November 5, 2003

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Thompson:

The National Committee on Vital and Health Statistics (NCVHS) commends you for your commitment toward government wide adoption of clinical data standards that you first announced on March 21, 2003. NCVHS recognizes and appreciates that there is new momentum to adopt clinical data standards that is driven by you and the Consolidated Healthcare Informatics Initiative (CHI). Consequently, NCVHS is now working closely with CHI to study, select and recommend domain specific patient medical record information (PMRI) terminology standards. We have mutually developed a process that allows NCVHS to discuss in open, interactive sessions CHI recommendations as part of the CHI Council acceptance process.

The NCVHS has the following comments on the attached set of CHI domain area recommendations:

- The NCVHS concurs with the CHI recommendations for Interventions and Procedures: Part B, Laboratory Test Order Names.

- The NCVHS concurs with the CHI recommendations for the Medication Domain as modified in the attached document. We further note:
    - the need for additional funding for the Food and Drug Administration (FDA) to expedite the publication of a publicly available version of their Unique Ingredient Identifier (UNII) codes and to provide continued funding to maintain the UNII code standard;
    - that the dosage and administration sub-domain be investigated in the next phase of the CHI process; and
    - that the FDA National Drug Code (NDC) process be investigated and improvements identified be expeditiously pursued.

- The NCVHS concurs with the CHI recommendations for the Immunization Domain as modified in the attached document.

We understand that the next stage is formal government adoption which the NCVHS supports. We are excited about the value of this continuing process.

Sincerely,

/s/

John Lumpkin, M.D., M.P.H.
Chair, National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs
Enclosures

Consolidated Healthcare Informatics Initiative
Final Recommendation Information Sheet1

Domain Title(s) & Team Lead:

Interventions & Procedures (Part B):
(Part B) **Laboratory Test Order Names**: Jim Sorace, CMS

Scope:

Laboratory Test Order Names:

The standard will be used as the representation of laboratory test orders within an information system. It does not include laboratory results naming, lab test result values, anatomy & physiology, genes and proteins, as they are focuses of separate domain reports.

Domain/Sub-domain	In-Scope (Y/N)
Lab test order name clinical pathology	Y
Lab test panel order name clinical pathology	Y
Laboratory test order information clinical pathology	Y
Anatomical Pathology all areas noted above	Y
Anatomy and Physiology	N*
Ordering Test based on a Gene/Protein	N*

* Indicates that this domain is outside the scope of this group and will be the subject of a report by another work group. However, ordering systems will ultimately incorporate these vocabularies.

Alternatives Identified:

Laboratory Interventions & Procedures:
LOINC
CPT codes
SNOMED CT

1 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Final Recommendation:

Laboratory Test Order Names:

For laboratory test order names the workgroup recommends LOINC. LOINC has received prior recommendation as the CHI standard for Laboratory Test Result Names. Our recommendation recognizes that LOINC is flexible enough to meet the needs of the Laboratory Test Order domain as well. This recognizes that LOINC is the most complete, flexible, available, and widely accepted terminology of laboratory tests names.

Content Coverage:

The most current version of LOINC is 2.09. It contains over 33,000 names including 2382 allergy, Blood bank 607, Cell markers 532, Challenge terms (chemistry) 1462, Chemistry 5063, Coagulation 373, Cytology 47, Drug/Toxicology 4253, Drug Dosage 365, Fertility testing 111, Hematology 1081, HLA 335, Microbiology/Serology 6696 Molecular pathology 261, Pathology 138, serology 851, skin test 31, UA 195, Panels 65. Regenstrief also has an application named RELMA that allows users to enter a list of their local test names and map them to LOINC codes see (http://www.loinc.org/). Regenstrief also plans to collaborate directly with NLM in mapping LOINC into UMLS/MESH.

