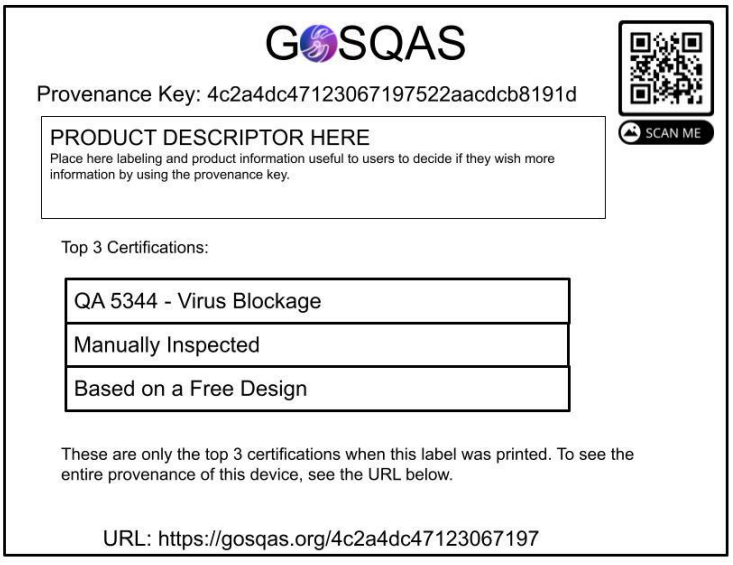
Why a Global Open Source Quality Assurance System (GOSQAS)? Motivating Solutions for Diverse Use-Cases

Trust Through Transparency

by Victoria F. Jaqua, RT(R)(CT), RCIS
Medical Community Lead for Open Source Medical Supplies

From 2020-2023, strong need gaps have been identified within the humanitarian response networks, referencing the distributed manufacturing response to the Covid-19 pandemic documented in Design | Make | Protect and ongoing medical aid projects. We seek to address these gaps by creating a Global Open Source Quality Assurance System (GOSQAS), which is supported by an alliance of international members spanning the open source hardware, open source medical, and humanitarian aid community. GOSQAS potentially solves problems inherent to distributed manufacturing of medical supplies and humanitarian non-governmental organizations (NGO), specifically around delivery verification, fraud, quality assurance/testing documentation, and donor-vendor relationship management.

GOSQAS creates a secured transparent view into the transaction and delivery pathway between manufacturers and recipients, which heretofore operate behind proprietary systems, if at all. This view is accessible from a “Provenance Key” as depicted below, possibly via a sticker label affixed to a shipment:



Whoever has the key to the asset can lookup the entire asset provenance of the device.

GOSQAS asset provenance tracking has the potential to fight counterfeiting, organize documentation on behalf of makers, and record 3rd-party quality assurance documentation through a relatively simple, easy-to-access website using minimal cryptography. GOSQAS can assist humanitarian organizations with crisis manufacturing and medical supply tracking by providing a unique identifier, discoverable only to the sender and recipient, that maps the movement of a product or design from point A to B and stores documentation in a secure database.

For independent and often solo designer/manufacturers who contribute to crisis humanitarian calls-to-action, GOSQAS would function as an organizational memory and discoverable self-audit.

GOSQAS addresses two major problems:

1. Establishing vendor/recipient relationships for humanitarian medical donations
2. Assuring quality of decentralized distributed and additive manufacturing

---

GOSQAS intends to be an independent, transparent, accessible and voluntary third-party provenance tracking system which addresses the following need gaps with proposed solutions.

Problem 1: Vendor/recipient relationships via humanitarian medical donations

Imagine the following scenario: Humanitarian NGO A purchases medical equipment from Vendor B and sends the equipment to Hospital C. A year later, Hospital C contacts NGO A about an equipment malfunction. NGO A has no connection to Vendor B outside of a complete purchase order. NGO A is unable to help Hospital C because the equipment was delivered and the request closed. Vendor B is unable to help Hospital C because there is no maintenance record, product lot #, or malfunction history to determine a replacement or repair action. In order to maintain the donated equipment, Vendor B must have a direct relationship with Hospital C outside of the purchasing NGO, ideally beginning at the delivery of equipment to Hospital C. NGOs do not initiate or maintain relationships between vendors and hospitals as the NGO's primary role is needs assessment and procurement. Vendors fulfill NGO purchase orders with no indication where the equipment will eventually arrive. Hospitals receive working equipment but, with no vendor relationship, are unable to properly maintain the equipment. These problems compound when we consider the multitude of NGOs and humanitarian aid organizations, of varying size and logistic breadth, sending multiple aid shipments around the world every day. **The lack of a vendor/recipient relationship and asset provenance creates waste, confusion, frustration, delays patient care, and potentially causes equipment abandonment (dumping) when it would be more cost effective to repair on site.**

