The Management of Pathology using GS1 Standards

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# Table of Contents

1. About this document .......................................................................................................................... 5
   1.1. Background .................................................................................................................................. 5
   1.2. Scope ......................................................................................................................................... 5
   1.3. Purpose ....................................................................................................................................... 5

2. Executive Summary .............................................................................................................................. 5
   2.1. Recommendations ...................................................................................................................... 5

3. Pathology ............................................................................................................................................ 6
   3.1. Background .................................................................................................................................. 6
   3.2. Stake Holders and Requirement ................................................................................................. 6
   3.3. Scope of Pathology ...................................................................................................................... 7
   3.4. Current Workflow ...................................................................................................................... 7
   3.5. Current Challenges ..................................................................................................................... 8

4. GS1 Standards ................................................................................................................................... 9
   4.1. Identifiers .................................................................................................................................... 9
   4.2. Bar codes and RFID Tags ........................................................................................................ 9

5. Best Practice Identifiers for Asset Management .............................................................................. 9
   5.1. Asset Identification ................................................................................................................... 10
   5.2. Asset Labelling .......................................................................................................................... 10
   5.3. Physical Location Identification ............................................................................................... 10
   5.4. Location Labelling .................................................................................................................... 10
   5.5. External Service Provider Identification .................................................................................. 10
   5.6. Patients ..................................................................................................................................... 11

6. Best Practice ..................................................................................................................................... 11
   6.1. Process ....................................................................................................................................... 11
   6.2. Benefits ...................................................................................................................................... 13

7. Deployment ....................................................................................................................................... 14

8. Creating GS1 Identifiers and Labels ............................................................................................... 14
   8.1. Asset Identifiers and labels ....................................................................................................... 14
   8.2. Physical Location Identifiers and Labels ................................................................................ 15
   8.3. Sample Carriers and GS1 Identifiers ...................................................................................... 15

9. KPI’s and Reporting .......................................................................................................................... 16

10. Getting Started ............................................................................................................................... 16

11. Appendix 1 – GS1 Standards ........................................................................................................ 18
   11.1. GS1 Keys for Asset Management .......................................................................................... 18
       11.1.1. GIAI – Global Individual Asset Identifier ....................................................................... 18
       11.1.2. GLN – Global Location Number .................................................................................... 18
       11.1.3. GSRN – Global Service Relation Number ................................................................. 18
       11.1.4. SSCC – Serial Shipping Container Code .................................................................... 18
       11.1.5. GTIN – Global Trade Item Number ............................................................................ 18
11.1.6. Global Returnable Asset Identifier - GRAI ................................................................. 19
11.1.7. GDTI – Global Document Type Identifier ................................................................. 19
11.2. GS1 Bar Codes ...................................................................................................................... 19
  11.2.1. GS1 128 ........................................................................................................................ 19
  11.2.2. GS1 DataMatrix ............................................................................................................. 19

12. References ............................................................................................................................. 20
1. About this document

1.1. Background

This document was commissioned by the Health and Social Care Information Centre in order to show how GS1 standards could be used to improve the management of Pathology within the NHS. It explains the use of automatic Identification and data capture technology to improve data accuracy, to reduce administration time and provide better management control. In addition the document shows how GS1 standards can help trusts to meet the challenge of a paperless NHS by 2018 as set by Lord Hunt.

1.2. Scope

BSI PAS 55-1 defines asset management as the

**systematic and coordinated activities and practices through which an organization optimally and sustainably manages its assets and asset systems, their associated performance, risks and expenditures over their life cycles for the purpose of achieving its organizational strategic plan.**

It then categorises these activities using the Plan-Do-Check-Act (PDCA) framework.

The scope of this paper is limited to the use of GS1 standards in the Do-Check activities and processes and in particular in the establishment of asset information management systems and the monitoring and measuring of results against the asset management policy and strategies. The document covers all items covered within the Pathology process.

The scope of the paper does not include recommendations regarding the clinical testing procedures or results analysis. In addition it does not include any recommendations regarding the consolidation of pathology services outlined in the Carter Review.

