



Joint Initiative on SDO Global  
Health Informatics Standardization



# **Health Informatics – Automatic identification and data capture and labelling – Patient and caregiver Identification**

## **Mid-term report for consultation purpose**

September 2011



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## Purpose of this document

This mid-term report is intended to raise a wide awareness for the expert group's possible solutions.

To assist the expert group in preparing the final solution, a short series of questions is included in this report.



## Amendment History

Version	Date Issued	Brief Summary of Change	Owner's Name/Signature
1.0	25.08.2011	Draft document	CH
1.1	06.09.2011	Final for distribution (minor changes)	CH

This is a controlled document. Only the final version (marked as such) is of relevance outside the expert group.

## 1 Introduction

As of 18 March 2010, the Joint Initiative Council adopted a work proposal which has been submitted to the participating SDOs for evaluation. The six (6) SDOs have confirmed their interest in participating in this work effort, which will be lead by GS1, following the GS1 GSMP procedures. As a second step, the final solution of the assembled expert work group will be presented as an ISO Technical Specification and submitted through the fast track procedure to ISO TC 215.

## 2 The Expert Group

The following experts participated to the group:

### 2.1 Work Group Members

Function	Name	Company / organisation
WG Co-Chair	Christian Lovis	University Hospital Geneva
WG Co-Chair	Ian Shepherd	Synapse Consulting Limited / CEN
WG Member	Paul Ashford	ICCBBA
WG Member	Henri Barthel	GS1 GO
WG Member	Abdelmalek Benelmouffol	University Hospital Geneva
WG Member	Chuck Biss	GS1 GO
WG Member	Jim Bracken	GS1 Ireland



Function	Name	Company / organisation
WG Member	Jeff Chan	GS1 Hong Kong
WG Member	Christy Chen	GS1 Taiwan
WG Member	Daniel Clark	GS1 Canada
WG Member	Cristina De Martini	Zebra
WG Member	Pat Distler	ICCBBA
WG Member	Barbara Dorner	GS1 Austria
WG Member	Siobhain Duggan	GS1 Ireland
WG Member	Kim Ferree	GS1 US
WG Member	Frederique Fremont	C.H.I. Robert Ballanger
WG Member	Anna Gawronska-Blaszczyk	GS1 Poland
WG Member	Jorgen Georgsen	Dept of Clinical Immunology, Odense University Hospita & ICCBBA
WG Member	Christof Gessner	MxDx Consulting / HL7 & IHE
WG Member	Scott Gray	GS1 GO
WG Member	Nathan Habeck	Baxter Healthcare
WG Member	Michaela Haehn	GS1 Germany
WG Member	Andrew Hearn	GS1 GO
WG Member	Christine Hanko	GS1 Hungary
WG Member	Dennis Harrison	GS1 US
WG Member	Karolin Harsanji	GS1 Sweden
WG Member	Gary Hartley	GS1 New Zealand
WG Member	Christian Hay	GS1 Switzerland
WG Member	Tom Heist	GS1 GO
WG Member	Tina Ho	GS1 Hong Kong
WG Member	Nathalie Jabbour	GS1 Australia
WG Member	Brendan Kernan	GS1 Ireland
WG Member	Janice Kite	GS1 GO
WG Member	Ulrike Kreysa	GS1 GO
WG Member	Frederic Law-Dune	GIP-DMP
WG Member	Neil Lawrence	NHS Connecting for Health
WG Member	KC Leung	GS1 Hong Kong
WG Member	Feargal Mc Groarty	St. James's Hospital
WG Member	Sharon McMillan	St Michaels Hospital
WG Member	Ann Mountain Wilson	McGill University Health Centre
WG Member	Alice Mukaru	GS1 Sweden
WG Member	Giada Necci	GS1 Italy



