcribed Health Records, ASTM, West Conshohocken, PA, 2002.

ASTM E1985 Standard Guide for User Authentication and Authorization, ASTM, West Conshohocken, PA, 1998.

ASTM E1986 Standard Guide for Information Access Privileges to Health Information, ASTM, West Conshohocken, PA, 1998.

ASTM E1987 Standard Guide for Individual Rights Regarding Health Information, ASTM, West Conshohocken, PA, 1998.

ASTM E1988 Standard Guide for Training of Persons Who Have Access to Health Information, ASTM, West Conshohocken, PA, 1998.

ASTM E2017 Standard Guide for Amendments to Health Information, ASTM, West Conshohocken, PA, 1999.

ASTM E2084 Standard Specification for Authentication of Healthcare Information Using Digital Signatures, ASTM, West Conshohocken, PA, 2000.

ASTM E2085 Standard Guide on Security Framework for Healthcare Information, ASTM, West Conshohocken, PA, 2000.

ASTM E2086 Standard Guide for Internet and Intranet Healthcare Security, ASTM, West Conshohocken, PA, 2000.

ASTM E2147 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, ASTM, West Conshohocken, PA, 2001.

ASTM E2182 Standard Specification for Clinical XML DTDs in Healthcare, ASTM, West Conshohocken, PA, 2002.

ASTM E2183 Standard Guide for XML DTD Design, Architecture and Implementation, ASTM, West Conshohocken, PA, 2002.

ASTM E2184 Standard Specification for Healthcare Document Formats, ASTM, West Conshohocken, PA, 2002.

ASTM E2211 Standard Specification for the Relationship Between a Person (Consumer) and Supplier of an Electronic Personal (Consumer) Health Record, ASTM, West Conshohocken, PA, 2002.

"Better Coding Through Improved Documentation: Strategies for the Current Environment," *Journal of AHIMA*, MacDonald, Ellen, MPH, RHIA, CCS, January 1999.

Comprehensive Accreditation Manual for Hospitals – 2001, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL, 2001.

The Computer-based Patient Record: An Essential Technology for Health Care, Committee on Improving the Patient Record, Division of Health Care Services, Institute of Medicine, Richard S. Dick, Elaine B. Steen, and Don E. Detmer, Editors, National Academy Press, Washington, DC, 1997.

Crossing the Quality Chasm: A New Health System for the 21st Century, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, DC, 2001.

HL7 Version 3 Standard: Clinical Document Architecture, Release 1.0, HL7 Inc, Ann Arbor, MI, 2000.

Medicare Reimbursement Policy and Teaching Physicians' Behavior in Hospital Clinics: The Changes of 1996, Stern, Robert S, MD, *Academic Medicine*, v77, January 2002.

MTIA 2000 Transcription Market Assessment, MTIA, Seattle, WA, 2000.

NCVHS Report to the Secretary on Uniform Data Standards for Patient Medical Record Information, National Committee on Vital and Health Statistics, July 12, 2000.

"Ongoing Coding Reviews: Ways to Ensure Quality," *Journal of AHIMA*, Thompson, Neil S., RHIA, and Koch, Doreen, RHIT, January 1999.

"Practice Brief: Authentication of Health Record Entries (Updated)," *Journal of AHIMA*, 2000.

"Practice Brief: Electronic Signatures (Updated)," *Journal of AHIMA*, 1998.

"Practice Brief: Verbal/Telephone Order Authentication and Time Frames," *Journal of AHIMA*, February 2001.

Reading between the lines: Improving legibility to reduce medical errors, Opus Communications, Marblehead, MA, 2001.

Security and Electronic Signature Standards, Proposed Rules; Department of Health and Human Services, August 12, 1998.

Standards for Privacy of Individually Identifiable Health Information; Final Rule, Department of Health and Human Services, April 14, 2001.

To Err Is Human: Building a Safer Health System, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, DC, 2000.

