

Recommended Identification, Capture, and Master Data Sharing Specifications for Long Lasting Insecticidal Nets

TraceNet Working Group | Version 1.0, January 2020

Table of Contents

ANNEX	В.	AGENCY UPTAKE TIMELINES	14
ANNEX	Α.	EXAMPLE OF A LOGISTIC LABEL FOR A BALE OF LLINS	14
5.0	IMP	LEMENTATION SUPPORT	13
4.0	MA	STER DATA SHARING	12
	3.3	Bale	11
	3.2	Bag containing an individual LLIN	10
	3.1	Individual LLIN	10
3.0	DES	CRIPTION OF AIDC REQUIREMENTS FOR LUNS	10
2.0	٥V	ERVIEW OF THE STANDARDIZATION ROADMAP FOR LLINS	9
	1.3	Data carriers	8
	1.2	Recommendations for serialization	8
	1.1	Application identifiers	7
1.0	GEN	NERAL GUIDANCE	7
RECOM	MEN	DATIONS	7
ACRON	YMS		6
CONTR	IBUT	ORS	5
FORWA	RD		4

Foreword

In May 2019, the U.S. President's Malaria Initiative (PMI) and The Global Fund to Fight AIDs, Tuberculosis and Malaria (Global Fund) co-convened the TraceNet Working Group to seek industry input on implementing product identification, data capture, and data sharing standards to further efforts towards improving traceability of long lasting insecticidal nets (LLIN). Group members include manufacturers, procurement agents, and implementing partners, including representatives from select donor-funded country programs.

Beginning in June 2019, the group met bi-weekly to discuss the benefits, opportunities, and challenges of implementing standardized application identifiers, data carriers, and data sharing mechanisms, to provide a recommendation on a realistic path forward to implement global standards for LLINs.

The next page lists the TraceNet members who have contributed to the development of this recommendation. These recommendations are envisioned to be a major input for developing the contract requirement implemented by procurement agents for the U.S. Agency for International Development (USAID), Global Fund, and other agencies.

The co-chairs would like to thank everyone who has contributed to developing these recommendations over the past year. We would also like to extend our appreciation to members of the GS1 global healthcare team for their support in the development process.





Contributors

Nick Brown Binesh Haria Sylvester Kazi Sridhar Sivakumar Volker Frenz Andy Butenhoff Rita Li Chen Meiying Grace Adeya Collins Agoro Mattu Bockarie-Davis Tori Ghine Marcus Hall Kaitlyn Roche Dana Tatnell António Langa Abdul Mussa Philippe Marien Tache Godwin Aidenagbon Kingsley Godson Mouna Jarmouni **Clarisse Morris** Peter Alvarez Elisa Zwaneveld Yosry el Eshraky Vanessa Klaassen Christen Fornadel James Jing Rafael Perez del Castillo Christopher Lourenco Meyyappan Palaniappan John Lucas Kaoru Tsurumi Kiyotaka Ito Yoshito Ishida Clerisse Lemke J. Chris Warren Aurélie Delbaere Dr. Ramanathan Natarajan Anand Samiappan Na Li

A to Z Textile Mills Limited BASF **Disease Control Technologies** Fujian Yamei Industry & Trade CO., Ltd. Fujian Yamei Industry & Trade CO., Ltd. GHSC-PSM GHSC-PSM GHSC-PSM GHSC-PSM GHSC-PSM GHSC-PSM GHSC-PSM **GHSC-PSM** Mozambique GHSC-PSM Mozambique **GHSC-PSM** Niger **GHSC-PSM** Nigeria **GHSC-PSM** Nigeria The Global Fund for AIDS, Tuberculosis & Malaria The Global Fund for AIDS, Tuberculosis & Malaria GS1 Global Office GS1 Global Office **IDA** Foundation **IDA** Foundation Innovative Vector Control Consortium LIFE IDEAS Biological Technology Ltd. Mainpol GmbH **Population Services International** Shobikaa Impex Private Limited Sumitomo Chemical Co., Ltd. Sumitomo Chemical Co., Ltd. Sumitomo Chemical Co., Ltd. Sumitomo Chemical Co., Ltd. U.S. President's Malaria Initiative U.S. President's Malaria Initiative Vestergaard V.K.A. Polymers Private Limited V.K.A. Polymers Private Limited Yorkool International Limited

Acronyms

Al	application identifier
AIDC	automatic identification and data capture
GDSN®	GS1 Global Data Synchronization NetworkTM
GLN	Global Location Number
GTIN	Global Trade Item Number
HRI	human readable interpretation
LLIN	long lasting insecticidal net
PMI	U.S. President's Malaria Initiative
SSCC	Shipping Container Code
USAID	U.S. Agency for International Development

Recommendations

1.0 General guidance

This section provides general guidance applicable to the requirements detailed through the rest of the document.