Function	Name	Company / organisation
WG Member	Michael Nusbaum	M.H. Nusbaum & Associates
WG Member	Benjamin Ostman	GS1 Finland
WG Member	Silverio Olivera Paixao	GS1 Portugal
WG Member	Bradley Pedrow	GS1 US
WG Member	Jesper Petersen	GS1 Denmark
WG Member	Pimsiri Pimaiklang	GS1 Thailand
WG Member	Neil Piper	GS1 UK
WG Member	Chris Ranger	NHS Connecting for Health
WG Member	Melvin Reynolds	CEN
WG Member	Jean Sargent	University Southern California, Health Sciences
WG Member	Sue Schmid	GS1 Australia
WG Member	Eugen Sehorz	GS1 Austria
WG Member	Tania Snioch	GS1 Australia
WG Member	Gopal Valecha	GS1 India
WG Member	Thomas Wennebo	GS1 Sweden

## 2.2 Staff Support

Function	Name	Organisation
Modeller		
GDD		
Process Manager	Tom Heist	GS1 GSMP
GS1 Healthcare Expert	Christian Hay	GS1 GO
GS1 MO liaison	Tania Snioch	GS1 Australia
GS1 AIDC Expert	Scott Gray	GS1 GO
GS1 AIDC Expert	Chuck Biss	GS1 GO
GS1 Healthcare Manager	Ulrike Kreysa	GS1 GO
Healthcare Traceability Liaison	Janice Kite	GS1 GO



### 3 Scope

The care delivery process involves a series of Automatic Identification and Data Capture (AIDC) mechanisms to uniquely identify the patient, the caregiver and the healthcare product(s) at the delivery of care to assure patient safety.

Global standards are being created for the uniform AIDC marking and labelling of healthcare products. The objective of this work group is, after considering the business needs surrounding this area, to complete the standards for identification and marking/labelling for the patient and care giver enabling AIDC applications for the care delivery process as well as unique patient identification for other purposes, such as Individual Electronic Health Records (IEHR)

Important work has already been undertaken in the field of Patient identification (ISO TS 22220) and Caregiver identification (ISO TS 27527). That work addresses the management or rules for identification, privacy issues, the handling of demographics, etc. For consistency, terminology from these Technical Specifications is used in the present work item. Therefore:

- The Patient is referred to as the “Subject of Care” (SoC), which includes situations where care is provided to prevent health issues (i.e. vaccination)
- The Caregiver is referred to as the “Individual Provider” (IPr)
- Hospitals and organisations delivering health care services are referred to as “Healthcare Provider”.

### 4 The Business Requirements

#### 4.1 General

The group collected nearly one hundred business requirements, which have been vetted and consolidated into 34 applicable requirements for Subject of Care identification, and 3 additional requirements specific to the Individual Provider.

Initial difficulty remaining within the boundaries defined for the work effort, that is to focus on automatic identification data capture, and not to enter in the data processing, where existing systems, standards and/or solutions exist (i.e. IHE<sup>1</sup> processes was overcome).

#### 4.2 Subject of Care (SoC)

The requirements identified for this effort are:

- Identify globally and uniquely Subject of Care for AIDC purposes

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<sup>1</sup> IHE : Integrating the Healthcare Enterprise, see [www.ihe.net](http://www.ihe.net)



- Decentralize identification management, uniqueness that does not harm privacy
- Indicate multiple or specific instances of a SoC's treatment (i.e. replacement of identification band, etc.)
- Maintain where practical backward compatibility (i.e. taking into account pre-existing GS1 implementations, the embedding of existing identification keys or the linkage to existing identification keys, etc.)