Websites

AAMT
AHIMA
ANSI HISB

www.aamt.org
www.ahima.org
http://www.ansi.org/rooms/room_41/

ASTM	www.astm.org
HCPPro	www.hcpro.com
HHS	http://www.dhhs.gov/
HHS/CMS/HIPAA	http://www.cms.gov/hipaa/hipaa2/default.asp
HHS/Data Council	http://aspe.hhs.gov/datacncl/index.htm
HHS/NCVHS	http://ncvhs.hhs.gov/
HHS/OCR	http://www.hhs.gov/ocr/hipaa/
HIPAA Administrative Simplification	http://www.aspe.hhs.gov/admsimp/
HL7	www.hl7.org
IEEE	www.ieee.org
Institute of Medicine	www.iom.edu
JCAHO	www.jcaho.org
Medical Records Institute	www.medrecinst.com
MoHCA	www.mohca.org
MTIA	www.mtia.com

Appendices

APPENDIX 1: AUTHORS AND PARTICIPANTS

Authors

- C. Peter Waegemann, CEO, Medical Records Institute, peterw@medrecinst.com¹³
- Claudia Tessier, Executive Director, Mobile Healthcare Alliance, ctessi@attglobal.net¹⁴
- Andrew Barbash, CIO, eHealthConnector, Inc., andrewbarbash@yahoo.com
- Barry H. Blumenfeld, Corporate Manager, Partners Healthcare System, Bblumenfeld@partners.org
- Jonathan Borden, Assistant Professor of Surgery, Tufts-New England Medical Center, Boston, MA, jonathan@openhealth.org
- Robert M. Brinson Jr, CEO, ePhys, Inc., rmbjr@ephys-hc.com
- Todd Cooper, Technical Director, Medical Device Communications Industry Group, t.cooper@ieee.com
- Peter L. Elkin, Associate Professor of Medicine and Medical Informatics, Mayo Medical School, Mayo Clinic, elkin.peter@mayo.edu
- J. Michael Fitzmaurice, Senior Science Advisor for Information Technology, Agency for Healthcare Research and Quality, MFitzmau@ahrq.gov
- Susan Helbig, Director, Health Information Management Services, VA Puget Sound Health Care System, susan.helbig@med.va.gov
- Kathleen Milholland Hunter, President & CEO, K&D Hunter Associates, Inc., dmillho1@tampabay.rr.com
- Brenda Hurley, Director of MT Development, MedWare, Inc., bhurley@medware-inc.com
- Brian Jackson, Director of Product Management, Language and Computing, brian@landc.be
- James M. Maisel, President, Zydoc.com, jmaisel@zydoc.com
- David Mohr, Chair, Mayo Integrated Clinical Systems, Mayo Clinic, dmohr@mayo.edu
- Kathy Rockel, Transcription Manager, Transcription Relief Services, Inc., KRockel@transrs.com
- Joseph H. Schneider, Assistant Professor, Baylor College of Medicine, drjoes1tx@yahoo.com
- Thomas Sullivan, Chair, eMAC, American Medical Association, sullivan@massmed.org
- Joe Weber, CEO, Narratek, joeweber@alum.mit.edu

Participants (those who attended at least one meeting of the Consensus Workgroup and/or contributed by submitting changes, corrections, and comments to circulated drafts but did not author portions of the Report)

- Above, plus
- Daniel Albohn, Manager, New Business Development, Sony Electronics, Inc., daniel.albohn@am.sony.com
- Bonnie Bakal, American Association for Medical Transcription, Bbakal@aol.com
- Jeffrey Blair, Vice President, Medical Records Institute, jeffblair@medrecinst.com
- Alfred S. Buck, Partner, Edward Martin & Associates, Inc., abuck17455@aol.com
- Linda Byrne, linbyrne@msn.com
- Paul Carpenter, Chair, Document Oversight Group, Mayo Clinic, pccarp@mayo.edu
- Christopher Carr, Director of Informatics, Radiologic Society of North America, carr@rsna.org
- Gary Dickinson, Manager, Health Care Standards, Per-Se Technologies, Inc., gary.dickinson@per-se.com

¹³ Co-chair and primary author.