1.3. Purpose

This document is designed to assist and advise trusts, and their solution partners, in using GS1 Standards to ensure pathology operations are run in the most effective and efficient way, ensuring value for money while at the same time delivering best possible service for the patient.

2. Executive Summary

2.1. Recommendations

- GS1 identifiers and bar codes should be used to identify all elements of the pathology process – sample carrier, physical locations, staff and patients.
- If appropriate, RFID tags can be considered, particularly for samples that need to be stored for a number of years and found at intervals.
- Paper records, manual writing out of labels and manual data inputting should be replaced by automated bar code or RFID reading devices which are able to update relevant systems such as LIMS etc automatically.
- As a sample moves through a workflow, the unique ID should be read using an appropriate scanner and a realtime audit trail created. This should be accessible by clinical staff to align care delivery with expected sample reporting.
- Recording all events that affect a sample such as location, person auctioning an activity from taking the sample to picking up and taking to and dropping of at the lab enables tracking of responsibility and follow up if required. This is particularly important when looking at samples moving between path labs for specialist testing.
- New bar code scanners procured by Pathology should be capable of reading 2 dimensional bar codes such as the GS1 DataMatrix as agreed by the GS1 Healthcare User
3. Pathology

3.1. Background

Pathology is a critical service within the whole NHS. Around 95% of clinical pathways rely on patients having access to efficient, timely and cost effective pathology services. Pathology impacts all patients from before they are born to after they die.

The breadth and scale of pathologies reach within the NHS is summarised by the following key facts:

- 95% of clinical pathways rely on patients having access to efficient, timely and cost effective pathology services.
- Over 50% of biochemical tests are related to chronic disease management.
- Pathology is involved in over 70% of all diagnoses made in the NHS.
- Nearly 800 million tests performed annually (14 for each person in England and Wales).
- 300,000 patients have a test each working day.

The demand on pathology is accelerating due to several reasons, including:

- An aging population with associated higher rate of chronic disease.
- The shift towards personalised medicine.
- Advances in disciplines such as genomics and metabolomics that is increasing the demand on pathology for predictive and preventative investigations.
- The potential for Summary Care Records to support identification of trends and warning signs in individuals health events.

3.2. Stake Holders and Requirement

Pathology involves a number of areas of patient care. Samples are a critical part of a patients care and a visible audit trail would be beneficial to a number of areas.

Table 1 Requirements below shows what various stake holders require of any Loan Stock system.

<table>
<thead>
<tr>
<th>Table 1 Requirements</th>
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</thead>
<tbody>
<tr>
<td>Clinical</td>
</tr>
<tr>
<td>Finance</td>
</tr>
<tr>
<td>Pathology Laboratory</td>
</tr>
<tr>
<td>Management</td>
</tr>
</tbody>
</table>
3.3. Scope of Pathology

Pathology is sometimes referred to as the Basis of Medicine. Pathology is the branch of medicine which is involved in understanding the cause and processes of disease. It does this by looking at changes in the tissues of the body and in blood and other body fluids. Some of these changes show the causes, while others reflect the severity of the disease and are used to follow the effects of treatment.

Pathologists are specialist medical practitioners working in the field of pathology. Their role is to carry out tests on various tissues including blood, body secretions and samples of tissue taken at surgery or as a part of a medical examination, in order to understand what is causing an illness.

Pathologists increasingly see patients and are involved directly in the delivery of care. At the present time, pathology has seven different main areas of activity. These relate either to the methods used or the types of disease which they investigate. These are:

- Anatomical Pathology
- Chemical Pathology
- Forensic Pathology
- Genetics
- Haematology
- Immunopathology
- Microbiology
- General Pathology

A breakdown of pathology services would eventually lead to the paralysis of the entire health system, relegating hospitals to little more than emergency first aid centres with no ability to undertake critical diagnostic functions (the Royal College of Pathologists of Australasia).

3.4. Current Workflow

The following diagram gives a high level overview of the typical pathology workflow as it currently occurs, with heavy reliance on paper-based and manual data entry processes.
3.5. **Current Challenges**

Pathology departments currently offer a good level of service but the challenges that will be placed on them in the future require transformational change in some of the operations and processes in order for them to meet these demands.