Acquisition:

The LOINC database can be obtained from the Regenstrief LOINC website (http://www.regenstrief.org/loinc/). The LOINC database and associated documents and programs are copyrighted, but the copyright permits all commercial and non-commercial uses in perpetuity at no cost. If the LOINC database or its contents are distributed as a database, such distributions must include all of the parts of the formal LOINC term, the LOINC short name, the LOINC code, the deprecated flag, and the copyright. No such notice is required when LOINC codes are used in messages to report test results.

Costs related to training & education, integration into existing systems and other implementation related issues can only be estimated in context of the specific implementation project and estimates will not be provided as part of this document.

Conditions:

Conditions for LOINC recommendations:

Please note that recommendations 1 to 5 are LOINC specific while numbers 6 and 7 are suggestions for further collaboration between the LOINC and HL7 communities. The

work group stresses that the recommendation to use LOINC is conditional on successfully addressing items 1 and 2 in this section.

Introduction of a hierarchy to LOINC would allow for standard aggregation of terms across the healthcare system, ease in identifying needed terms, and identification of terms to assign within an institution. Further this would assist development of useful Laboratory Test Ordering Applications by allowing healthcare providers to search under a common name (e.g. Chem 6) with the application performing the mapping to the laboratories underlying LOINC codes in a consistent manner. A similar example is outlined in the LABORATORY TEST RESULTS NAMES report. The hierarchy should support generic test codes that do not specify a specimen or method (allowing these to be mapped latter by the institutions laboratory to the exact specimen and method requirements in use at that time). It would also be desirable if the hierarchy noted the preferred order code for the test, thus helping to standardize order forms.

The naming of panels is problematic and needs further development. LOINC is currently working actively on this problem. As most individual analyte tests are ordered as parts of panels, providing a workable solution for this issue is extremely important, and would significantly increase the speed of adoption by vendors. Further panel codes that allow the laboratory to specify the exact test to be run need to be developed. For example in the area of disease surveillance reference laboratories frequently change there test panels based on the most recent epidemiological findings, also the subsequent testing on the sample may depend on what organism is initially found.

The improvements noted in the LABORATORY TEST RESULTS NAMES report in content coverage, definitions, and unrecognized synonymy is noted and also very relevant for ordering.

LOINC has been working to integrate genomic test by allowing users to search for relevant genetic test using a disease specific key word strategy. This will need to be expanded to include gene array and proteomic based laboratory tests. LOINC is aware of these issues. LOINC may also consider allowing users to search by gene name if appropriate.

Recognizing there are copyright issues, the availability of a map from LOINC to CPT codes would be helpful to produce administrative data (claims) from clinical applications.

HL7 Laboratory Order formats are very flexible and broad. LOINC in collaboration with HL7 might consider developing a series of more narrowly focused domain and use case message standards that are specific for the various sections found in both clinical pathology (chemistry, microbiology, hematology etc.) and anatomic pathology (surgical, cytology and autopsy). Each standard should include an audit trial that would include referrals to reference laboratories or changes to the order. The purpose of this trail would be to ensure that both the original message content and any subsequent changes could be reconstructed. As the current standard is very flexible, this work actually represents developing subsets of the current standard, and is a refinement of the work already in progress.

LOINC in collaboration with HL7 might recommend the addition of global positioning

system data and other relevant information from “field samples”.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet2

Domain Title(s) and Team Lead

Medications
Steven Brown MD, Department of Veterans Affairs

Scope

Domain/Sub-domain	In-Scope (Y/N)
Active Ingredient	Y
Clinical Drug including dosage form as administered	Y
Manufactured Dosage Form	Y
Drug product, including finished dosage form	Y
Medication Package	Y
Labeling Section Headers	Y
Special Populations	Y
Drug Classifications	Y
Adverse Events	N
Dosage & Administration	*N*
Indications	*N*
Contraindications	*N*
Pharmacokinetics & Pharmacodynamics	*N*

The Medications Group addressed each sub-domain separately. Accordingly, this report will describe Alternatives, Final Recommendations, Acquisition, and Conditions for each. Content coverage was a key evaluation criterion for each sub-domain and is felt to be adequate for each recommended terminology. Sub-domains that did not have any alternatives with adequate content coverage were deferred.