¹⁴ Co-chair and primary author.

- Gail Graham, Director, Information Assurance, Department of Veterans Affairs, gail.graham@hq.med.va.gov
- John Holbrook, johnholbr@aol.com
- Peg Hughes, Director of Professional Practices, American Association for Medical Transcription, phughes@aamt.org
- Robert Knight, Technology Solutions Manager, Lanier Healthcare, LLC, rknight@lanierhealthcare.com
- Deborah Kohn, Principal, Dak Systems Consulting, dkohn@daksystcons.com
- Michael F. Leisey, Vice President, Sales & Marketing, DTS America, Inc., mike@dtsam.com
- Paul Nash, Group Publisher, HCPro, pnash@hcpro.com
- John Quinn, Principal, Cap Gemini Ernst & Young, US LLC, john.quinn@cgey.com
- Carla Robelli, JCAHO, crobelli@jcaho.org
- Mark Shafarman, Clinical Information Architect, Mark.Shafarman@oracle.com
- Paul Stinson, Lanier Healthcare, LLC, pstinson@lanierhealthcare.com
- Steve Teplansky, Sony Electronics, Stephen.teplansky@sony.com
- Leo Van Geyt, VP Sales and Marketing, Language and Computing, leo@landc.be
- Allen Wenner, Vice President, Content Design, Primetime Medical Software, Inc., awenner@medicalhistory.com

APPENDIX 2: GLOSSARY OF TERMINOLOGY AND ABBREVIATIONS

AAMT	American Association for Medical Transcription
accountability	The property that ensures that the actions of an entity may be traced uniquely to that entity (ASTM E1762).
AHIMA	American Health Information Management Association
AI	Artificial intelligence
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials
auditability	The ability to audit (officially and methodically examine and verify) a system.
authentication	The corroboration that an entity is the one claimed. Verification of correct information, document author, computer user, organization, or system.
author	The person creating and authenticating an entry into a health record through handwriting, speech, direct input, etc. Synonym: originator.
CA	Certificate authority
CDA	Clinical document architecture (3-level standard of structured information, based on messaging, developed by HL7)
clinical imaging	Analog and digital x-rays, nuclear imaging, ultrasound, fluoroscopy, videotaped encounters, etc.—creating documentation through image connectivity.
CMIP	Common management information protocol
CMIS	Common management information service
CMS	Centers for Medicare and Medicaid Services
CMT	Controlled medical terminology
connectivity	The ability to connect disparate information systems in order to import or share information. It usually does not have the features of interoperability.
CPR	Computer-based patient record, often used as synonym for EPR
data integrity	The property that data have not been lost, altered, or destroyed in an unauthorized manner or by unauthorized users; it is a security principle that protects information from being modified or otherwise corrupted, either maliciously or accidentally.
date-, time-, place-stamp	For information systems it is the computer functionality of automatically including date, time, and location within a document. In traditional paper-based systems, this function must be conducted manually.
dif	Direction interchange format
digital signature	A system that can offer nonrepudiation because of correct identification of the author through a centralized certification authority and certificates, by the process of affixing a signature through software or keying in a specific code, and the requirement of non-changeability of the document after the signature has been affixed. The latter involves asymmetric encryption based on private and public keys. Digital signatures usually require a public key infrastructure (PKI).
direct input	Data entry by a practitioner into the electronic health record without intermediate assistance, i.e., the method of a practitioner recording onto a computer screen or mobile healthcare computing device without outside services.
document	Traditionally, and particularly with paper-based systems, a defined set of information contained on one or more pages requiring a signature for authentication and accountability. With