Current challenges that need addressing include:

- Heavy reliance on written labels and test requirements can lead to errors in transcribing, data inputting into system etc. Pathology Labs use complex, sophisticated and automated
technology to perform the tests protocols but are heavily reliant on manual data input processes.

- Manual data input processes limits the ability to dynamically manage the workflow in order to process samples by order of priority or in order to meet clinical timeframes e.g. results ready in line with ward rounds.
- Financial cost of dealing with re-tests can extend beyond the pure retest cost and potentially into additional elements such as additional nights stay for patients because results not available etc. In a worst case it could be detrimental to the care of the patient and their recovery.
- Ability to react to future growth demands could be compromised, without additional investment, if efficiency is not increased.

4. GS1 Standards

4.1. Identifiers

The Department of Health recommends GS1 standards in “Coding for Success” NHS England and the HSCIC also strongly recommends GS1 standards. ISB 1077 and ISB 0108 define the use of GS1 standards and how they should be used by the NHS and its suppliers. for identifying products, patients, locations and assets and for the use of bar codes and RFID. The benefits of using GS1 standards include

- GS1 identifiers are unique, they do not need to be changed when trusts separate or merge and they can be used by suppliers and contractors without requiring the maintenance of complex look up tables.
- Readers can recognise and select GS1 bar codes and RFID tags through ISO standard features
- Data in GS1 bar codes and RFID tags has a well-defined structure that can be understood by any relevant application

GS1 strongly recommends that the identifiers are not used to encode information since such schemes are rarely flexible enough for the long term. It is normally better to use the identifier purely as a key to look up information in a database.

4.2. Bar codes and RFID Tags

GS1 linear or one dimensional bar codes (GS1-128) may be too large to fit on some items. GS1 two dimensional bar codes (GS1 DataMatrix ) can be much smaller and can be read more reliably, they are also likely to be common on pharmaceutical and other products purchased by the trust. For these reasons it is recommended that any deployment should develop a roadmap that leads to two dimensional bar codes. However, two dimensional codes may not be readable by some legacy bar code readers in the trust.

Fundamentally using GS1 standards provide an infrastructure of identifiers, bar codes and RFID tags that can be used by any application in any organisation. GS1 standards enable integration of systems within the trust and allow information from external providers systems to be incorporated easily into the trust and service provider's information management and control systems.

5. Best Practice Identifiers for Asset Management

This section reviews where GS1 standards apply to the information which BSI PAS 55 2 Guidelines state should be considered for inclusion in an asset information management system.
5.1. Asset Identification

Each asset (slide, test tube etc) should be identified by GS1 Global Internal Asset Identifier (GIAI). GIAIs are unique and can therefore continue to be used when passed or transferred between pathology labs. The GIAI is assigned and printed in the form of a barcode for attachment to the sample carrier at either the point the sample is taken or at point of manufacture.

5.2. Asset Labelling

A label containing the GIAI in both human readable format and in a GS1 bar code and/or GS1 RFID tag should be attached to each sample carrier at the point of use. This will ensure that applications, including those of external labs can use the bar codes directly within their systems. Application by the manufacturer is also possible at the point of manufacturer. In this instance the process will allow for the system to link the unique GIAI already on the sample carrier with the other information such as patient ID, test protocols etc in the system. In this instance, the GIAI applied by the manufacturer would be based around their company prefix, not the prefix of the trust using the device. The Global nature of the GS1 system however will ensure uniqueness.

5.3. Physical Location Identification

Where possible, each relevant location should be identified by a GS1 Global Location Number (GLN). Relevant locations will include those within the hospital itself where the sample is taken e.g. ward, path lab etc and also those of external labs that make receive and carry out tests. See also the paper “Identifying Locations in NHS Hospitals”

The GS1 UK web site provides a Numberbank function where GLNs and their description can be created. This ensures that GLNs are formed correctly including the necessary check digit. A bulk up and download facility is available making it straightforward to integrate GLNs into the service provider and hospital internal systems. For more information email healthcare@gs1uk.org or phone 0808 1728390.