Proposed Solutions

Medical supplier/end-user relationship

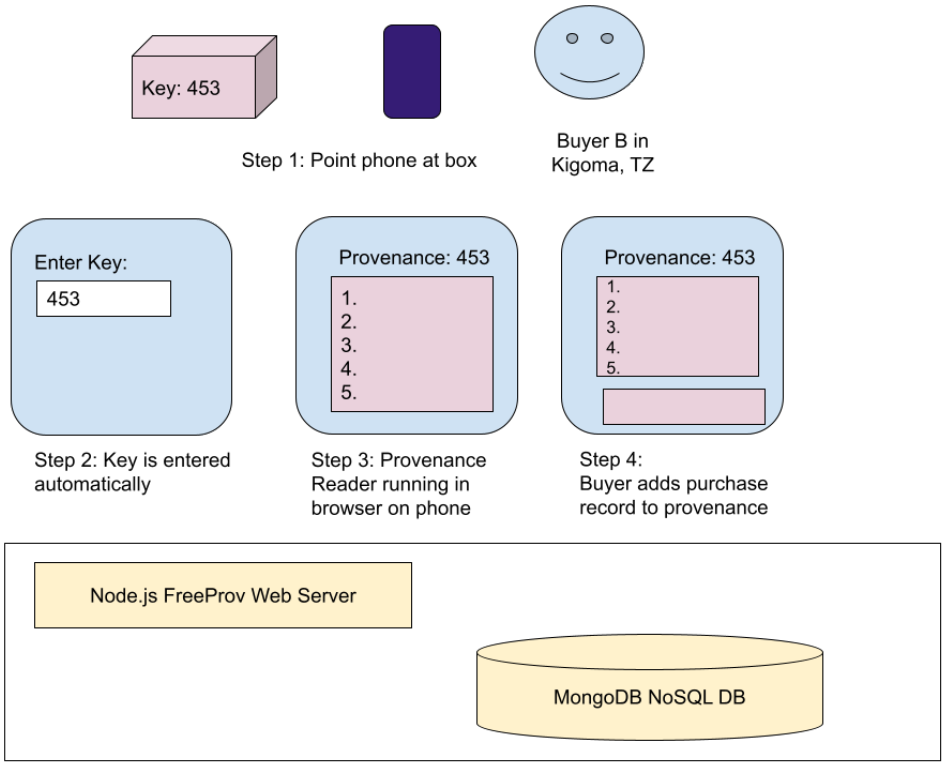
A GOSQAS unique identifier can be applied to a humanitarian shipment and discoverable only to the vendor, purchasing NGO, and recipient facility in the transaction. The recipient can use this unique identifier to log product reference/lot numbers, report malfunctions, and track maintenance reports with the vendor. A robust use of this interface would allow a vendor to map equipment concerns logged within GOSQAS, and alert their internal teams to identical issues arising over a large end-user demographic. An NGO could use this identifier to observe the ongoing relationship between vendors and end-users, track impact, anticipate future outreach opportunities, and verify the life cycle of donor shipments.
Because GOSQAS is an independent, third-party system using simple cryptography, any organization anywhere in the world (including resource-limited communities) would be able to access the platform and record provenance without requiring the NGO or vendor to maintain a proprietary database. It could also function as a project platform for biomedical engineers who repair medical equipment in low-middle income countries (LMIC) at most risk for dumping.

