Svenska Läkaresällskapet

2013-04-12

SIS, Swedish Standards Institute
Sankt Paulsgatan 6
SE-118 80 Stockholm

Remiss SIS 10537 – Hälso och sjukvårdsinformatik-Health informatics – System of concepts to support continuity of care (ISO/DIS 13940:2012)

Svenska Läkaresällskapet (SLS) är en politiskt och fackligt obunden organisation, som arbetar för förbättrad hälsa och sjukvård med patientens bästa för ögonen.

Efter hörande av SLS sektioner har Kommittéen för språkvård lämnat yttrande på standardförslaget. Se bifogad svarsblankett.

För Svenska Läkaresällskapet

Stockholm den 12 april 2013

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SIS/TK 334, Hälso- och sjukvårdsinformatik
Svar på SIS-remiss 10537
avseende prEN ISO 13940

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Uppgifter om svarslämnaren

☒ Företag/Organisation/Myndighet ☐ Enskild person

Företag/Organisation/Myndighet: Svenska Läkaresällskapet

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Remissvar

- ☐ Avstår
- ☐ Tillstyrker utan kommentarer
- ☒ Tillstyrker med kommentarer
- ☐ Avstyrker med motivering
- ☐ Har erfarenhet inom det område förslaget täcker
- ☐ Har tillämpat förslaget
- ☐ Ej berörd
- ☐ Kommentarer till föreslagen svensk titel

Datum

Svarslämnare: Svenska Läkaresällskapet 2013-04-12

Kommentarer på: SIS-remiss 10537 **Förslag: prEN ISO 13940**

1	2	(3)	4	5	(6)	(7)
ID	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/Note** (e.g. Table 1)	**Type of comment[1]**	**Comment (justfication for changes)**	**Proposed change**	**Fylls i av SIS**
SE	0	0.8.4, Fig 4	ed	Output health state is the most important input to the clinical process evaluation. The health conditions resulting from treatment activities are logically input to health care evaluation.	An arrow from Output health state to clinical process evaluation should be added. The current arrow from output health state to healthcare evaluation could be redirected to come from health condition after treatment – or such an arrow added with the current arrow left unchanged .	
SE	3	Entire clause	ed	Notes have been labelled "NOTE # to entry", which is in conflict with the ISO/IEC Directives, Part 2, 2011, even if ISO 10241-2:2011 actually uses that long notation. There is no normative statement about the notation of notes either in ISO 704 or ISO 10241, and for that reason the Directives have to be considered as normative.	Delete “to entry” in notes.	
SE	3	3.3	te	A definition must not begin with an indefinite article	Delete initial "a", change definition to: promise to provide activities according to acceptance of a request or of an assignment	
SE	3	3.5	ed	The word "as" seemes to have been introduced by mistake, has no meening in the definition	Delete "as", change definition to: agreement, approval, or permission to some act or purpose given voluntarily by a competent person	
SE	3	3.9	ed	The term entry has been misprinted	Change entire term entry to: **3.9 entity** concrete or abstract thing of interest, including associations among things [ISO 18308:2011]	
SE	3	3.12	ed	The term entry has been misprinted	Change entire term entry to: **3.12 information model** formal model of a bounded set of facts, concepts or instructions to meet a specified requirement. [ISO 10303-1:1994]	
SE	3	3.19	ed	Space erroneously inserted before first letter of definition	Delete space before "human" in the definition	