1.1 Application identifiers

The GS1 application identifiers are referred to within and required for conformance to this specification include:

AI	DEFINITION	DESCRIPTION
00	Serial Shipping Container Code (SSCC) ¹	This data field uniquely identifies a logistic unit.
01	Global Trade Item Number (GTIN) ²	This data field uniquely identifies a trade item.
02	GTIN of contained items ³	This data field uniquely identifies the trade item(s) contained inside of a logistic unit.
10	Batch or lot number ⁴	This data field indicates a batch or lot number as defined by the manufacturer.
11	Production date ⁵	This data field indicates the release date as determined by the manufacturer represented in YYMMDD format.
21	Serial number ⁶	This data field contains a serial number. When combined with a GTIN, a serial number identified an individual instance of a trade item.
37	Count of trade items contained in a logistic unit ⁷	This data field indicates the variable count of trade items contained within a logistic unit.

1.1.1 Use of release date in lieu of production date in Al (11)

The release date is "the date from which the supplier guarantees a shelf-life of at least 2 years, unless stated otherwise, under actual conditions of storage in the area where the technical grade active ingredient or formulation is to be marketed."⁸ In practice, this is generally the date that a LLIN is released for dispatch and use after the authorized person has certified that all planned and documented arrangements, inspections and tests have been satisfactorily completed.

Release date will be used in lieu of production date on the label to align with WHO guidance on LLIN labeling and to ensure that the same point in the process is being reflected on the label across all manufacturers.

Given that there is not a GS1 application identifier for release date, the release date will be encoded in Al (11) Production date in YYMMDD format. At a minimum, year (YY) and month (MM) must be accurately encoded to reflect the year and month of release; when a specific date (DD) is not possible to encode, two zeros (e.g., 00) can be used in its place.

¹ GS1 General Specifications – Section 3.3.1 Identification of a logistic unit (SSCC): AI (00)

² GS1 General Specifications – Section 3.3.2 Identification of a trade item (GTIN): AI (01)

³GS1 General Specifications – Section 3.3.3 Identification of trade items contained in a logistic unit: AI (02)

⁴ GS1 General Specifications – Section 3.4.1 Batch or lot number: Al (10)

⁵ GS1 General Specifications – Section 3.4.2 Production date: AI (11)

⁶GS1 General Specifications – Section 3.5.2 Serial number: AI (21)

⁷ GS1 General Specifications – Section 3.6.5 Count of trade items or trade item pieces contained in a logistic unit: AI (37)

⁸ Food and Agriculture Organization of the United Nations. International Code of Conduct on Pesticide Management: Guidelines on Good Labelling Practice for Pesticides. (2015) Available: http://www.fao.org/3/a-i4854e.pdf

1.2 Recommendations for serialization

Serial numbers used to enable unique identification of LLINs must be random (as opposed to sequential). The character sequence resulting from the combination of the GTIN and the serial number will be unique to a given LLIN for at least five years after it has been released for sale or distribution.

The SSCC must remain unique and not be reallocated for a minimum of one year from the shipment date of the logistic unit from the SSCC assignor to the trading partner.⁹ The relationship between the SSCC and the sequencing of the bale (e.g. 1 of 50, 2 of 50) need not be maintained by the manufacturer.

It is not recommended to require aggregation between individual LLINs (serial number) and the bale (SSCC) until the point in time that country recipients can leverage this technology and the cost/benefit of such a capability can be sufficiently assessed.

1.3 Data carriers

The barcode symbol data carriers referred to here and required for conformance to this specification are GS1 DataMatrix¹⁰ and GS1-128 linear barcode.¹¹

At the request of the procurement agency and before initial shipment, the vendor will submit actual samples of the barcode symbol (e.g., label, package) for review by the respective procurement agency. Barcode symbols should meet print quality "Grade C" (1.5 or above).¹² Should any barcode symbols be found defective or unreadable at the time of custody transfer to the procurement agency, the vendor should be contacted.