Secure proof of delivery

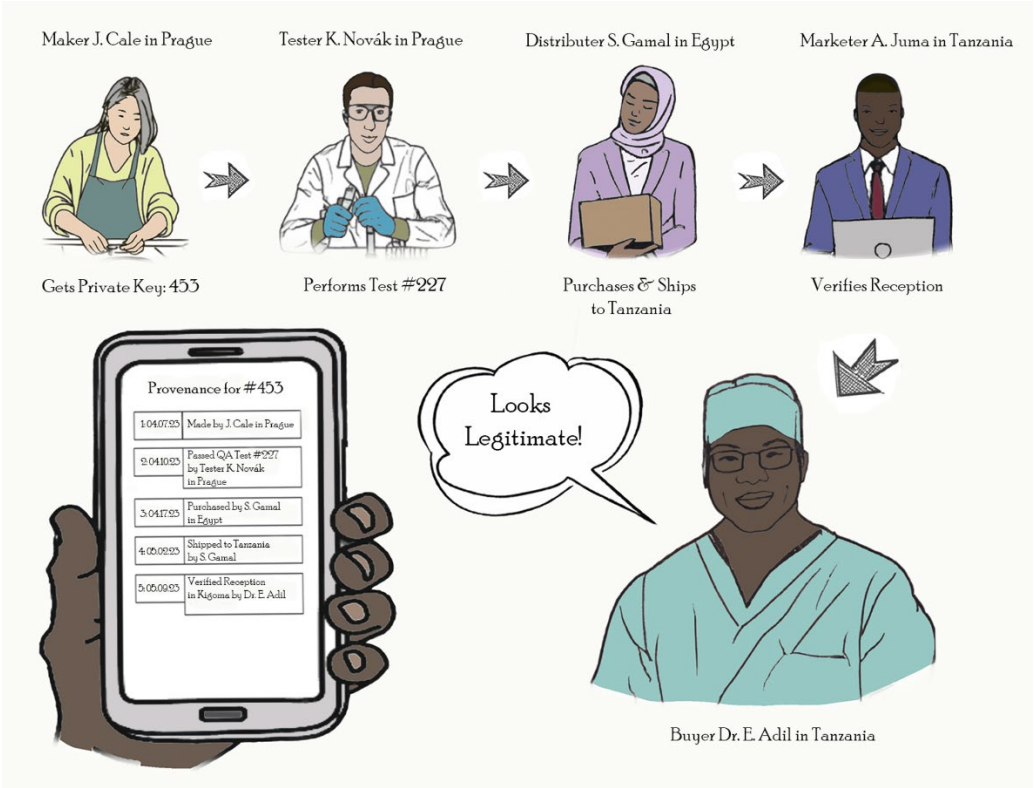
Humanitarian shipments are most effective when they arrive (and stay) at their intended destination. Transport companies can provide invoice and delivery to central hubs, but shipments transported from central hubs to rural areas, crisis/conflict zones, or lower-resourced communities can take longer to verify through texts, phone calls or other communication platforms.

A GOSQAS identifier could be placed on not only a shipment pallet, but also on each shipment box or individual equipment (especially useful for large, expensive devices). This identifier can log movement from central hub to recipient destination, and the donor could ask the recipient to scan the identifier at any time after delivery, to be sure the equipment was still with the recipient. Photos and location coordinates could be uploaded each time the identifier is scanned. An identifier permanently affixed to a device would ostensibly find “lost” equipment and reconnect with vendor history even after a considerable time lapse from shipment.

The image below depicts a 4-step process of an asset key holder to view the entire provenance of the medical asset.



The steps shown below show how the data making up the provenance for an item made in Prague and shipped to Kigoma, Tanzania, would be entered as the asset moves.



Problem 2: Decentralized distributed and additive manufacturing

Distributed manufacturing, especially during a humanitarian crisis, can occur across small, decentralized teams and nodal networks. These maker teams, operating in “makerspaces”, are often not registered non-profits or manufacturers with internal documentation systems: they are often volunteers who pivot to crisis response and focus their effort on designing and manufacturing only. Some distributed manufacturers in crisis areas may have limited access to electricity, internet, testing partners, and logistic verification systems. Maker teams in these environments usually respond within short time constraints and may be unable to scale outside of initial rapid response. Nodal networks may employ a distributed piece-work system, where volume is manufactured across multiple teams and sent to one collection point for mass assembly. **Due to response time constraints, and pivoting teams that may self-organize in crisis-affected areas, there may not be transparent, secure, and accessible pre-existent logistic and documentation networks to record key manufacturing data critical to the end-user, especially when employing open source designs.** Makerspace-manufactured protective gowns will sit on a shelf, unable to reach an Ebola clinic, without an effective provenance system. A 3D printed tourniquet may never reach the limb of an injured child in Burma because the receiving medic team was unable to verify the testing and quality assurance behind the manufacturing.

Proposed Solutions

Collection point for testing and production QA documentation

The current regulatory pathway for medical devices, including low-risk Class 1 devices, requires testing and validation to be done internally by the manufacturer, which results in a secretive pathway to any quality assurance data. Distributed manufacturers (often called “makers”) for humanitarian causes will often design custom products or find the easiest to produce, most accessible design possible- which is often open source. There is currently no regulatory pathway for open source designs themselves, only for the manufacturer of a design. Yet, a distributed manufacturer using an open source design might be challenged to afford or access third-party testing within strict time constraints.