2 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

Sub-Domain

Active Ingredients. An active ingredient is a substance responsible for the effects of a medication. Frequently, an active ingredient is a known chemical substance. Known chemical substances may be called by the base substance (e.g. propanolol), or by a base substance – salt combination (e.g. propanolol hydrocloride). In certain instances the structure of the ingredient is not known precisely. For example, beef gelatin is a complex molecular mixture defined by the process used to create it.

Alternatives Identified

FDA Established Names
United States Adopted Names (USAN)
United States Pharmacopoeia National Formulary of drug substances and pharmaceutical ingredients (USP-NF).
Chemical Abstracts Service (CAS) number
MolFile chemical structure representation and code
International Union of Pure and Applied Chemists (IUPAC) chemical name.
Other approved names including British Approved Names (BAN), Japanese Approved Names (JAN) and International Nonproprietary Names (INN)

Final Recommendation

Primary Standard: FDA Established Name for active ingredient & FDA Unique Ingredient Identifier (UNII) codes. This selection was made because of the widespread use and free availability to the public of these names and the impending free availability of authoritative UNII codes that are in the public domain from the FDA through NLM. Until UNII Codes are available, the subgroup declines to recommend a code number scheme for active ingredients.

Comment [WAH1]: There is no such thing as a "USAN generic name", just a USAN. These may be found in the publication entitled "The USP Dictionary of USAN and International Drug Names". In this publication, the USAN name is **bolded** and has the [year] that it was adopted by USAN in brackets. There are many OTHER entries in this publication that are not USAN, such as USP, NF, INN, BAN, JAN and code names. It also contains some pending USAN names.

Secondary Standards in order of precedence
USP-NF name& UNII codes
USAN name and UNII code
INN names & UNII codes
IUPAC chemical names and UNII codes
Common name and UNII codes

Comment [WAH2]: What is a 'laboratory name"? 21 CFR 809.30 (e) defines a "laboratory name" as the name of the laboratory that develops an in-house test using the analyte specific reagents.

Acquisition

FDA Established Names

FDA Established Names are in the public domain, and are administered by the FDA with input from the manufacturer, the USAN council, and the USP.

UNII Codes

The FDA developing an electronic repository listing all medication ingredients used in the United States. Each will have a unique ingredient identifier (UNII) code based on molecular structure, manufacturing process, and/or other characteristics. The FDA and the NLM are collaborating to make the ingredient information repository, including all publicly available medication ingredients, structures, Molfiles, and names, available to the public at no cost.

Conditions

Until UNII Codes are available, the subgroup declines to recommend a code number scheme for active ingredients. The group expects an initial publication of 2000 UNII codes to be available in 2003.

Sub-Domain

Clinical Drug including dosage form as administered. A "clinical drug" is a name for a pharmaceutical preparation consisting of its component(s), defined as active ingredients and their strength, together with the dose form of the drug as given to the patient. For example, an amoxicillin 250 milligram oral tablet is a clinical drug. It expresses the equivalence of pharmaceutical preparations at a generic level, in the form in which medications are prescribed for the patient.

Alternatives Identified

The Semantic Clinical Drug (SCD) of RxNorm, as distributed in the Unified Medical Language System
Core clinical drug portions of SNOMED CT
NNDF plus produced by First Databank
The MediSource Lexicon produced by Multum Informmation Services
DRUGDEX produced by Micromedex
Master Drug DataBase produced by Facts and Comparisons

Final Recommendation

The CHI Medications subgroup has identified the Semantic Clinical Drug (SCD) of RxNorm, a portion of the UMLS as the most promising candidate for a CHI standard for clinical drug nomenclature. Because RxNorm is still under development, it is recommended on a provisional basis.

Acquisition

Free distribution via NLM

Conditions

RxNorm is recommended on a provisional basis because still under development.