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SE	3	3.20	ed	In the definition, the word "person" refers to term entry 3.19	Change "person" to italics and the definition to: role undertaken by a *person*	
SE	3	3.22	ed	A definition must not begin with an indefinite article	Delete initial "a", change definition to: representation of a process	
SE	3	3.28	ed	Misprinting	Insert line feed before NOTE 1.	
SE	5	5.1, UML model	te	Healthcare professionals perceive and manage demands for health care – but support seems not the best expression	Change the name of the relation between healthcare professional and demand for care to “manages”.	
SE	5	5.1, UML model	te	The use of "role" is incomprehensive. The model states that an organization *has* an organization role, but e.g. healthcare organization *is an* (specialisation of) organization role. Undoubtedly, a healthcare organization *is an* organization by simple semantic relation, so a healthcare organization *has* an organizational role. Accordingly, all generic relations from specified roles (organization role and person role) should be associations with the name of *has*. This comment has impact on the definition in 5.2.3, 5.2.4.1.	Change relations in the model according to the comment.	
SE	5	5.2.2	te	The definition includes not only those persons and organizations having a role to provide professional healthcare, which has the effect that healthcare third party, too, is a healthcare provider. The definition uses the word "direct" to exclude the third parties, but that meaning is not obvious. A provider is never an "ad hoc" actor in healthcare but has an expressed task to provide healthcare. Thus, the definition should be more strict.	Suggest the following definition: *healthcare actor* having a task to provide *healthcare*	
SE	5	5.2.3	te	The concept is about persons having roles – not about the roles as such	Change definition to: “*person* having a role in a *healthcare organization*” There are consequent changes to be made in the UML model	
SE	5	5.2.4.1.	te	See comment to 5.1!	Change definition to: *person* who has a role to provide assistance for activities of daily living or social support	

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SE	5	5.2.7	te	Legally authorized proxy will not have the right to order activities (commonly only to demand or accept) but they can deny activities to be performed in the same way that competent subjects of care have. Only health care professionals can order activities after needs assessment.	Change definition to: "person being legally authorized to take decision regarding health care activities on behalf of a subject of care"	
SE	6	6.2.2	te	Several health conditions will be observed in a clinical process. Some of these are considered to be problems and those are the important ones as they represent the indications for activities. Health problem is already indirectly included in the standard in the concept health problem list.	Add a new concept "Health problem" defined as: "health condition considered by a health care as a subject to actions" NOTE 1 Health problem is a specialization of health condition. NOTE2 Health problems can be single observations but are usually more compound as a summary of several observations. Single observations are often criteria for the more compound heatlh condition considered to be a heatlh problem. NOTE 3 All types of health conditions can be specialized as health problems; perceived, assessed or possible conditions. Examples: Diabetes, stroke, heredity for breast cancer.	
SE	6	6.2.2.1	te	A perception by a human health care actor is always based on an observation. If the definition not need to make distinctions between observations and perceptions (non-human and human registrations) the term could be observed instead of perceived.	Consider change term for this concept to "observed condition".	
SE	6	6.2.1.2.1	te	From a clinical perspective it is logical that a further assessment (not only the genesis and/or prognosis) qualifies the concept assessed condition. The assessment of prognosis is partially covered by the concept "prognostic condition" which is the possible resulting condition due to the clinical course. Assessments of the severity of the condition as well as	Change definition of assessed condition to: "observed condition assessed by a healthcare professional concerning the genesis and/or the course, the severity or the impact of the health state of the condition"	

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				the impact on the health state should be included as qualifying that an observed condition is an assessed condition. NB: Is the numbering of this entry correct?	Consequently change note 1 to: ”Assessments of other kinds than concerning the genesis (pathogenesis, reason for etc), the clinical course, the severity or the impact on the health state do not qualify an observed condition to be specialized as an assessed condition”. Change number to 6.2.2.1.1	
SE	6	6.2.2.2.1	te	Information about whether or not considered conditions have been verified is important in clinical practice. Further concepts regarding this should be included.	Add two new concepts as specialisations of considered condition: 1 “concluded condition: considered condition that has been verified by relevant observations”. 2. “discounted/ruled out condition: considered condition that not has been verified by relevant observations”.	
SE	6	6.3.1 and 6.3.2	te	The terms for the concepts named concern and interest should be synonyms. The concept of concern/interest should be considered to represent coherent information about the healthcare-/clinical process. Also the concern should not be circular defined as focusing a concern. The term concern is not defined. The concept concern is dealing with information needed for continuity aspects in healthcare/clinical processes – this should be reflected in the definition. Clinical process interest/concern should be defined as a specialization of health concern. Another concept for a concern related to different parts of a clinical process is needed – that is concern for a healthcare process as another specialisation of health concern.	change definition of health concern to: “information needed for continuity of care for a specific subject of care” NOTE 1 “a concern is an information carrier/container. The concern is the identifier of associated information assessed relevant for the continuity of care in a healthcare-/clinical process.” NOTE 2 “the instances in the real world are represented by the process concepts healthcare- and clinical process with their id. The information about these instances is represented by the concepts for “concern”. And consequently change definition and name of clinical process interest renamed “clinical process concern” to: “health concern for a specifiied clinical process” Add a new concept:	

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					"healthcare process concern" defined as: "health concern for a specified healthcare process". NOTE 1 "a process concern include all relevant information related to that process. This include all health conditions, all healthcare activities and their lifecycles." Change name of clinical process interest to "clinical process concern".	
SE	7	7.2.1.4	te	A contact is a period – the period as such does not establish the clinical process.	Change definition to: "contact during which a clinical process is established"	
SE	7	7.2.3	te	The word "appointment" should not be used in the definition. The phenomenon described is a contact which has been put into a time frame, not the time per se, which gives a quite simple definition.	Change definition to: "scheduled contact"	
SE	7	7.3.1	te	The delay should relate to the scheduled time for the planned activity – the activity could be planned long before scheduled. The delay should be possible to relate to any period of time.	Change definition to: "period of time between the time when a healthcare activity is scheduled and the time when it is started"	
SE	7	7.3.2	te	The formulation is misleading – it is not the condition that is delayed	Change the concept name to: "delay by health condition"	
SE	7	7.3.3	te	The formulation is misleading – it is not the resource that is delayed	Change the concept description to: "delay by resource"	
SE	7	7.3.4	te	The formulation is misleading – it is not the preference that is delayed	Change the concept description to: "delay by subject of care preference"	
SE	7	7.3.6	te	The naming implies only a relation to a clinical process – and that has all episodes – this concept is about all the clinical process.	Change name of concept to: "clinical process episode"	

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SE	8	8.2	te	The involvement of the subject of care should be included in the definition (compare with the definition of contact). Utilizing resources should relate to healthcare activity and should not be needed in the process definition. A health care process should always be related to one or several health issues. The activities in a health care process are not always for the benefit o the subject of care, i.e. when a legally authorized proxy demands care.	Change definition to: “process where a subject of care and healthcare professionals interact in performing healthcare activities addressing one or more health issues for a subject of care”	
SE	8	8.2.1	ed	The definition sentence is malformed	Change definition to: *"healthcare process* encompassing all *healthcare provider activities* and other prescribed *healthcare activities"* NOTE Health care activities included in a clinical process can be health care provider activities, prescribed health self care activities and prescribed healthcare activities performed by other carers.	
SE	8	8.3	te	A workflow is the sequence of the activities – both the planned and how they really were performed. Is scheduled then the correct word??	Change the first word in the definition to “sequence”	
SE	8	8.4	ed	Some mistake in printing – double texts – also non-coordinated activities should be included	Delete the second part of definition and leave: ”activities to direct and control a healthcare organization with regard to quality”	
SE	8	8.5	te	Resources should in general be related to performance of activities – not to processes and it should include healthcare activities in general.	Change definition to: ”activities to direct and control the supply of the resources required to perform healthcare activities”	
SE	8	8.7.2	te	Is the characteristic of re-usable always relevant and does it add any value in the definition?	Delete re-usable from the definition.	
SE	8	8.9	ed	The term management is used for all other types of response or handling – e.g. risk management, resource management or activity management – why not here	Change the term to: adverse event management	
SE	9	9.5	te	The use of the phrase "standardized *care plans*" may	Change definition to:	