GOSQAS allows manufacturers who use open source designs to also open source their testing and quality assurance (QA) methods, which are discoverable via the unique identifier. The manufacturer may do internal production line testing on components, bring finished product to a third-party testing partner (such as a university) and upload testing documentation to GOSQAS as a permanent attachment to the project. This quality assurance verification is then discoverable to the end-user throughout the entire pathway of the manufacturing process.

Some makers engage only in the design and testing of open source prototypes. In this case, a prototype could live within GOSQAS- documentation current and secured, ready for a new manufacturer to bring the project to the next stage when the identifier is shared to them. In this way, GOSQAS can secure the IP of an open source project rather than losing design files, testing procedures, prototype versions, and other important data to proprietary databases. **This**

is especially important for makers who are not engineers and may not have the technologic bandwidth to maintain a GitHub repository, especially through initial project stages in a resource-limited environment. The world is full of skilled makers who excel at making quality products but do not have the time or resources to also manage inventory, tracking, or other business processes.

Intake process database for nodal networks

Nodal manufacturing networks can spring up quickly and produce large volumes of life-saving equipment quickly. They operate by portioning tasks and volume into manageable amounts across various teams, who then collect finished pieces and deliver in bulk to a central hub for mass assembly, testing, and distribution. Networks may also solely distribute, instead of manufacture, by picking up the assembled product and batch delivering to the end-user.
GOSQAS can potentially operate as an intake process database, where various nodes can record how much they made, to what specifications, and where they delivered the piece-work. Central hubs can verify receipt, testing procedures performed, and assembly finish dates, which ideally gives the network an early alert system to any faulty manufacturing or materials to be removed from the assembly line.
The GOSQAS identifier can track the multiple moving parts of a nodal network, keeping team members informed and streamlined. **GOSQAS would essentially be a pre-existing communication platform for this network, allowing it to focus primarily on making, testing, and delivering without a) requiring the creation of a new internal tracking team from scratch each time the network responded to a crisis and b) losing critical documentation to proprietary platforms and individual user-accounts (Google Suite, Slack, etc).**

Real time evidence of manufacturing response

In the spring of 2020, OSMS tracked the international distributed PPE manufacturing movement via live tallies on Facebook. The tallies used data from live comments to reduce the possibility of bots (such as poll bots) and production overinflation. Community participation engaged strongly on these tallies, and people who were previously unaware of the manufacturing movement were pulled into it, thus increasing awareness of need areas and response actions. Data from the tallies was manually curated into graphs, foundational to the OSMS white paper.
With a GOSQAS unique identifier, a distributed manufacturer can record their personal production, inventory, component need/surplus, testing documentation and delivery confirmation within GOSQAS and share this information within the manufacturing network as “proof of work”, alerting other makers who wish to join the cause.

This identifier would be vital to potential donors who request proof of initial impact before sponsoring a scaled project. Because GOSQAS is an independent, third-party platform, records maintained within the system would provide transparent trust of delivery and quality.

Accessible inventory and distribution reporting

There are many proprietary inventory tracking systems at various costs and requiring various skill levels to operate, generally designed to keep asset tracking private. Most manufacturers in crisis response are making and delivering small batches in the initial stages of a project. They may not have time to ramp production **and** learn a new software system. They need a **simple, pre-existing platform, operable in low-resource settings, to record inventory and verify distribution.**

The GOSQAS unique identifier allows any user of the identifier to record and discover the provenance. If a maker 3D prints twelve orthopedic splints, and delivers them on foot to a first-aid clinic in Botswana, but the maker doesn't have internet access for GOSQAS, the recipient (or assigned user with internet access) can still record the splint intake within GOSQAS.

Life cycle/impact of open source medical designs

Open source medical designs existing in project databases such as GitHub or Thingiverse may log design iterations, but not the movement of the product from new manufacturer to end user. A maker could assign a GOSQAS identifier to a design and request any makers or recipient of the design to log production, testing, and end-user delivery. Tracking the scale of an open source medical design proves community and design outreach beyond prototype or proof of concept. **This organizational memory is crucial to the continued development and adaptation of open source licensed medical supplies, which have the proven ability to impact a crisis area within strict time constraints.**

In the flurry of a humanitarian emergency, distributed manufacturing and humanitarian NGOs can move at breakneck speed to fill early supply chain gaps. Concurrently, that speed can result in lost or never-captured critical documentation. A pre-existing, user-accessible, discoverable provenance such as GOSQAS would support makers and humanitarian donors in their efforts to deliver safe, usable medical equipment where it is needed most. Over time, this trust-through-transparency system has the potential to save many lives.