	direct input into computer-based systems, a document is a set of defined fields or elements that can be printed for legal or other reasons, such as history and physical, discharge summary, nursing note.
document imaging	Process of transferring an analog paper-based document (typed/signed or handwritten) or an analog photographic film document into a digital image so that it can be electronically stored and retrieved.
DRGs	Diagnosis related groups
DTDs	Document type definitions
ease of use	A user's perceived comfort in utilizing any aspect of an electronic health record system, i.e., a quality that generates wide acceptance among practitioners.
ECG	Electrocardiogram, electrocardiograph
editing	The process of reviewing and correcting recorded information before a signature is affixed to a document.
EEG	Electroencephalogram, electroencephalography
EHR	Electronic health record
electronic signature	The act of attaching a signature by electronic means. Several types of electronic signatures exist. They do not offer full nonrepudiation.
EMR	Electronic medical record limited to an organization or enterprise
EPR	Electronic patient record, often used as synonym for CPR
free text	Free-flowing, nonstructured style of speaking, writing, or inputting information.
GI	Gastrointestinal
handwriting	Writing performed by hand on paper or other media.
health information	Any information, whether oral or recorded in any form or medium that (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual. (HIPAA, 1996)
healthcare documentation	The recording of healthcare processes within the regulatory and legal requirements, typically including descriptions of patient's past history, clinical observations, diagnostic studies, healthcare interventions, medication history, clinical course, outcome, and care-related documents.
HHS	(Department of) Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hospital/health information system
HISB	Health Informatics Standards Board
HL7	Health Level 7
htm	Hypertext markup (language)
HTML, html	Hypertext markup language
HTTP	Hypertext transmission protocol
ICR	Intelligent character recognition
ID	Identifier
IEEE	Institute of Electrical and Electronic Engineers
information capture	The process of capturing human thought, observations, speech, digital information for the purpose of recording.

Internet protocol	A brief term for TCP/IP (transfer control protocol/Internet protocol), representing the three functions of file transfer, remote computer log-in, and email.
IOM	Institute of Medicine
IrDA	Infrared Data Association
ISO	International Standards Organization
JAVA	An object-oriented programming language.
LAN	Local area network
macro	Stored keystrokes, often used to avoid typing repetitive text.
medical transcription	The process of interpreting and transcribing dictated health information.
MHCD	Mobile healthcare computing device
MoHCA	Mobile Healthcare Alliance
MPI	Master person index
MRI	Magnetic resonance imaging
MT	Medical transcription, medical transcriptionist
natural language understanding	The process of using a computer system to analyze and understand the language that a person uses naturally; understanding means knowing the concepts of a word or phrase.
NCVHS	National Committee for Vital and Health Statistics
NLU	Natural language understanding
nonrepudiation	Inability to deny that an entity involved in a communication has participated in a part or all of that communication.
normal	Routine or standard text for a report.
NTP	Network time protocol
OCR	Optical character recognition; Office of Civil Rights (HHS)
OUI	Organizationally unique identifier
PACS	Picture archiving and communication systems
PDA	Personal digital assistant
pdf	Portable document format
PKI	Public key infrastructure for nonrepudiation involving digital signatures, a certificate authority (CA), digital certificates, and asymmetric encryption.
PMRI	Patient medical record information
POC	Point of care
practitioner	A person engaged in the practice of a profession or occupation such as physician, nurse, therapist.
provider	A person, group, or organization that provides medical services or support and issues a bill for those services.
report generation	The process of structuring and recording information for the purpose of creating sets of information (documents or reports) required in health care, such as discharge summaries, history and physicals, or progress notes. The process of analyzing, organizing, and presenting recorded patient information for authentication and inclusion in the patient's healthcare record.
retrievability	Capability of allowing information to be found efficiently.
RF	Radio frequency
ROI	Return on investment
ROSE	Remote operation service element
RPC	Remote procedure call
rtf	Rich text format
schema	A diagram, underlying framework, or scheme used with XML.
shareability	The ability to share information in disparate, noncompatible, and non-interoperable information systems.
SNMP	Simple network management protocol