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				cause confusion with the concept "standardized care plan template". Actually standardized care plan templates are exactly what you develop using a clinical pathway, giving possibility to a clear definition.	"structured pattern for a *healthcare workflow* to be used in *standardized care plan templates*"	
SE	10	10.2.7.2	te	Subjects of care should be included among actors that can evaluate also processes – not only activities. All evaluations of healthcare processes should be included – not only those done systematically. The current NOTE is probably misworded.	Change definition to: "healthcare activity where the results of a healthcare process are assessed against requirements" change in the current NOTE – healthcare processes should be clinical processes. and add a NOTE: "All types of health care actors including the subject of care can evaluate healthcare processes."	
SE	10	10.2.7.3	te	Subjects of care should be included in actors that can evaluate also processes – not only activities.	Change definition to: "healthcare activity where the effects of a clinical process on the health state of a subject of care are assessed against requirements" NOTE Requirements include the target condition and/or a comparison to the health condition representing the input health state	
SE	10	10.2.8	te	The purpose of the activity is already defined in "healthcare activity".	Delete "for their own sake" from the definition	
SE	10	10.2.11	te	Unnecessary long and complex definition – all healthcare activities are initiated by some healthcare actor. Also the subject of care can initiate automated activities.	Change definition to: "healthcare activity performed automatically by a healthcare device"	
SE	11	11.2.4	te	The definition differs remarkably from previous discussions and is a fundamental and unacceptable change of one of the basic concepts and steps in the	Change definition to: "assessment by healthcare professionals	

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				clinical process. Need for care is the result of a professional assessment as defined in the concept for needs assessment. Subjects of care can not define needs for care but describes their perspectives on required healthcare in demands for care and in the dialogue in the needs assessment. Need for healthcare is the result of the activity Needs assessment and the two definitions must correspond. For clarity the definition and notes for needs assessment is quoted: ”healthcare provider activity where a healthcare professional assesses a subject of care‘s needs for healthcare"	concerning the requirements for healthcare activities in relation to the assessed condition of the subject of care”	
SE	12	12.2	te	The formulation “related to the health of a subject of care” could be interpreted too limiting – a health record contain information about health and healthcare including activities, assessments etc.	Change definition to: “repository of data and information regarding the health of and healthcare for a subject of care”	
SE	12	12.3	te	Unnecessary complicated definition. Data should be sharable also without a continuity facilitator mandate – unnecessary restriction. Why exclusively – if mixed the electronic part still is sharable.	Change definition to: “data repository containing electronic information that could be communicated”	
SE	12	12.4	te	The purposes of the component should not be included in the definition – unnecessary limiting.	Change definition to: ”part of a health record that is identifiable”	
SE	12	12.6	te	The word specific is unnecessary in the naming and in the definition – the specificity is given by what is needed for provision of health care	Delete ”specific” from concept name and definition.	
SE	12	12.8.1	te	The concept should be valid also for non-electronic data – unnecessary limiting. The purposes must be wider than related to contacts – e.g. for assessments and evaluations.	Delete electronic from definition. Change definition to: ”health record extract that provides a synoptic subject of care health data set concerning health	

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					conditions and healthcare activities"	
SE	Annex A	Fig A.2 clinical process model	ed	Output health state is the most important input to the clinical process evaluation. The health conditions resulting from treatment activities are logically input to health care evaluation.	An arrow from Output health state to clinical process evaluation should be added. The current arrow from output health state to healthcare evaluation could be redirected to come from health condition after treatment – or such an arrow added with the current arrow left unchanged .	
SE	Bibliography	Ref [29]	ed	The reference Fogelberg M., Holmberg G., Areblad M., Björkman L., Ehnfors M., Enberg G., Hallberg A., Lundgren P-A., Lundmark T., Midbøe L., Schönström N., Schwieler Å., Sjöberg B., Wallin S-B., Vikström A., *SAMBA – Structured Architecture for Medical Business Activities,* Carelink/Swedish Federation for Medical Informatics (SFMI), 2003, Web document on URL is no longer available on the SFMI site but will be constantly available on URL: http://www.fogare.se/dokument/samba/samba_E__v_3_1.pdf	Change URL to: http://www.fogare.se/dokument/samba/samba_E__v_3_1.pdf	

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