Barcode symbols, with their associated human readable interpretation (HRI), should be positioned according to accepted industry practice and as discussed below. As part of the regular manufacturing/production process, barcode symbol print quality and data content will be verified and graded in accordance with the appropriate sections within the GS1 General Specifications.¹³

⁹GS1 General Specifications – Section 4.4.1.1 Allocating Serial Shipping Container Codes – General Rule

¹⁰GS1 General Specifications – Section 5.7 Two dimensional barcodes – GS1 DataMatrix symbology

¹¹ GS1 General Specifications – Section 5.4 Linear barcodes – GS1-128 symbology specifications

¹²GS1 General Specifications – Section 5.5 Barcode production and quality assessment

 $^{^{13}\,}GS1\,\,General\,Specifications\,\,available:\,https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf$

2.0 Overview of the standardization roadmap for LLINs

This section lays out an implementation roadmap for trade item and location identification, data capture, and data exchange for LLINs at various levels of the packaging hierarchy. This includes a phased approach, where capabilities are implemented over time. The following minimum use of GS1 identification keys and data carriers are recommended for LLINs at various packaging levels:

IDENTIFY			
ENTITY	REQUIREMENT	PHASE	
Trade items	Assign and provide ¹⁴ GTINs for all levels of the trade item packaging hierarchy.	Phase 1	
Locations and/or legal entities	Assign and provide ¹⁵ Global Location Numbers (GLNs) for sold-from, manufacture-from, and ship-from.	Phase 1	

	CAPTURE					
PACKAGING LEVEL		REQUIREMENT	HUMAN READABLE INTERPRETATION (HRI)	PHASE		
Bale		 GS1-128 barcode symbology encoded with: (00) SSCC (02) GTIN of contained items (37) Count of contained items (10) Batch/lot number (11) Production date 	Information printed in human readable form: (00) SSCC (02) GTIN of contained items (37) Count of contained items (10) Batch/lot number (11) Production date	As soon as possible but no later than Phase 3		
Bag with LLIN	85	 GS1 DataMatrix symbology encoded with: (01) GTIN (10) Batch/lot number (11) Production date 	Information printed in human readable form: • (01) GTIN • (10) Batch/lot number • (11) Production date	Phase 2		
Individual LLIN		 GS1 DataMatrix symbology encoded with: (01) GTIN (10) Batch/lot number (11) Production date (21) Serial number 	Information printed in human readable form: • (01) GTIN • (10) Batch/lot number • (11) Production date • (21) Serial number	Phase 2 for GTIN, batch/lot number and production date Phase 3 for serial number		

SHARE			
DATA TYPE	REQUIREMENT	PHASE	
Master data	Provide mandatory and required trade item attribute data via the GS1 Global Data Synchronization Network™ (GDSN®)	Phase 2	

¹⁴ Identifiers can be submitted to IPAs through the GTIN/GLN submission form, available: https://www.ghsupplychain.org/global-standards/gtinglnsubmissionform

¹⁵ ibid

3.0 Description of automatic identification and data capture (AIDC) requirements at each level of the packaging hierarchy

This section provides implementation guidance and examples of the AIDC requirements at each level of packaging referenced in the roadmap.

3.1 Individual LLIN

The individual LLIN is considered a trade item. The recommended data carrier on the individual LLIN is the GS1 2D DataMatrix. The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

- (01) GTIN
- (11) Production date¹⁶
- (10) Batch/lot number
- (21) Serial number

The GTIN for an individual LLIN intended to be traded as a "loose net" should be different from the GTIN of an individual LLIN intended to be traded when packaged in a polybag, even if the net itself, in both instances, has an otherwise identical product profile to minimize risk of errors in identification of the trade item in procure-to-pay processes.

The HRI detailing the encoded data should be written adjacent to (i.e. under or next to) the data carrier. The data carrier and the associated HRI should be positioned either on the care label or a secondary label. If positioned on a secondary label, the secondary label must be positioned adjacent to the care label. Both the label and ink must be durable such that they last 3+ years and pass the WHO 20 wash test.

An example of the data carrier encoded with the required data for the individual LLIN is included:



3.2 Bag containing an individual LLIN

A bag containing an individual LLIN is considered a trade item. The GTIN assigned to the bag containing the individual LLIN must be the same as the GTIN on the individual LLIN contained inside of that bag.