Sub-Domain

Manufactured Dosage Form. A manufactured dosage form is the way of identifying the drug in its physical form. A 1999 Food and Drug Administration (FDA) Draft Guidance for Industry states, "A dosage form is the way of identifying the drug in its physical form. In determining dosage form, FDA examines such factors as (1) physical appearance of the drug product, (2) physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, (4) frequency of dosing, and (5) how pharmacists and other health professionals might recognize and handle the product.

Alternatives Identified

Approved Drug Products with Therapeutic Equivalence Evaluations (Appendix C of FDA's "Orange Book")
FDA/CDER Data Standards Manual
Health Level Seven, Inc.

Final Recommendation

FDA/CDER Data Standards Manual

Acquisition

All dosage form terms are readily available through the FDA's website, and are in the public domain.

Conditions

Sub-Domain

Packaged drug product. A drug product is one or more finished dosage forms, each of which contain one or more ingredients.

Alternatives Identified

FDA's NDC Product Name/Code
First Data Bank
Drug Facts and Comparisons
Micromedex/ Physician's Desk Reference

Final Recommendation

Food and Drug Administration's (FDA) National Drug Code (NDC) Product Name/Code. We would also like the full Council to encourage the FDA to improve and revise NDC codes and NDC code generation processes in an expeditious fashion to address well-known issues.

Acquisition

Product names/codes are readily available through the FDA's website, and are in the public domain.

Conditions

Sub-Domain

Medication Package. A drug package is, generally, any container or wrapping in which any drug is enclosed for use in the delivery or display of such commodities to retail purchasers. If no package is used, the container shall be deemed to be the package. It does not include: (a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors; (b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or (c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i). (d) Containers used for tray pack displays in retail establishments. (e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part."

Alternatives Identified

Only one option was found, and that is the package name/code developed and used by FDA in its CDER Data Standards Manual.

Final Recommendation

Package name/code as defined in the FDA/CDER Data Standards Manual

Acquisition

All package terms are readily available through the FDA's website, and are in the public domain.

Conditions

Sub-Domain

Labeling Section Headers. Product "labeling" includes information for the safe and effective use of the product. For prescription drug products, this is the information contained in the FDA regulated package insert or prescribing information, which includes all written, printed, or graphic matter accompanying a drug product 3 described in 21CFR 201.57

Alternatives Identified

No other vocabulary/terminology for drug prescribing information exists containing the content of this specification and the exchange capabilities. Therefore no other standard specification was considered. The terminology may be utilized in part or in its entirety, offering flexibility to users.

Final Recommendation

The FDA sponsored LOINC Clinical SPL section terminology now acheiving approval status within HL7 .

Acquisition

LOINC terminologies and code sets are non-proprietary.

Conditions

3 Terms defined in the glossary (see 4. Glossary) are cited in double quotes on first mention within this document. Acronyms are not quoted but are expanded in the glossary.

Sub-Domain

Special Populations. Regulated drug product information is intended to be the comprehensive prescribing information for the safe and effective use of drugs. In product labeling considerations of differences in response in special populations is characterized in many parts of product labeling. There may be differences noted in dosage, contraindications, warning and other sections of drug product labeling. These sub-population differences described in labeling are based upon evidence provided by the product sponsor either from clinical studies or post-marketing adverse events.

Alternatives Identified

OMB Directive 15, 1997; FDA Guidance on the Collection of Race and Ethnicity Data in Clinical Trials (includes international participants)
HL7 Race:
HL7 Ethnicity:
HL7 Native entity:
CDC – Detailed listing and codes for race and ethnicity:
ISO
X12
FIPS Federal information processing standards
Health Level Seven Administrative Gender and Gender Status
FDA/International Conference on Harmonization on Age classifications
EMEA classification
SNOMED -
DSM4
MeSH
CPT
Other(s)

Final Recommendation

HL7 vocabulary tables for the characterization of race and ethnicity and gender. Numerous other areas deferred. This recommendation is identical to that for the CHI Demographics domain and differences, if any, should be reconciled.