It is important to ensure each relevant location is identified by one and only one GLN. Estates will probably already have a database of hospital locations to which a field for the GLN can be added. As the layout of the hospital changes estates can add new GLNs as necessary. (See GS1 UK paper “Recommendations on the use of GLNs in trusts”)

It is suggested that the estates function takes the lead in managing and maintaining an internal database of GS1 GLN physical location identifiers and the installation of the associated GLN bar code labels.

5.4. Location Labelling

A label containing the GLN in both human readable format and in a GS1 bar code and/or GS1 RFID tag should be attached to each location. This will enable applications, including those of the pathology lab collection service, to use the bar codes and RFID tags directly within their systems. For example delivery services or other outsourced services will be able to use the location bar code to record where they have delivered to, or where they have picked up from, whether this is within the hospital or outside.

5.5. External Service Provider Identification

External supplier of products and services should be identified by their own unique GLN. This will enable the trust to use this identifier in their internal systems and in their electronic orders without having to maintain complex internal cross reference tables. This includes suppliers of sample carriers, disposables and services such as external labs used for some specialist testing protocols.

The recently announced NHS eProcurement strategy mandates that all suppliers to the NHS must use a GS1 GLN to identify themselves.
5.6. Patients

In order to identify which patient a sample has been taken from, GIAI of the sample carrier should be linked to the NHS number.

6. Best Practice

6.1. Process

Best practise will use unique identifiers, barcodes and scanners to create a permanent identification link between patients and their specimens.

Using a terminal, that can be mobile if required so that it can be taken to the patient bedside, the barcode on the patients wristband or notes is scanned. This is then combined with the test information and a label created that is added to the sample. Additional information can also be recorded and added to the label and the electronic record is that of the person taking the sample (who also has a barcode ID) as well as the time to complete the samples provenance.

The electronic record can be sent directly to the LIMS system in the lab and ensure workflow reflects the urgency of the sample etc.
The Management of Pathology using GS1 Standards

Sample Taken from Patient

Pathology form raised in system by clinician under the patient record

Bar code and reference number are created and attached to sample

Sample is scanned into workflow and tracked through process. Results automatically recorded and stored against patient details from barcode

Sample sent to lab and scanned at pick up and drop off.

Results sent and stored in system

Using the bar code / reference number, results are posted directly to the patient record

Alert is sent to clinician linking them directly to the patient record and the result
6.2. Benefits

Benefits of using automated data collection through barcode and RFID readers, combined with GS1 standards can provide a number of benefits:

- Multi-disciplinary teams having timely information and specialist advice to enable better treatment planning.
- Better workflows between wards and labs to help improve turnaround times and improve patient care.
- Better identification and management of samples to enhance patient convenience and safety and reduce the cost impact of re-testing.

The use of GS1 standards and automated data collection enables solutions to be implemented that improve how things work within pathology and also deliver benefits at the interface between pathology and the services it supports.

One of the challenges around building a business case within pathology is that in many cases the benefits are seen outside of pathology itself, in terms of financial terms or outcomes. Hence investment needs to be seen in the round and not just in silos. Improvements are often at the interface with users or through achieving greater efficiencies and effectiveness in the services of clinical users.

Reviews have highlighted that process improvements, including better identification enabling improved collection, processing and reporting had significant impacts in other areas such as patient safety in operating theatre, by improving availability of group and screen results prior to surgery and to length of stay. In one pre-improvement example, an estimated 38 hour stay ended up being an 8 day stay due to issues with sample collection and reporting missing ward rounds. The greater visibility enabled by clear identification of the patient, sample, care giver, reporting regime etc would have helped to prevent this occurring.

It is also important to recognise that improvements in processes outside the lab will have to go in conjunction with changes within the lab. If a sample is wrongly labelled at the start of the process, i.e. when it is taken, this will impact the whole process through the lab. As such, solutions to deliver accurate sample identification through the use of GS1 standards and automatic data capture techniques need to be holistic in scope. Therefore any solution must include clinical services involved in the collection of samples and sample management. These services will see benefits through reduced repeat testing, reduced delays in diagnosis and treatment etc.