Identification of the bag and application of a data carrier and associated identifiers to the exterior of the bag is **not required** if the data carrier on the LLIN contained within the bag is readable, both visually and using scanning technology, through a transparent portion of the bag without needing to open or damage the bag in any manner.

Т

¹⁶ Per Section 1.1.1, AI (11) Production date should be encoded as the release date

The recommended data carrier on the bag is the GS1 2D Data Matrix. The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

- (01) GTIN
- (11) Production date¹⁷
- (10) Batch/Lot

The HRI detailing the encoded data should be written adjacent to (i.e. under or next to) the data carrier. Data carriers, with associated HRI, should be positioned directly onto the exterior of the bag.

An example of the data carrier encoded with the required data for the bag containing an individual LLIN is included:



3.3 Bale

The bale, containing a variable number of trade item units for logistic purposes, is considered a logistic unit. The recommended data carrier is the GS1-128 linear barcode, with the option to also include the GS1 2D DataMatrix encoded with the same information. The minimum GS1 identification key, Al, and HRI recommended for inclusion are:

- (00) SSCC
- (02) GTIN of trade items in logistic unit
- (37) Count of trade items contained inside of a logistic unit
- (11) Production date¹⁸
- (10) Batch/lot

The HRI should be written adjacent to (i.e. under or next to) the barcode symbol data carrier. Data carriers, with associated HRI, should be included on a label that is adhered to the exterior of the bale. A sample logistic label for LLINs is included in Annex A.

An example of the data carrier encoded with the SSCC for the bale is included:



An example of the data carrier encoded with the additional variable information for the bale is included:



(02)10857674002017(37)50(11)201231(10)NYFUL01

Т

¹⁷ Per Section 1.1.1, AI (11) Production date should be encoded as the release date

¹⁸ Per Section 1.1.1, AI (11) Production date should be encoded as the release date

4.0 Master data sharing

Product master data is information that describes a product, created by the owner of that product and used by trading partners to perform a number of business processes from planning and procurement to delivery. Examples of product master data attributes for LLINs may include the GTIN, brand name, manufacturer name, manufacturer location, shape, dimensions, material, denier, color, and active ingredient(s) (i.e. insecticides).

A number of donors and their international procurement agents are implementing the GS1 Global Data Synchronization NetworkTM (GDSN®) to exchange product master data with their suppliers to use as the basis of their product catalogues. Using the GDSN to synchronize product master data will help improve supply chain data quality and management for trading partners – both suppliers and recipients.

The original manufacturer or brand owner of the LLIN and its associated GTIN and GLN is responsible for generating the master data and managing that data through the GDSN synchronization process, including updating data as necessary to ensure that all trading partners have accurate master data about the LLINs being procured. The procurement agents will be responsible for defining which data attributes are required for LLINs and must share this information with manufacturers no later than six (6) months before the master data synchronization deadline.

Т

5.0 Implementation support

To support manufacturers in their implementation, it is recommended that donors and/or their procurement agents host periodic information sharing sessions throughout the implementation timeline – at a minimum, in advance of each phase deadline – to ensure that industry is aligned on what needs to be implemented and empowered with access to resources and guidance to inform how to implement in alignment with this document.

Annex A. Example of a logistic label for a bale of LLINs

[Brand Name] Long Lasting Insecticide Nets				
Manufactured by:	Manufactured for:			
Factory XYZ	National Malaria Control Program			
Address	Address			
Address	Address			
SSCC	G TIN			
006141411234567890	10857674002017			
Batch Number	Production Date			
NYFUL01	201231			
GLN From	GLN To			
0858939248292	0858939007009			
Count	Sequence			
50	3 of 250			
(02)10857674002017(3 (00)0061	7) 50 (11) 201231 (10) NYFUL01			

Annex B. Agency uptake timelines

Implementation timelines for LLINs

The following timelines have been developed by donors and their procurement agents for supplier compliance with the specifications outlined in Section 2. These timelines will be formalised in the contracts developed for procurement of each in-scope item by the procurement agent at its discretion.

Agency	Phase 1	Phase 2	Phase 3
The Global Fund	30 Jun 2020	30 Dec 2020	30 Jun 2022
USAID / PMI	30 Jun 2020	30 Dec 2020	30 Jun 2022

Recommended Identification, Capture, and Master Data Sharing Specifications for Long Lasting Insecticidal Nets

TraceNet Working Group | Version 1.0, January 2020