Acquisition

Non-proprietary, available via HL7

Conditions

Sub-Domain

Drug Classifications. Drug classifications are hierarchical structures to categorize each medication. There are multiple clinically relevant methods for classifying medications, including mechanism of action, physiologic effects, intended therapeutic use, FDA approved indications, chemical structures, and other pharmacological properties. Relevant non-clinical medication classification schemes also exist. Classification schemes may be applied to one or more different types of medication-related substances. (e.g., active ingredients and packaged products). The most desirable classification scheme can only be determined by the intended use of the classification.

Alternatives Identified

National Drug Code Directory Classification system maintained by FDA
The World Health Organization ATC system
AHFS
USP
Multum
First Databank
NDF RT
Galen
Many many others

Final Recommendation

NDF-RT classification schemes for mechanism of action and physiologic effect
Numerous other areas deferred

Acquisition

NDF-RT classification schemes for mechanism of action and physiologic effect are freely available from the Department of Veterans Affairs, and will be made available via the NLM's Unified Medical Language System

Conditions

No conditions on the two recommended classification schemes. On the overall topic of classification schemes, a disclaimer recognizing that many classification needs will not be met by the CHI partial recommendation is issued.

Consolidated Health Informatics Initiative
Final Recommendation Information Sheet4

Domain Title(s) and Team Lead

Immunizations: Jason Goldwater, CMS

Scope

The implementation of a data standard for immunizations would provide an organized and streamlined means of communicating between Federal partners by offering a real-time means of transferring information regarding immunization encounters, vaccine events, patient records and other immunization-related information. Additionally, a common vocabulary would allow direct interfacing with multiple facilities within the Federal sector, regardless of location or size. This would enhance immunization surveillance activities, give more robust data with respect to patient safety, would standardize communication to/from providers/users of vaccine information such as primary care physicians and schools, and would provide an up-to-date standardized method of communication to keep vaccination records current and complete. This standard was divided into two phases; the first phase dealt with the recommendation of a messaging standard, and the second phase dealt with the selection of a clinical terminology..

No subdomains were identified.

Alternatives Identified

HL7 (Health Level 7)
SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms)

Final Recommendation

For the messaging standard, HL7 2.4, and future versions, as defined by CDC in the Immunization Guide (currently version 2.1) for Immunization Data Transactions using Version 2.4 of the Health Level Seven (HL7) Standard Protocol – Version 2.4 (September 2002) available at http://www.cdc.gov/nip/registry. For the clinical terminology, the conditional recommendation is to use the CVX (clinical vaccine formulation) and MVX (manufacturer) codes from HL7, and to identify sub-domains, such as adverse events, that will be revisited within 12-18 months to determine whether

4 Information Sheet designed specifically to facilitate communication between CHI and NCVHS Subcommittee on Standards and Security resulting from May 20, 2003 testimony. CHI may seek assistance to help further define scope, alternatives to be considered and/or issues to be included in evaluation process.

an appropriate, and robust, terminology exists to fulfill those data needs. These recommendations will be aligned with those determined by the Medications workgroup, and may utilize a number of reference terminologies, such as MedDRA, RxNorm, etc.

Range of Coverage

The HL7 standard for immunization data transactions, as promulgated by CDC, is complete. They have defined the immunization messages described above, and organizations using this standard have removed "Z" segments from their data transactions. This removes the possibility of uniquely defined elements being removed from the transaction, which limits flexibility with the standard, but creates a common vocabulary that is interoperable with any system. The standard can be implemented at the present time. Additionally, CDC also maintains and updates the CVX and MVX code sets that are utilized by a number of healthcare organizations.

Acquisition

HL7 is created through a consensus-based method in which a group of volunteers representing interested parties works in an open process to create a standard. The data standards are created and refined in subsequent versions. HL7 Version 1.0 was published in September 1987; Version 2.3.1, which is currently used with immunization data transactions, was published in March 1997. There is no use license with this standard; it is available for any healthcare organization to use.

Conditions

This is a conditional recommendation based on the following:

From 1995 through the spring of 1999, the National Immunization Program, Centers for Disease Control and Prevention, worked with Kaiser Permanente, Indian Health Service, and several states with immunization registries, including California, Georgia, Illinois, Michigan, and New York, to develop a standardized way for handing immunization data exchange within HL7 version 2.3.1. This culminated in the publication of the "Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol," initially in June 1999, subsequently updated as version 2.4 in September 2002. The guide itself, separate from the HL7 standard, is currently versioned at 2.1. This implementation guide details several message formats, a core data set, and mentions several external code sets (including clinical vaccine formulation and manufacturer codes – CVX and MVX codes, respectively). These components are intended to allow the electronic sharing of immunization data between separate and otherwise disparate entities (the need

specifically described in the CHI Immunization Team's purpose statement). In addition to coordinating the development of the implementation guide and promoting its use in various states and organizations, CDC has been designated by the HL7 organization as the "keeper" of the CVX and MVX code sets.

This HL7-based system, including both messaging and vocabulary standards, is now widely implemented. In these implementations, the HL7 messaging and vocabulary standards have been found to be sufficient to allow various organizations, public and private, to share immunization data, improving our ability to assess the vaccination status of individuals and population groups and to keep vaccination records current and complete. Because of this, the CHI immunization team conditionally recommends that CHI adopt the HL7 messaging standards *and* CVX and MVX external code sets for immunizations.

The workgroup acknowledges that while the HL7 code sets and the domains they address are sufficient today for the limited purpose of exchanging immunization information, they will not be adequate to completely meet future needs as defined by the NCVHS Subcommittee on Standards and Security in its Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information, July 6, 2000. To meet these more ambitious purposes (e.g., to facilitate the development of decision support; reduce the costs of developing and implementing healthcare applications; ensure more consistent interpretation of categorizations and term relationships both within and among organizations, as well as across applications; facilitate our ability to assess immunization coverage for populations; allow healthcare organizations to better integrate their various IT applications into one system; etc.) and to address the full informational content of the immunization realm, this information will need to be subsumed within a more comprehensive and fully configured drug reference terminology, such as RxNorm, as will likely be espoused by the NCVHS. The CHI cannot recommend a more replete terminology such as this for current adoption, however, because one is not yet sufficiently developed.

Additionally, the CHI Immunizations Group also believed that the immunization-messaging standard applied specifically to the encounter, while the vocabulary directly applied to the drug/biologic used in the immunization delivery. Drugs are defined as those products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, manifestations or symptoms of disease or alter structure/function of the body were considered the area of initial interest[5]. This definition encompasses products represented by a single molecular entity and more complex products such as biologicals, including vaccines. As such, the CHI Immunizations workgroup should align itself with the Medications workgroup where product related information standards are being developed. Labeling/product information for biologics, including vaccines, can be regulated under the same sets of regulations for drugs, such as adverse events.

The CHI Medications group reviewed a large number of potential candidate

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5 FD&C Act Section 503

terminologies for representing drug product information. One criterion, respect for existing regulatory authority, bears special mention. The FDA is the United States regulatory authority for approving the safe and effective use of drug products in the US, and is collaboratively responsible for national and international harmonization of a number of drug-related issues. Product information, including the naming and coding of medications and their associated products, packaging, and other descriptive information is an FDA regulatory responsibility. The CHI medications group, as well as the Immunizations group, recommendations reflect this authority. While a number of medication-related terminologies include FDA determined and sanctioned names, selecting non-FDA terminologies, as government standards would effectively usurp FDA's legal role. CHI medication group selections that are not solely administered by FDA, such as LOINC names for label section headers, have significant FDA input nonetheless. Therefore, these conditionally recommended standards should be revisited in 12-18 months when the FDA electronic information models have been further developed. Some of the sub-domains of information to be analyzed include: contraindications, adverse events and dosage and administration, to name a few.