Fighting Fakes with Tech:
Exploring Digital Solutions to Combat Fake Medicines

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What is Avastin®? It is not a top 10 selling anti-cancer drug manufactured by Genentech (Roche). What it is… A $2,000 vial of cornstarch.

Avastin Notice Waves Geocoded by Distinct Zip Codes
Global Counterfeit Medicine Trends (2009-2011)

Number of incidents in closed supply chain: 1,510

Number of countries w/incidents: 69

2Mackey et al., AJTMH 2015
Manufacturers produce finished medicine product for global distribution.

API is produced by raw material suppliers and then shipped to international manufacturers.

Healthcare facility receives medicine for dispensing, but may not have sufficient records to establish pedigree or verify authenticity.

Patients (end-users) lack the ability to verify if a medicine is authentic at point-of-sale for their own safety.

Solutions exist largely in isolation at each point to authenticate and verify, but there is no unifying legal or systems-based framework to ensure the integrity of the global supply chain.

Medicine is traded and shipped through multiple transactions and trading partners requiring authentication, verification, and track and trace at each point in the supply chain.

Data exchange?
Fake Medicines Anti-counterfeit Solutions

**SERIALIZATION:** Identifying a medicines by using unique printed codes, images or holograms on packaging to verify authenticity

**AUTHENTICATION:** Scanning or recording data on a medicine product at point of supply to verify authenticity

**TRACK AND TRACE:** Logistic technology that follows the current and past locations of medicine products through the supply chain

**LAB, FIELD, AND CHEMICAL TESTS**
**MAIN FINDINGS**

- **Review:** Extracted 60 articles describing cutting-edge digital fake medicines tech and also several case studies in the grey literature.

- **Key characteristics:** (1) do not operate in isolation; (2) are underlying technology to unify solutions; (3) designed to overcome barriers of adoption/implementation/scale up; and (4) complement NOT replace existing technology.

- **Categories:** Two parent categories dealing with physical supply chain and Internet pharmacies.

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A technology-based solution to enhance drug safety?

Blockchain? Could revolutionize drug safety by: (1) enhancing counterfeit drug surveillance; (2) proactively detect counterfeit risk characteristics; and (3) act as post-market surveillance shared ledger.

Blockchain is a distributed (decentralized) ledger that has the potential to make digital transactions more trustworthy, accountable and transparent.

Shared supply chain via P2P network of drug supply chain participants sharing and validating transactions on manufacture, trade, and distribution of medicines.

Enhanced safety as a security layer for e-pedigree documentation evidencing the source and integrity of medicine through authentication via cryptography.
Current Drug [Block]chain Stakeholders

1. **Organizations**
   - This group includes non-profit organizations, government agencies, academic institutions, trade associations, professional societies, and other organizations.

2. **Private Sector**
   - This group comprises established companies, spin-offs, start-ups, management consulting firms, trade shows/conferences, and pharmaceutical manufacturers engaged in blockchain.

3. **Legal and Policy Frameworks**
   - This includes legal, regulatory, and policy frameworks interested in drug safety and combating fake medicines that could be leveraged for implementation of blockchain technology.

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**Translation**

**Implementation**
FUTURE DIRECTIONS

**Problem:** Patients around the world continue to remain susceptible to fake medicines. There is a host of technology but it is not well integrated in order to ensure the integrity of the global drug supply chain and protect patients.

**Digital?** Digital technologies present several opportunities and can serve as a unifying framework for anti-counterfeit solutions. However, greater study and investment are needed.

**Next steps:** Research is necessary regarding technical and design aspects of digital technology in the context of disparate drug supply chains, ensuring robust partnership and verification of data, and how to leverage current policy frameworks.
Collaborators: Gaurvika Nayyar (co-author) and IEEE Standards Association (Blockchain Activities)

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Key References


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Thank you for listening and we welcome any questions/comments