Centre to Centre referral

The majority of core laboratory services are highly automated, however, the referral of samples between centres is paper driven. It is estimated around 6 million pieces of paper are sent between NHS laboratories and manually input into computer systems every year. This consumes over 300 resource years and introduces the risk of errors and delay in patients receiving results.

As consolidation of specialist services grows, the volume of lab to lab communications will also increase. An overarching tracking system, the National Pathology Exchange (NPEx) has been developed to, amongst other things, give visibility of an audit trail of samples movements. However, the full value will not be achieved while manual processes are needed as inputs and outputs. As such there is real value in using GS1 identifiers and automatic data capture solutions to both realise the full benefits and reduce errors.

Benefits could include:
- enable the delivery of a faster service to patients and clinicians
- estimated cost savings of £1 to £3 per sample on data entry and handling.
- Results can be received electronically saving at least one day
- Reduce opportunity for errors during manual data entry
- Creation of an auditable sample trail – barcode used from end to end
- Reduces ad-hoc enquiries due to electronic visibility of sample audit and real time tracking.

The use of barcoded labels on samples and linking the patient ID, care giver ID and sample ID electronically through scanning barcodes, enables several benefits:
7. Deployment

As part of the deployment of the e-procurement strategy for the NHS, to be issued in Q2 2014, manufacturers, service providers and trust and their support functions such as pathology services will be required to adopt GS1 standard throughout the operation and processes. The e-procurement strategy will set out a clear timeframe for adoption together with appropriate support materials. These will routine detailed advice to support.

8. Creating GS1 Identifiers and Labels

The successful deployment of the system requires that there is no duplication in the creation of GS1 identifiers. This will require that all parties in the pathology system to put in place a governance process for the creation of GS1 identifiers.

The example bar code sizes shown below are the minimum size specified by GS1 standards and this should ensure that they can be read in the widest possible situations. Actual readability will depend on the quality of the printer, the capability of the scanner and the light conditions. Modern scanners in well lighted environments may successfully read smaller bar codes than those specified in the GS1 standards.

GS1 DataMatrix bar codes can be very small depending on the level of error correction required and the size of data to be encoded. This makes them suitable for marking small assets, although the human readable information on the asset label may limit how small the label can be. Note however that camera based scanners are required to scan GS1 DataMatrix bar codes.

Care should be taken to ensure that any labels meet the requirements of infection control.

8.1. Asset Identifiers and Labels

As outlined above, ideally, and as part of the e-procurement strategy, manufacturers and suppliers will assign and implement GIAI’s before shipment. However, there will be instances when the a label has to be printed and assigned at the point the sample is taken. GIAIs can be up to 30 characters long. The example bar code below is for a GIAI made up of an 8 digit company prefix of 50123450 and a 5 digit asset number of 00008. The 8004 is the application identifier showing that the following digits represent a GIAI. (Note the brackets are for human readability only and are not encoded in the bar code).

The first step is to agree the layout of the labels See below for an example layout which provides a clear human readable number which will normally be sufficient for manual processes.
Label suppliers can provide pre-printed labels with sequential GIAI bar codes, optionally with an integrated GS1 passive UHF RFID tag. These tags can be attached to new assets as part of the receipt process. The bar code label can then be scanned to create the record in the asset database. Other information about the asset can then be entered.

For relabeling existing assets the pre-printed GIAI label should be attached to the asset. The GIAI should then be scanned and the old asset ID entered (via another scan if this is bar coded). The association between the new GIAI and the old asset ID can then be uploaded into the asset database.

It is suggested that existing assets are relabeled as they are repaired or serviced. The remaining assets can be relabeled as part of an asset audit required by the finance department.

If a suitable bar code label printer is available then labels can also be printed on demand.

8.2. Physical Location Identifiers and Labels

GS1 GLNs consist of 13 numeric digits including a check digit. Assuming that the trust has been allocated an 8 digit GS1 company prefix this allows for 10,000 unique locations to be identified. If necessary a 7 digit company prefix can be allocated giving 100,000 locations. In either case GS1 can allocate additional company prefixes if more locations are required.