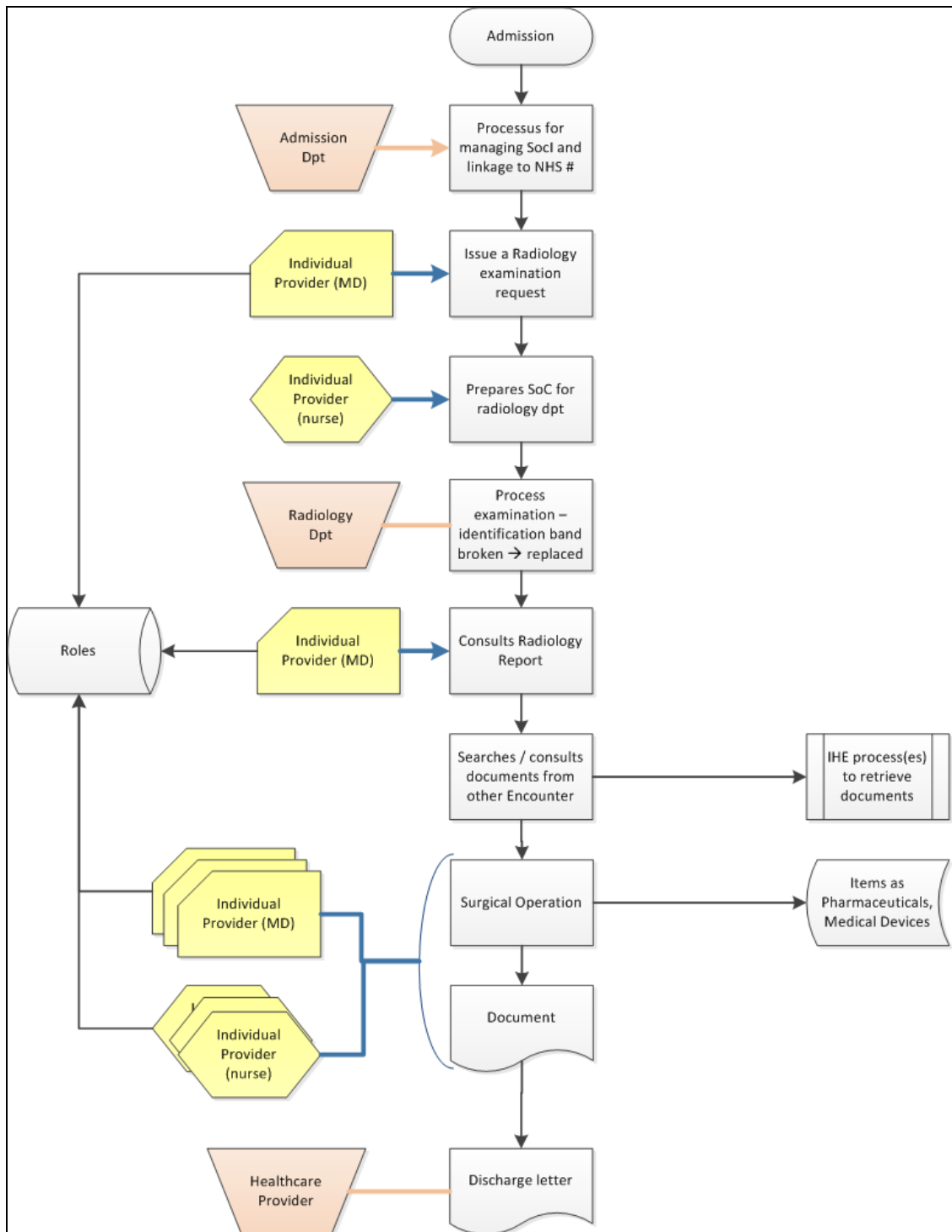
### 4.3 Individual Provider (IPr)

The requirements identified for this effort are:

- Identification of Individual Providers by role,
- Decentralize identification management to secure uniqueness,
- Allow linkage to local rule management systems in place

## 5 Use cases

The expert group has developed two use case examples to illustrate the validated business requirements. As an example:





Use Case ID	UC-1																											
Use Case Name	Subject of Care admitted after an accident (single Healthcare Provider involved)																											
Use Case Description	<p>Mr Jones is entering Hospital X with a broken leg. Mr Jones is known in this hospital as he suffers renal insufficiency and has been treated / examined periodically for years. He also has a NHS number.</p> <p>The hospital registers Mr Jones' admission and issues an identification band with Mr Jones' SoCi. Dr Expert prescribes a radiology examination and requires information about the condition of Mr Jones' renal functions. After successful treatment, the hospital issues a discharge letter for Mr Jones' general practitioner.</p>																											
Actors (Goal)	<p>Admission Department to generate SoCi linked to NHS number.</p> <p>Individual Provider to link SoCi to radiology examination request.</p> <p>Radiology Dept Technician to prepare SoC, proceed to examination and re-issue identification band</p> <p>Radiology Dept to link report ID to SoCi.</p> <p>Individual Provider to access clinical information about chronic disease.</p> <p>Individual Providers proceed to surgical operation on Mr Jones; linkage of pharmaceuticals and medical devices to SoC record.</p> <p>Healthcare Provider to issue discharge letter ID</p>																											
Performance Goals	Un-ambiguous AIDC processes throughout the use case																											
Preconditions	Roles and identifications are available.																											
Post conditions	-																											
Scenario	<p><b>Begins when...</b> Mr Jones arrives at the Healthcare Provider.</p> <p><b>Continues with...</b> the sequence of administrative and clinical steps</p> <table border="1"> <thead> <tr> <th>Step #</th> <th>Actor</th> <th>Activity Step</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Admission Dept</td> <td>Registers Mr Jones' admission, issues SoCi, link this to NHS number, issues identification band</td> </tr> <tr> <td>2</td> <td>Individual Provider (MD)</td> <td>Is identified, including his role. Issues a radiology analysis request for Mr Jones.</td> </tr> <tr> <td>3</td> <td>Individual Provider (technician)</td> <td>Is identified, including his role. Prepares Mr Jones for examination, and has to remove his identification band before the imaging investigation and then reissue a new identification band after the investigation, allowing Mr Jones to be identified by automatically reading his identification band.</td> </tr> <tr> <td>4</td> <td>Radiology Dept</td> <td>Issues a report, with its ID linked to Mr Jones.</td> </tr> <tr> <td>5</td> <td>Individual Provider (MD)</td> <td>Consults radiology report</td> </tr> <tr> <td>6</td> <td>Individual Provider (MD)</td> <td>Searches information about Mr Jones' chronic disease.</td> </tr> <tr> <td>7</td> <td>Individual Providers (MDs, nurses, etc.)</td> <td>Proceed to surgical operation. Report on pharmaceuticals and medical devices used.</td> </tr> <tr> <td>8</td> <td>Healthcare Provider</td> <td>Issues a discharge letter for Mr Jones' following care to be delivered</td> </tr> </tbody> </table> <p><b>Ends when...</b> Mr Jones leaves the Healthcare Provider</p>	Step #	Actor	Activity Step	1	Admission Dept	Registers Mr Jones' admission, issues SoCi, link this to NHS number, issues identification band	2	Individual Provider (MD)	Is identified, including his role. Issues a radiology analysis request for Mr Jones.	3	Individual Provider (technician)	Is identified, including his role. Prepares Mr Jones for examination, and has to remove his identification band before the imaging investigation and then reissue a new identification band after the investigation, allowing Mr Jones to be identified by automatically reading his identification band.	4	Radiology Dept	Issues a report, with its ID linked to Mr Jones.	5	Individual Provider (MD)	Consults radiology report	6	Individual Provider (MD)	Searches information about Mr Jones' chronic disease.	7	Individual Providers (MDs, nurses, etc.)	Proceed to surgical operation. Report on pharmaceuticals and medical devices used.	8	Healthcare Provider	Issues a discharge letter for Mr Jones' following care to be delivered
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## 6 Proposed solutions

The work group has identified potential solutions direction for the previously noted identification needs as noted below.

What is illustrated is not meant to be used for implementation purposes and is provided to indicate the basic technical directions the work group is considering based upon the gathered and agreed to business requirements. When the final solution is approved within the agreed to process for this work effort, necessary detailed changes to the GS1 General Specification will be made to support implementation.

### 6.1 Expert groups’s proposition

The Subject of Care and Individual Provider will be represented by two identification numbers built on the form of an existing GS1 identification “Key”.

Both would follow the format:

Format of the Element String		
Application Identifier	GS1 Company Prefix → ← Service Recipient Number	Check Digit
8018	N <sub>1</sub> N <sub>2</sub> N <sub>3</sub> N <sub>4</sub> N <sub>5</sub> N <sub>6</sub> N <sub>7</sub> N <sub>8</sub> N <sub>9</sub> N <sub>10</sub> N <sub>11</sub> N <sub>12</sub> N <sub>13</sub> N <sub>14</sub> N <sub>15</sub> N <sub>16</sub> N <sub>17</sub>	N <sub>18</sub>