SNTP	Simple network time protocol
SOAP	Subjective, objective, assessment, plan (a style for documenting patient care)
speech recognition	Computer-generated voice to text translation.
SR, S/R	Speech recognition
structured text	Process that requires authors to put specific information into specific fields with passive guidance by the information system. In paper-based systems, a form encourages a practitioner to fill in fields or boxes. Electronic systems use the same principle for templates or macros.
TCP/IP	Transmission control protocol/Internet protocol
template	A structure to be used repeatedly for report generation, containing standard headings and formatting for a specific report.
turnaround time	Time from dictation until report is available for care and integrated into patient's record.
txt	Text
unstructured data	Synonymous with free text.
USB	Universal serial bus; a standard physical interface as a serial port on a computer.
validation	The process of verifying or confirming. Someone other than the author usually does it.
WAN	Wide area network
WML	Wireless markup language
WMTS	Wireless medical telemetry service
XSLT	Extensible style language template
XML, xml	Extensible markup language; a method to structure data with document-type definitions (DTDs).

APPENDIX 3: COMPARISON OF INFORMATION CAPTURE STYLES

The graphic below groups different information capture methods into three style categories: unstructured, structured, and interactive. In general:

- The users who wish to place a priority on minimizing the time to capture information prefer unstructured methods. These are typically the users that create or input data into the information capture device.
- The users who place a priority on improving the efficiency of reviewing or analyzing the information have gravitated toward structured information capture methods. These individuals may or may not be the creators of the data.
- The users who place a priority on improving the quality and efficiency of patient care by using more effective workflow processes have increasingly moved toward interactive methods.

While the table below organizes information capture methods into useful categories, it does not include the complementary processes that relate to all the categories, such as authentication, verification, editing, backup, recovery, security. In short, it keeps the information capture concepts simple.

Some information capture methods are directly related to specific devices or technologies, but others are relatively independent of specific technologies. For example, voice recording requires devices using analog or digital recording technologies such as microphones, telephones, cassette, and digital recorders. On the other hand, information capture methods such as the use of prompts to guide data entry can be used with almost all information capture devices. It should also be noted that many technologies are being morphed and integrated into new combinations of information capture devices. For example, it is not unusual to see the functions of PDAs and mobile phones integrated into one device, nor is it unusual to see mobile phones and notebook computers integrated into a single device. Because information capture methods may relate to many different devices and since so many devices are becoming integrated, this document cannot attempt to relate specific information capture methods to specific technologies or devices.

TABLE 2: COMPLEXITY, VALUE, AND CHARACTERISTICS OF INFORMATION CAPTURE STYLES

*Least complex
Lower value*

*Most complex
Higher value*

Unstructured	Structured	Interactive
<ul style="list-style-type: none"> ▪ Handwriting. ▪ Voice recording (dictation). ▪ The use of transcription to convert unstructured handwriting or voice into ASCII computer text that is more readable but still unstructured. ▪ Direct entry by clinicians using free text (unstructured) keyboard entry. 	<ul style="list-style-type: none"> ▪ Static, fixed. ▪ Information entry guided by templates. ▪ Information entry guided by prompts given visually on a screen or audibly with voice response technology. ▪ Guided choice using point and click, touch screen, light pens, etc. ▪ Data entry via standardized controlled vocabularies using point and click. 	<p>As the computer accepts structured text and data, it compares this information against pre-stored information, knowledge, or rules and then responds to the user. This is a dynamic process. The responses may include:</p> <ul style="list-style-type: none"> ▪ A branch to a sub-set of questions that are specifically relevant to a user response (such as drill-down questions, problem knowledge couplers).