Alternatively GS1 standards also support a 20 character alpha numeric GLN extension component which substantially increases the number of locations that can be identified with a single GS1 prefix. However the use of the GLN extension is not common and it is recommended that it is not used unless there are special reasons for doing so.

It is recommended to use a GLN for each physical location unless there are special reasons for using an SGLN.

The GLN bar code label can include a human readable description of the location if required as shown in the example below. However in many cases the location will already have a name label.

Ward 10

![Ward 10 GLN label](image)

The GS1 UK web site provides a Numberbank function where GLNs can be created and linked to a description. This ensures that GLNs are formed correctly including the necessary check digit. A bulk up and download facility is available making it easy to integrate GLNs into the trust’s internal systems. For more information email healthcare@gs1uk.org or phone 0808 1728390.


8.3. Sample Carriers and GS1 Identifiers

It should be recognised that some manufacturers of carriers may use a GTIN (application identifier 01) or a GRAI (application identifier 8003) with serial number or a GIAI (application identifier 8004) to identify their products. For this reason it is recommended that the application identifier should be
included in the asset identifier field in the asset database. For example an asset with GIAI of 50123450 should be held in the database as 800450123450.

The asset database should be able to hold the largest asset identifier that the GS1 standards allow which is 36 alph numeric characters as shown below.

- GIAI is a maximum of 30 characters; the GIAI AI 8004 is 4 characters making a total of 34
- GRAI plus serial number has a maximum of 30 characters, the GRAI AI 8003 is 4 characters making a total of 34
- GTIN plus serial number has a maximum length of 14+20, the GTIN AI 01 is 2 characters making a total of 36

9. **KPI’s and Reporting**

The success of any system will be on creating the necessary KPI’s and reporting mechanisms to ensure processes are being followed and the desired performances to meet businesses improvement targets are being achieved.

Any KPI’s need to be linked to specific pathology objectives set by the trust but should include areas such as:

- Number of failed tests and reason
- Ration of level of stock holding of consumables in relation to usage
- Number of tests completed to pre-defined timeframes e.g. emergency tests completed within 1 hour etc.
- Number of tests that do not complete full cycle from sample taken through to report received by care giver.
- Average time for a test to complete the full cycle.
- Average time for sample to complete key stages of the cycle – to enable identification of any pinch points requiring resolution to enable a smoother process flow.

10. **Getting Started**

Ideally, any move towards deploying GS1 standards within the pathology area would be done in conjunction with all clinical areas who use the service as they will achieve benefit as well. However, it is recommended that creating a pilot to prove the benefits within the pathology controlled process area would be a solid first step. This would enable the benefits to be proven to the other clinical areas.

For samples taken within the pathology area of control, barcoded labels could be applied at point sample is taken, replacing handwritten labels.

- Find out more about GS1 standards and who else is implementing them both within your trust and in other loan stock areas by contacting GS1 on 0808 1728390 or healthcare@gs1uk.org
- Visit other trusts who have implemented improved systems
- Assess current performance
  - % samples requiring retest due to label illegibility
  - % of time spent inputting data manually into the LIMS (or similar) system.
- Build a business case based on the benefits
- Agree a business case plan across the impacted clinical areas
- Assess and update or replace existing asset database to ensure support for GS1 identifiers
- Identify a suitable solution partner with experience of GS1 standards to source printers, labels and scanners
- Agree GLN labelling of physical locations with estates
- Agree ownership of creating and maintaining a GLN database for entities
11. Appendix 1 – GS1 Standards

GS1 keys identify items related to processes in a wide variety of industry sectors including healthcare. These keys all start with a sequence of numeric digits, called the GS1 Company Prefix (GCP), which GS1 allocates to individual companies. Subsequent digits or characters are added to the prefix to create unique identifiers for specific items.

When a key is encoded in a GS1 bar code it is prefixed by an Application Identifier (AI) number which identifies the key. The information in a GS1 bar code is also printed in human readable form adjacent to the bar code. The Application Identifier is enclosed in parentheses in the human readable form but the brackets are not encoded in the bar code itself.