Format of the Element String		
Application Identifier	GS1 Company Prefix → ← Service Provider Number	Check Digit
n n n n	N <sub>1</sub> N <sub>2</sub> N <sub>3</sub> N <sub>4</sub> N <sub>5</sub> N <sub>6</sub> N <sub>7</sub> N <sub>8</sub> N <sub>9</sub> N <sub>10</sub> N <sub>11</sub> N <sub>12</sub> N <sub>13</sub> N <sub>14</sub> N <sub>15</sub> N <sub>16</sub> N <sub>17</sub>	N <sub>18</sub>

Where the Application Identifier would define the role (“8018” for Subject of Care and “nnnn”... to be assigned... for Individual Provider) and the GS1 Global Company Prefix, Service Recipient or Provider Number and Check Digit (N<sub>1</sub> through N<sub>18</sub>) would identify the Subject of Care or Individual Provider respectively.

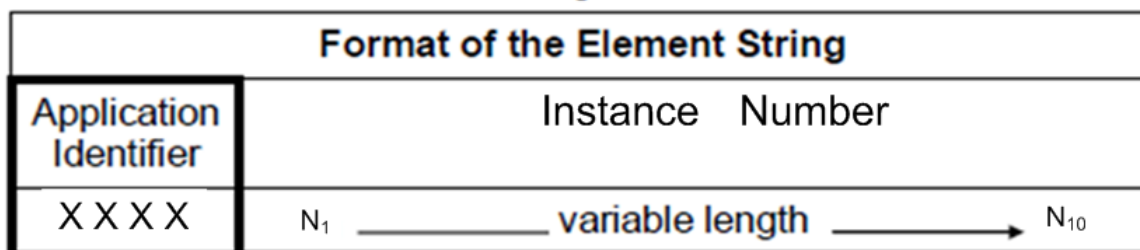
The Global Company Prefix is licenced to the user by its local GS1 Member Organisation. The user is then responsible to ensure that the identification number identifies uniquely the recipient or provider of service (in other words, the key points to one single service relation). There are various ways to achieve uniqueness in this respect, which the user has to evaluate and implement; however in no case would the same number be assigned to two parties independent of whether they be care recipient or provider.



## 6.2 Identification of Care Instances

The expert group has recognised that Subject of Care identification may, optionally, need to be further identified with a sequence indicator corresponding to all encounters during the episode of care. This requirement was also identified as a need within the domain of blood transfusion identification (ISBT 128). This attribute data added to the identification solutions noted would i.e. allow documentation of Subject of Care identification capture from an identification band both before and after its replacement (i.e. radiology examination, etc.).

The proposed format of this attribute data (numeric only, variable length) would be:



This allows a flexible, optional, solution for appending an encounter or instance number to the Subject of Care identification, where the IT processes support such additional information.

## 7 Work group considerations and questions

Through this mid-term report the group intends to solicit input on a series of questions in regard to the proposed solutions.

The responses will help fine tune the solution which then will have to be formulated in appropriate terms for the GS1 General Specifications.

Responses are expected latest per 30 September 2011. The chapters below are to be used for providing feed-back, which then has to be sent by email to the following two addresses: [christian.hay@gs1.org](mailto:christian.hay@gs1.org) and [tom.heist@gs1.org](mailto:tom.heist@gs1.org)



*Please provide us some information about yourself as respondent:*

Your Name:

The organisation you are working for:

Where can we reach you for eventual clarifications?

email

phone (including country code)

### **7.1 Question: Subject of Care and Individual Provider**

Could you support the proposition made by the expert group (see § 6.1)?

YES

NO

General Comments (please include comments about i.e. "... two identification numbers built on the form of an existing GS1 identification Key"):



## 7.2 Question: characteristics of the key

Could you support the structure of the key?

- Numeric only

YES

NO

- With a numbering capacity comprised between 100 Million and 10 Billion instances

YES

NO

General Comments (please include comments about numeric only versus alpha-numeric, and the numbering capacity over the years as the keys should never be reused):



### 7.3 Identification of Care Instances

Could you support the proposition?

- Numeric only

YES

NO

- Variable length

YES

NO

- With a maximum of 10 digits (variable length)

YES

NO

General Comments: