USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

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

TraceNet Working Group | Version 2.0, February 2024





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Revision History

Date	Version No,	Description of Change	Authors
08 Jan 2020	1.0	 Initial USAID Global Health Supply Chain Program-Procurement and Supply Management (GSHC-PSM) document 	R. Smith K. Roche V. Ketani
March 2024	2.0	 The following notable updates have been made: Updated Contributors, Foreword, Cover Page, and Acronyms Updated Section 1.1.1 (updated guidance from production date to release date) Added Section 1.3 (Determining trade item variants) Updated Section 1.4 (clarified min and max X-dimensions for data carriers) Updated Section 3.3 (clarified guidance on multiple bale barcodes, necessary barcode types, and label adhesion quality) Updated Section 4 (added sub-sections 4.2 and 4.3, Transaction data sharing and Event data, respectively) Updated Annex A (enhanced artwork) Updated sources cited (footnotes 8, 17) 	J. Moser R. Smith V. Ketani

Disclaimer

This document refers to the global standard known as GS1¹. GS1 is a neutral, not-for-profit, international organization that develops global standards and solutions to improve the efficiency and visibility of supply chains across industries. GS1, in partnership with the user community, has developed a global standard for healthcare supply chains that is already in use by several International Procurements Agencies (IPAs). This document provides information on how to use that standard in the context of international tenders for health commodities procured; however, it should not be interpreted as an endorsement of any specific data standards for countries that receive any health commodities, regardless of whether their procurement is executed by the IPAs, and also does endorse a specific standards agency.

Suppliers should contact the IPA with which they have a contractual relationship to determine if this requirement is applicable to the trade items your company supplies. In any document that speaks to packaging guidelines, each company is also individually responsible for meeting all statutory and/or regulatory requirements for the company and its products. This guidance does not intend to supersede any regulatory requirements, including but not limited to those of national regulatory agencies (NRAs) for health commodities. Consult with your company's legal counsel or regulatory and quality compliance teams for more specific information about statutory and regulatory requirements on a country-by-country basis.

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). The working group determined that GS1 standards—standards that establish a common language across business entities to identify, capture and share supply chain data—were best suited to accomplish these goals. Group members included manufacturers, procurement agents, and implementing partners, including representatives from select donor-funded country programs. The working group met bi-weekly to discuss the benefits, opportunities, and challenges of implementing standardized LLIN identifiers, data carriers (barcodes), and data-sharing mechanisms for the products.

Through this consultative process, the TraceNet working group members published Recommended Identification, Capture, and Master Data Sharing Specifications for Long-Lasting Insecticidal Nets.

In December 2023, the TraceNet Technical Working Group re-convened to review and update guidance document. Version 2.0 of the recommendations reflects lessons learned from the implementation of LLIN identification, capture, and data sharing requirements since the initial publication.

Acronyms

AI	application identifier
AIDC	automatic identification and data capture
EPCIS	Electronic Product Code Information Services
GDSN®	GSI Global Data Synchronization Network ${}^{\rm TM}$
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	Serial Shipping Container Code
USAID	U.S. Agency for International Development
WHO	World Health Organization

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Recommendations

1.0 General guidance

This section provides general guidance relevant to the entire document.

I.I Application identifiers

The GSI application identifiers referred to below and required for conformance to this specification include:

1.1.1 Use of Application Identifier (11), production date, o signify release date

The release date is "the date from which the supplier guarantees a shelf-life of at least 2 years, unless stated otherwise, under ideal conditions of storage in the area where the technical grade active ingredient or formulation is to be marketed."⁹ 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

AI	Definition	Description
00	Serial Shipping Container Code (SSCC) ²	This data field uniquely identifies a logistic unit.
01	Global Trade Item Number (GTIN) ³	This data field uniquely identifies a trade item.
02	GTIN of contained items ⁴	This data field uniquely identifies the trade item(s) contained inside of a logistic unit.
10	Batch or lot number⁵	This data field indicates a batch or lot number as defined by the manufacturer:
	Production date ⁶	This data field indicates the release date as determined by the manufacturer represented in YYMMDD format.
21	Serial number ⁷	This data field contains a unique serial number . When combined with a GTIN, a serial number identifies an individual instance of a trade item.
37	Count of trade items contained in a logistic unit ⁸	This data field indicates the variable count of trade items contained within a logistic unit.

- 2. GSI General Specifications Section 3.3.1 Identification of a logistic unit (SSCC):AI (00)
- 3. GSI General Specifications Section 3.3.2 Identification of a trade item (GTIN): AI (01)
- 4. GSI General Specifications Section 3.3.3 Identification of trade items contained in a logistic unit: AI (02)
- 5. GS1 General Specifications Section 3.4.1 Batch or lot number: AI (10)
- 6. GS1 General Specifications Section 3.4.2 Production date: AI (11); Per the GS1 General Specifications, the day of the month shall not be expressed as 00 after 1 Jan 2025 and a valid day of the month must be included
- 7. GSI General Specifications Section 3.5.2 Serial number: AI (21)
- 8. GSI General Specifications Section 3.6.5 Count of trade items or trade item pieces contained in a logistic unit: AI (37)
- 9. Food and Agriculture Organization of the United Nations. International Code of Conduct on Pesticide Management: Guidelines on Good Labelling Practice for Pesticides (revised) (2015). Available: https://www.who.int/publications/i/item/9789241509688

arrangements, inspections and tests have been satisfactorily completed. The LLIN community is engaged in ongoing discussions and review on the definition of LLIN shelf-life.¹⁰

Given that there is not a GSI application identifier for release date, the release date will be encoded in AI (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.

I.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 Serial Shipping Container Code (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.¹¹ 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.

Aggregation between individual LLINs (serial number) and the bale (SSCC) may be requested and is dependent on the point in time that country recipients can leverage this technology and the cost/benefit of such a capability can be sufficiently assessed. If more serial numbers are allocated than are used, as is often the case, it is imperative to ensure that unused serial numbers be removed from repositories of valid serial number data by undertaking a reconciliation process.

1.3 Determining trade item variants

Per the GST GTIN Allocation Rules Standard, a separate, unique GTIN is required whenever two products are different in any way that is relevant to the trading process, intended use, or point-of-care. For LLINs, these distinguishing factors include, but are not limited to:

- Accessories: Items with accessories, such as hooks and strings, change how the item is to be purchased and handled versus nets without accessories. To standardize variant groupings, accessories should be a determining factor.
- Market-Specific Characteristics: If the procured LLIN contains labeling or product characteristics that are unique for a given market or set of markets, then that variant should be identified uniquely. Therefore, regulation-induced net artwork or certification marks should impact GTIN allocation. If a product does not possess country- or market-specific requirements as a determinant of how orders are placed or funded, then GTIN should remain standard—respective to the net dimension, branding, language(s), packaging level, etc.

The GST GTIN Allocation Rules Standard detail additional principles for distinguishing which variants require unique GTIN allocation. Allocating organizations should work with their local GST Member Organization to ensure that they are implementing these guidelines correctly.

I.4 Data carriers

The barcode symbol data carriers referred to here and required for conformance to this specification are GS1 DataMatrix¹² and GS1-128 linear barcode.¹³ DataMatrix barcode sizing should adhere to the minimum and maximum X-Dimensions according to the following categorization in the GS1 General Specifications: Trade items scanned in retail and general distribution or retail pharmacy and general distribution. 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).¹⁴ Should any barcode symbols be found defective or unreadable during physical inspection or 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 by an ISO-based verifier in accordance with the appropriate sections within the GS1 General Specifications.¹⁵

^{10.} These recommendations will be updated once the LLIN community defines a globally accepted definition of expiration date in the context of LLINs

^{11.} GS1 General Specifications – Section 4.4.1.1 Allocating Serial Shipping Container Codes – General Rule

^{12.} GS1 General Specifications – Section 5.7 Two dimensional barcodes – GS1 DataMatrix symbology specifications

^{13.} GSI General Specifications – Section 5.4 Linear barcodes – GSI-128 symbology specifications

^{14.} GS1 General Specifications – Section 5.5 Barcode production and quality assessment

¹⁵ GSI General Specifications available: https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications



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 GSI identification keys and data carriers are recommended for LLINs at various packaging levels:

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

		Identi	ify	
Entity	Requirement			Phase
Trade items	Assign and provi	ide^{i6} GTINs for all levels of the trade item pack	aging hierarchy.	Phase I
Locations a or legal enti	nd/ Assign and provi ties	ide ¹⁷ Global Location Numbers (GLNs) for sold	d-from, manufacture-from, and ship-from.	Phase
		Cantri	an	
Packaging le	ivel	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	3	 GSI 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		 GSI 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
		Shan	ų	
Data type	Requirement			Phase
Master data	Provide mandatı (GDSN®)	ory and required trade item attribute data via th	he GS1 Global Data Synchronization Network $^{\mathbb{T}^{M}}$	Phase 2



Description of Automatic Identification and Data Capture (AIDC) requirements at each level of the packaging hierarchy

3.0 General guidance

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 date¹⁸
- (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 test¹⁹. Because the tag is sewn in, care must be taken to ensure that the product identification information on the label is not obscured by the hem and that it does not interfere with the readability of the barcode at the point of scanning.

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



 World Health Organization, Global Malaria Programme. Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets (2005). Available: https://www.who.int/publications/i/item/whocds-whopes-gcdpp-2005.14

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

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.

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

- (01) GTIN
- (11) Production date²⁰
- (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. A GS1 2D data carrier may be included in addition to the GS1-128 symbol. When used, the GS1 2D symbol shall include all element strings included in the GS1-128 symbol(s) and may include additional element strings. Labels that are applied directly to the product should use an adhesive that is strong enough to adhere to the label for an extended shelf life.²¹

The bale is recommended to contain two barcodes representing the same GTIN to increase the visibility of a scannable barcode when product is being transported and stored. Per GSI guidelines, it is recommended that multiple barcodes be printed onto the logistic unit (e.g., bale), especially in instances where activities such as warehousing or distribution rely on efficient barcode scanning.²² It is advised that manufacturers and procurement agents coordinate on this guidance to ensure and achieve the overarching goal of ensuring bale barcode labels are visible.

The minimum GS1 identification key, AI, 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 date²³
- (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:

22. GST General Specifications - Section 6.2.1 Number of barcodes; GST Logistic Label Guideline - Section 8.1 Label placement on larger logistic units



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^{20.} Per Section 1.1.1, AI (11) Production date should be encoded as the release date

^{21.} GS1 General Specifications – Section 6.3.3.7 special packaging considerations for barcode placement

^{23.} Per Section 1.1.1, AI (11) Production date should be encoded as the release date



Data Exchange

4.1. 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.

4.2. Transaction data sharing

When the responding supplier implements the item identification and data capture requirements, the primary identification number on all transaction documentation provided to the relevant IPA—including but not limited to the packing list, commercial invoice, and advanced ship notice where relevant—is recommended to include GTIN(s) to identify trade item(s), SSCC(s) to identify logistic unit(s), and GLN(s) to identify the location (s) being referenced in the transaction documents.

4.3. Event data

The global regulatory environment, in addition to collaborative efforts across the global health community, is rapidly evolving with regard to serialized event data. IPAs do not currently have a requirement for routine sharing of serialized event data, but suppliers are expected to retain that data for a minimum of six (6) years after product leaves supplier custody and to provide this data within 30 days of a request in a mutually agreeable format.

Aggregation of data across packaging levels is valuable for accurate tracing, efficient tracing, and decommissioning of large shipments. It is anticipated that aggregation will play an increasingly important role in global and national traceability initiatives in the future. Although it is not a mandatory requirement, it is recommended that, as part of an organization's serialization strategy, suppliers consider aggregation and the ability to share aggregated, serialized event data in accordance with established standards (e.g., GSI Electronic Product Code Information Services (EPCIS)) and/or global good practices as an emerging business requirement.



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



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 formalized in the contracts developed for procurement of each in-scope item by the procurement agent at its discretion.

Agency	Phase I	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