More detailed information on all GS1 keys and bar codes is available at http://www.gs1.org/barcodes/technical/id_keys.

The complete GS1 identification and bar code standards are documented in the GS1 General Specifications available at http://www.gs1.org/genspecs.

11.1. GS1 Keys for Asset Management

The most common keys are summarised below.

11.1.1. GIAI – Global Individual Asset Identifier

The GIAI can be used to identify any asset including such things as, computers, vehicles, surgical instruments, pumps and specimens.

11.1.2. GLN – Global Location Number

The GLN can be used to identify physical locations and organisation entities where there is a need to retrieve pre-defined information to improve the efficiency of communication with the supply-chain. Global Location Numbers are a prerequisite for GS1 eCom message.

GLNs can have an additional extension component to identify sub locations.

11.1.3. GSRN – Global Service Relation Number

The Global Service Relation Number (GSRN) can be used to identify the relationship between an organisation offering services and the recipient of services. In the NHS the GSRN is used on the patient wrist band to identify patients and may also be used to identify healthcare professionals.

11.1.4. SSCC – Serial Shipping Container Code

The SSCC can be used to identify an item of any composition established for transport and/or storage which needs to be managed through the supply chain. The SSCC is assigned for the life time of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs are used to identify the pay load on a pallet, in a roll cage or in a package.

11.1.5. GTIN – Global Trade Item Number

The GTIN is the GS1 Identification Key for any item (product or service) that may be priced, or ordered, or invoiced at any point in any supply chain. The GTIN is then used to retrieve pre-defined information about the item. The key benefit is that information about the item can be retrieved about the product from the GTIN whether it is read in a GS1 bar code symbol, exchanged via a GS1 eCom message or accessed from the Global Data Synchronisation Network.
11.1.6. **Global Returnable Asset Identifier - GRAI**

The GRAI is used to identify returnable items such as pallet bases, roll cages, plastic containers or gas cylinder which are used in the movement of goods. The goods themselves are identified by a GTIN or an SSCC.

11.1.7. **GDTI – Global Document Type Identifier**

The GDTI is the Identification Key for a document type, for example a form, a certificate or a warranty. It can be combined with an optional, alpha-numeric serial number to identify specific instances of a form or warranty.

11.2. **GS1 Bar Codes**

When GS1 keys and attributes are encoded into GS1 bar codes they are preceded by codes, known as Application Identifiers. For example GIAIs are preceded by AI 8004 while a GLN for a physical location is preceded by AI 414. The standard for GS1 bar codes is that the data encoded in the bar code should also be shown in human readable form. For readability AIs are enclosed in brackets in the human readable text although the brackets are not contained in the bar code itself.

The bar codes likely to be used in asset management are either GS1 128 or GS1 DataMatrix. Examples are shown below.

11.2.1. **GS1 128**

This bar code can be read by virtually any bar code scanning device including the laser scanners in use at HPA Colindale. The data structure in the bar code is defined to enable batch numbers, expiration dates and a wide range of other information to be included.

GS1 128 bar code is a relatively large image the size of which varies with the information it contains. The example shows a GS1 128 bar code containing a GIAI.

![GS1 128 Example](image1)

11.2.2. **GS1 DataMatrix**

The GS1 DataMatrix bar code can carry more information than the GS1 128 bar code in a much smaller image; it can also be read even when the bar code image has been damaged in some way assuming that the optional error correction capability has been used. However GS1 DataMatrix requires an camera scanner, such as those in mobile phones. GS1 DataMatrix cannot be read by the laser scanners which may already be deployed in some departments.

Again the size of a GS1 DataMatrix bar code will vary with the information it contains and also what level of error correction is required. The example shows a GS1 DataMatrix containing a GIAI.

![GS1 DataMatrix Example](image2)
12. References

PAS 55-1:2008 Asset Management
Specification for the optimised management of physical assets
PAS 55-2:2008
Guidelines for the application of PAS 55-1
GS1 Company Prefix Governance Paper
GS1 GLN paper