

Template for comments and secretariat observations

Date: 20 March 2020	Document: ISO DIS 27269	Project: ISO TC215 WG1
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MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
US				ge	<p>The International Patient Summary (IPS) is an important Electronic Health Record (EHR) and Health Information Technology (HIT) Standard that includes crucial data for use in patient care, interventions and clinical decision making. Subsequent comments result from findings of the Health Level Seven (HL7) Reducing Clinician Burden Project Team in their assessment of the substance, extent and impact of clinician burden.</p> <p>Clinicians who receive patient summaries are often:</p> <ul style="list-style-type: none"> • Overwhelmed by a plethora of conflicting and/or duplicative fragments of data from many sources (information overload) • Unable to establish confidence in the trustworthiness, accuracy and integrity of data content, including fidelity to source • Unable to determine chronology and timeliness of data content • Unable to establish authorship of data content (including author's role and credentials) • Unable to ascertain provenance of data content and discrete elements • Unable to verify context (including vital inter-relationships) of clinical data content • Unable to establish confidence in externally-sourced content sufficient to allow such content to be fully integrated into their local health record and instead must keep it segregated, managed and accessed separately <p>In addition to the needle in the haystack problem (i.e., finding gold nuggets in an enormous avalanche of data fragments), clinicians are routinely confronted with patient summary content that is not concise or relevant, not obviously</p>	<p>To address the challenge of clinician burden, the IPS Standard must address key issues regarding how it is generated by the source/sending system and how it is captured, maintained and rendered to the ultimate patient summary user (e.g., clinician) by the receiving system.</p> <p>[See comments and proposed changes in the rows following.]</p>	

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					<p>trustworthy, not timely, not easily rendered in full context, and/or otherwise usable, useful, applicable or action-able as the basis for immediate uptake in patient care, interventions and decision-making.</p> <p>The burden also takes the form of numbing the mind, wasting valuable time and the ever-present fear of missing some crucial bit of information that might thus increase liability and pose risks to patient health and safety.</p>		
US				te	<p>Summaries vs Snapshots</p> <p>Distinguishing "patient summaries" from "patient record snapshots". The challenge of the IPS is that it describes not a patient summary but rather "snapshot" of what is deemed the latest patient information extracted from an Electronic Health Record (EHR) or other system. A "summary" instead would require that information is being summarized (summed up), following a process where the information is first captured, then aggregated (assembled/ combined) and evaluated (assessed/analyzed), from discrete element(s) having (possibly) been captured at multiple times, at (possibly) multiple locations, from (possibly) multiple sources/authors and highlighting the key values. Also, having a point or period of validity, i.e., "this summary reflects information captured, aggregated and summarized in the time frame of [minutes(s), hour(s), day(s), week(s), month(s)]".</p> <p>Objective: To reduce clinician burden (RCB) by designating whether an information set is a "patient summary" (intelligently-generated compilation/summarization of data over a specified period of time) or rather a "patient record snapshot" (data dump at a point in time).</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system conveys a (header) notation of whether the patient summary is really a summary or rather a snapshot.</p> <p>2) the receiving system captures, maintains and renders this notation to the ultimate patient summary user (e.g., clinician).</p>	

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US				te	<p>Composed by Human or Assembled by Software Algorithm Distinguishing patient summary content specifically:</p> <ul style="list-style-type: none"> • Composed by a Human Author; versus • Assembled by Software Algorithm <p>Patient summaries generated and transmitted in conjunction with referrals or care transitions are often composed by a human author (e.g., a clinician) who selects particular data content elements/sets to be included.</p> <p>Objective: To reduce clinician burden by designating data composed by a human author versus assembled by software algorithm</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system creates/conveys a notation of patient summary content composed by a human author versus that assembled by software algorithm, at the level of the entire PS (instance), at the level of a PS section (instance) and/or at the level of a PS element (instance).</p> <p>2) the receiving system captures/maintains/ renders this notation to the ultimate patient summary user (e.g., clinician), whether assembly or composition occurs as a function of the source and/or receiving system.</p> <p>3) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted content may include element(s) assembled by software algorithm and not reviewed/verified by a human author).</p>	
US				te	<p>Duplication of Content Distinguishing patient summary content specifically:</p> <ul style="list-style-type: none"> • Sourced by the sending system; versus • Sourced elsewhere then copied into the patient summary <p>Objective: To reduce clinician burden by identifying and/or suppressing potential data duplication</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system creates and conveys a notation of patient summary content captured directly by the sending/source system versus external content (sourced elsewhere) and previously imported into such system.</p> <p>2) the receiving system captures, maintains and renders this notation to the ultimate patient summary user (e.g., clinician).</p> <p>3) the receiving system provides the ability to hide (constrain) duplicate patient summary content element(s) according to scope of practice and/or organizational policy and after analyzing the content of two or more patient summary instances.</p>	

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US					<p>Known as to Recipient/Purpose of Use - or Not</p> <p>Distinguishing patient summary content where:</p> <ul style="list-style-type: none"> • The recipient and/or purpose of use is known (to the source/sender); versus • The recipient and/or purpose of use is unknown (to the source/sender) <p>Objective: To reduce clinician burden by targeting patient summary content to a specific recipient and/or for an intended purpose of use, including principles of "minimum necessary" and/or "need to know"</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) if the recipient and/or purpose of use is known, the source/sending system creates/conveys patient summary content limited to "minimum necessary" and/or "need to know" conventions/ rules.</p> <p>2) the source/sending system creates and conveys a notation in the patient summary (header) indicating that content was generated knowing the specific recipient and/or purpose of use or not.</p> <p>3) the receiving system captures, maintains and renders patient summary content including notation of the targeted recipient and/or purpose of use.</p> <p>4) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted content may include elements pertaining to a particular recipient type or purpose of use).</p>	

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US				te	<p>Assured Identity Verifying patient summary content is associated with a patient (based on his/her identifiers and identifying characteristics) such that a trusted level of confidence/certainty has been achieved</p> <p>Objective: To reduce clinician burden by ensuring confidence in the relationship of patient summary content and the identity of the associated person (patient, subject of care)</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems determine the identity of the person who is subject of patient summary content, including the set of matching characteristics utilized and thus the level of confidence/certainty in the match.</p> <p>2) the source/sending and receiving systems capture and maintain criteria for levels of confidence/certainty, for person identity matching and management, according to scope of practice and organizational policy.</p> <p>3) the receiving system captures, maintains and renders patient summary content given the subject person is affirmatively identified to a specified level of certainty.</p>	
US					<p>Known as to Who did What When Where and Why Verifying how patient summary content is associated with actions taken - i.e., actions taken to support individual health and to provide healthcare – and specifically who did what when where and why</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the relationship of content elements (data) with clinical (and other) actions taken</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system renders patient summary content elements showing their capture in context of actions taken (who did what when where and why).</p> <p>2) the receiving system captures, maintains and renders patient summary content elements in context of actions taken (who did what when where and why).</p> <p>3) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to who did what when where and why and based on scope of practice and/or organizational policy (e.g., unwanted content may include elements associated with particular who's, what's, when's, where's or why's).</p>	

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US				te	<p>Known Provenance Verifying how patient summary content is associated with its source and provenance ("source of truth"), with traceability to point of origination: be it human, device or software. Including who captured (human, device or software), what was captured (data content and context), when captured (date/time), where captured (physical location, network address, device ID) and why (purpose, rationale)</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the relationship of content elements (data) and its provenance</p>	[See proposed change - one row above.]	
US				te	<p>Known Clinical Context Verifying how patient summary content maintains its clinical context and vital inter-relationships with/between (e.g. and as applicable):</p> <ul style="list-style-type: none"> Problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations, assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, care plans and status Content elements and context/purpose of capture: e.g., blood pressure, its measurement (systolic, diastolic), its unit of measure (mm/Hg), its reason for capture, its context of capture (sampling site, sampling method, patient position, at rest/during/post exercise...) <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the relationship of content elements (data) and its clinical context</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render patient summary content element(s) bound to corresponding context element(s).</p> <p>2) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted elements may include those that lack certain corresponding context element(s)).</p>	

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US				te	<p>Known Accountability for Authorship Verifying if patient summary content has an accountable human author (with role and credentials)</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the relationship of content elements (data) and its accountable (human) authorship</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render patient summary content along with accountable human authorship elements including role and credentials, as applicable</p>	
US				te	<p>Known as to Chronology Verifying patient summary content in terms of time orientation (date/time of occurrence, chronology, sequence), and in terms of:</p> <ul style="list-style-type: none"> • What has happened: past, retrospective • What is now in progress: present, concurrent • What is anticipated, planned: future, prospective <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the relationship of content elements (data) to date/time chronology</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render patient summary content element(s) along with date/time chronology</p> <p>2) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted elements may include dates/times outside a given range or those lacking date/time or chronological orientation)</p>	
US				te	<p>Known Verification - or Not Distinguishing which patient summary content elements been formally verified (or not) with evidence of verification, verifier(s), date(s)/time(s) and method(s) - e.g., data verified after being captured via automated devices/software or data verified via a formal reconciliation process (medications, allergies, problems/diagnoses)</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in content elements (data) which has been formally verified</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render patient content element(s) along with verification details such as verifier(s) ID, verification date(s)/time(s) and verification method(s)</p> <p>2) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted elements may include those lacking verification and/or related details)</p>	

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US				te	<p>Known to be Updated (from Original Instance) – or Not</p> <p>Distinguishing which patient summary content element(s) have been updated (or not) from their original values with evidence of update, who updated, prior state(s), effective date(s)/time(s) - e.g., clinical data values whose prior state might have triggered one type of clinical decision versus current values which might have triggered another (and potentially opposing) type of clinical decision</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in content elements (data) which has been updated from a previous state or value</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render patient summary content element(s) along with update details such as updater(s) ID, update date(s)/time(s)</p>	
US					<p>Known to be Unaltered (from Source) – or Not</p> <p>Distinguishing which patient summary content element(s) have remained unaltered (maintaining fidelity to original/source content) or have been altered/transformed from source content/representation</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in content elements (data) which has remained unaltered from its source representation (or not)</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system tags patient summary content element(s) that have remained unaltered from their source representation</p> <p>2) the source/sending and receiving systems capture, maintain and render patient summary content element(s) that carry both: a) the original (unaltered) source representation; alongside b) values transformed thereafter (e.g., element(s) transformed from one code/value set or human language to another)</p>	

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US				te	<p>Known to be Complete - or Not Distinguishing which patient summary content element(s) are complete versus partial/pending</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in data which is complete (or not)</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system tags patient summary content element(s) that are complete versus those which are partial/pending</p> <p>2) the receiving system captures, maintains and renders patient summary content element(s) along with tags indicating whether complete or partial/pending</p> <p>3) the receiving system provides the ability to hide (constrain) unwanted patient summary content element(s) according to scope of practice and/or organizational policy (e.g., unwanted elements may include those which are incomplete)</p>	
US				te	<p>Known to be Comparable with Like Data – or Not Distinguishing which patient summary content element(s):</p> <ul style="list-style-type: none"> • Have characteristics in common with like data; • Allowing ready comparison (correlation/trend-ability) with like data. <p>Such data characteristics may include similar/same context and data definition - e.g., element name(s), data type(s), range, input/display/storage format, unit(s) and scale of measure, method and purpose of capture</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in the ability to establish trends and draw comparisons between like content element (data) occurrences over time</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving system capture, maintain and render patient summary content element(s) within their typical context (of corresponding elements)</p> <p>2) the source/sending and receiving systems capture, maintain and render patient summary content element(s) along with their specific data definitions: element name(s), data type(s), range, input/display/storage format, unit(s) and scale of measure, method and purpose of capture, etc.</p>	

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US				te	<p>Known to be (Sourced as) Structured – or Not Distinguishing which patient summary content element(s) are sourced as structured (coded) content or not</p> <p>Objective: To reduce clinician burden by ensuring confidence/clarity in data which was sourced as structured (including coded) content or rather unstructured (including narrative or free-text)</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending system tags patient summary content element(s) that were sourced as structured versus unstructured</p> <p>2) the source/sending and receiving systems capture, maintain and render coded patient summary content element(s) along with the coding convention (vocabulary/terminology set or value set) and version</p> <p>3) the receiving system captures, maintains and renders patient summary content element(s) along with tags indicating whether sourced as structured versus unstructured</p>	
US				te	<p>Known as to Method of Incorporation into Local Record Establishing if/how externally-sourced patient summary content is integrated (or not) into the receiver's health record (e.g., EHR)</p> <p>Objective: To reduce clinician burden by ensuring only trusted, timely, relevant, useful, usable and action-able content is incorporated directly into the local patient health record</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the receiving system captures and maintains inclusion criteria for incorporation of externally-sourced data content into a patient health record based on scope of practice and organizational policy</p> <p>2) the receiving system provides the ability to determine whether externally-sourced data content is incorporated into the patient health record based on inclusion criteria</p> <p>3) the receiving system provides the ability to capture, maintain and render externally-sourced data content separately from the patient health record so as to offer a true representation of inbound data content but at the same to avoid jeopardizing the integrity of the patient health record if such external content is potentially flawed or otherwise less than fully trusted</p>	

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US				te	<p>Medication List Reconciliation Establishing if/when the patient's current medication list was reconciled, including the human author (with role and credentials), when it occurred, where it occurred, whether it included prescribed as well as over-the-counter medications</p> <p>Objective: To reduce clinician burden by enumerating details of the most recent (as known to the patient summary source) medication list reconciliation event, such that when appropriate, this event, its results and conclusions can be referenced and not repeated</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render medication list reconciliation events, including who (reconciling person, their role and credentials), what (medications captured and included), when, where</p>	
US				te	<p>Medication Allergy List Reconciliation Establishing if/when the patient's current medication allergy list was reconciled, including the human author (with role and credentials), when and where it occurred</p> <p>Objective: To reduce clinician burden by enumerating details of the most recent (as known to the patient summary source) medication allergy list reconciliation event, such that when appropriate, this event, its results and conclusions can be referenced and not repeated</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render medication allergy list reconciliation events, including who (reconciling person, their role and credentials), what (medication allergies captured and included), when, where</p>	
US				te	<p>Allergy List Reconciliation Establishing if/when the patient's current allergy list was reconciled, including the human author (with role and credentials), when and where it occurred</p> <p>Objective: To reduce clinician burden by enumerating details of the most recent (as known to the patient summary source) allergy list reconciliation event, such that when appropriate, this event, its results and conclusions can be referenced and not repeated</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render allergy list reconciliation events, including who (reconciling person, their role and credentials), what (allergies captured and included), when, where</p>	

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US				te	<p>Problem/Diagnosis List Reconciliation Establishing if/when the patient's current problem/diagnosis list was reconciled, including signs and symptoms if appropriate and including the human author (with role and credentials), when and where it occurred</p> <p>Objective: To reduce clinician burden by enumerating details of the most recent (as known to the patient summary source) problem/diagnosis list reconciliation event, such that when appropriate, this event and its results and conclusions can be referenced and not repeated</p>	<p>Although not evidenced in current Standard language and yet to address this burden reduction objective, please specify how:</p> <p>1) the source/sending and receiving systems capture, maintain and render problem/diagnosis list reconciliation events, including who (reconciling person, their role and credentials), what (problems, diagnoses, signs and symptoms captured and included), when, where</p>	

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