	<ul style="list-style-type: none"> ▪ Speech recognition with the ability to parse the input into discrete words or data. ▪ The use of XML tags to identify data or text within a template or after parsing from voice recognition. ▪ The use of XML document type definitions (DTDs) to organize input into a standardized document. ▪ The use of transcription along with templates and/or XML to make the information more structured. ▪ Translation of text or data into codes. ▪ The completion of templated forms, combined with dictation, then integration of data from scanned forms with transcription. ▪ Information sent from other computer devices structured with a standard syntax. ▪ Data automatically captured from medical devices and possibly translated into structured text (e.g., XML). 	<ul style="list-style-type: none"> ▪ An alert, warning, or reminder triggered by data comparisons and knowledge rules. ▪ A clinical protocol or practice guideline triggered by a specific user response. ▪ A pre-approved drug formulary triggered by a medication order. ▪ A presentation of clinical tests or therapies with their relative costs triggered by a user entry of preliminary findings or diagnoses.
--	---	--

One can now use the representation of unstructured, structured, and interactive information capture concepts to better understand the complexity, value, and characteristics of the different information capture styles and technologies, as presented in the following table.

TABLE 3: INFORMATION CAPTURE MATRIX

	Unstructured	Structured	Interactive
Time needed to capture information	Relatively fast.	May be less than unstructured if the structure for the input is well designed and if the requirement for detail is not excessive. If this is not so, then structured input can be more time consuming than unstructured information capture.	May be as fast as structured or unstructured, or may take longer, depending on the level of detail that is appropriate for a specific condition or situation.
Time needed to access, review, or analyze information	Usually more time consuming than for structured information.	Relatively fast.	Similar to structured information and likely to be more appropriate and relevant for specific conditions and situations.
Completeness of information capture	Often incomplete due to loose or non-existent standards for completeness.	Usually meets the standard for completeness defined by the structure.	User is guided toward the level of completeness that is appropriate for the specific condition or situation.
Accuracy of information	Often lacks standards for accuracy.	Typically prompts the user to meet a uniform or standard level of accuracy.	Prompts user for the level of accuracy that is appropriate for the specific condition or situation.
Timeliness of information	May take hours or days before this information has been filed, transcribed, or entered into a computer to make it available for review and use.	Usually available for review and use immediately.	Usually available for review and use immediately.
Value for reimbursement	Relatively low.	Improved because the information meets a standard level for completeness and accuracy.	Significant improvement because the information is appropriate for specific conditions and situations.
Cost to acquire and install information capture system	Low.	Moderate to expensive.	Relatively expensive.

	Unstructured	Structured	Interactive
Ongoing cost to capture information	Low to capture information, relatively high to retrieve information, moderate to expensive to transcribe information.	Low to capture information, low to retrieve information, moderate to expensive to transcribe information.	Low to capture information, low to retrieve information.
Capability to improve quality of care	Limited to the availability of this information at the next episode of care and to its readability and completeness.	Enhanced because the information is available immediately and probably meets uniform standards for completeness, accuracy, etc.	Greatly enhanced by the availability of relevant information and clinical decision support at the time when care is being provided.
Capability to reduce medical errors and improve patient safety	Little impact.	Better documentation may or may not improve the current episode of care, but it does provide improvements for subsequent episodes of care.	Improvement at the time of care as well as for subsequent episodes of care.
Improvement in clinical research	Relatively low.	Improved because the information meets a standard level for completeness and accuracy.	Significant improvement because the information is appropriate for specific conditions and situations.
Improvement in public health	Relatively low.	Improved because the information meets a standard level for completeness and accuracy.	Significant improvement because the information is appropriate for specific conditions and situations.

Observations That Can Be Derived From the Information Capture Matrix

- It may be helpful to create healthcare information standards for structured information capture. These standards might be appropriate at an institution or departmental level. Candidates would include standards for completeness (i.e. data fields and DTDs), accuracy, standard units of measure, and standard definitions of terms.
- It may be helpful to create healthcare information standards for interactive information capture. These standards might be appropriate at a disease condition or situation level. Candidates would include standards for alerts, warnings, reminders, clinical protocols, practice guidelines, and problem knowledge couplers.
- It may be interesting to conduct some studies to compare the cost of implementing information systems that provide structured information capture against the cost of trying to retrieve useful information from unstructured formats.
- It may be interesting to study the cost of implementing an information system that enables interactive information capture against the cost of medical errors and patient injuries or deaths that occur in structured or unstructured environments.