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Innovative approaches to collecting, aggregating, and analyzing adverse drug events in smart hospitals

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Abstract

Background: The increasing integration of electronic health records (EHRs) and their secondary use provide new pathways to advance drug safety. Smart hospitals use advanced data collection to enhance pharmacovigilance and better detect adverse drug events (ADEs). Finland's secondary-use legislation embodies this data-sharing shift.
Objective: This work synthesizes current evidence and proposes strategies to strengthen ADE detection and analysis in smart hospitals by integrating multimodal data sources, including EHRs, sensor data, and the Internet of Medical Things (IoMT), to raise overall drug safety standards.
Methods: We review the Global Trigger Tool (GTT), sensor technologies, and IoMT for ADE detection and outline how these techniques can be combined, offering a more comprehensive approach to monitoring.
Results: Integrating GTT, sensors, and IoMT into a unified system could improve ADE detection and prevention. Combining pharmacovigilance tools with advanced technology can increase the volume and quality of ADE data and supports a preventive focus on patient safety.
Conclusions: The study underscores the importance of the smart-hospital concept and emerging data-collection methods in pharmacovigilance. By adopting a holistic approach to ADE detection and integrating diverse data sources, more robust drug-safety surveillance and patient care can be achieved when coupled with human oversight and regulatory compliance.

Keywords

Adverse drug events, drug safety, Global Trigger Tool, Internet of Medical Things, pharmacovigilance, sensors, smart hospitals

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Introduction

The utilization of multimodal electronic health record (EHR) data for research and the development of data-driven tools has become a global priority for enhancing the quality, effectiveness, and safety of medical treatments. Over the past decade, various international organizations and national governments have launched initiatives to harness EHR data for secondary use, recognizing its considerable future potential.[1] In parallel with these developments, "smart hospitals" are emerging as

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healthcare units characterized by integrated digital infrastructures, real-time data collection capabilities, and advanced data analytics, which collectively enable more efficient patient management.[2,3] While precise definitions can vary, a smart hospital generally refers to an institution that digitizes patient data, clinical data collection, and administrative tasks, linking them through interconnected platforms. Such platforms typically support advanced functionalities, including AI-enhanced diagnostic tools, IoMT-based patient monitoring, automated analytical tools, and adherence to robust interoperability standards, thereby creating a technologically advanced healthcare environment.[4,5]

Finland has positioned itself at the forefront of this transformation by fostering an environment conducive to innovative data utilization, culminating in the passage of specific national legislation in 2019.[i] This legislation is the result of a long process of reforms that have shaped a new "*secondary use*"-friendly environment.[6] Finnish researchers, supported by the public Finnish Innovation Fund SITRA[7] and guided by the Health and Social Data Permit Authority, Findata,[6,ii] have been proactive in exploring and prototyping new systems for comprehensive data gathering and exploitation.[8–10] One example of leveraging Finland's data infrastructure is the PreMed project, which focused on facilitating the secondary use of health data (from national registries and biobanks) for company-driven research and developing national services under the new legislation. This project explored the use of integrated registry and biobank data to advance personalized medicine, for instance, by examining the role of genetic data to support selection of individualized drug therapy.[iii] Studies associated with this ecosystem have demonstrated the feasibility of combining national registry data with biobank information for pharmacogenetic research.[8,9,12–14] While projects like PreMed have shown the power of integrating existing large-scale datasets, the broader vision of smart hospitals also encompasses the potential integration of real-time data streams. Such comprehensive data integration could significantly enhance ADE detection capabilities. For instance, linking real-time physiological data (like blood pressure from monitors) with medication administration records could enable automated alerts for potential ADEs, such as hypotension following a too high dose of an antihypertensive agent, offering a practical illustration of how these advanced methodologies could function.

While this legislative framework provides a robust foundation, significant effort is needed to optimize data harmonization and integration, particularly within the Finnish electronic health records. The development of new data collection systems is critical, especially when considering the potential novel data sources to complement existing EHR data. However, challenges persist, such as achieving seamless integration and full interoperability of EHR across diverse platforms, which is essential for realizing the full potential of these advancements, especially in complex cases like elderly emergency patients.[15]

In this article, we focus on leveraging the opportunity presented by the Finnish legislation on the secondary use of data, advanced real-time data collection technologies, and data analytics to detect adverse drug events (ADEs) and further refine this emerging multimodal, data-driven scenario through systematic data collection processes in hospital settings. Our objectives include demonstrating how a smart hospital approach and its associated technologies, as detailed in **Section 2**, can enhance both the quality and quantity of ADE data collection. The idea of using hospitals as main data sources of signals for computer-aided ADE detection purposes has its roots in research in the end of 1980s, when first proposals of a hospital pharmacoepidemiology powered by automated data management systems were outlined.[16,17] Recent advancements in data collection and analysis within Finnish hospitals have provided basis for improved pharmacovigilance. Initiatives such as care pathway quality registers have been implemented to ensure that state-of-the-art care is delivered within acceptable timeframes, and from these data, important drug safety information can also be extracted. Additionally, the introduction of medication reviews has further enhanced the accuracy and reliability of ADE detection. These efforts highlight the ongoing refinement of existing data systems, which serve as a starting point for more sophisticated tools.

The integration of sensors and the Internet of Medical Things (IoMT) into hospital settings is expected to play an increasingly important role in patient monitoring.[4,5,18–20] While these technologies currently show potential in monitoring clinical signs, their application in recognizing or predicting ADEs requires further research and validation. Nevertheless, a carefully designed data collection framework within hospitals could ensure the accurate tracking of the number of patients receiving specific drugs and the subset of those experiencing ADEs. Then these foundational data could be enriched with additional covariates—such as genomic background, other OMICS data, drug dosage, concomitant drug treatments, comorbidities, and real-world evidence—to allow comprehensive patient stratification through standard and emerging computational methods for ADE detection. This approach aligns with recent studies that position hospitals as key observatories to understand the temporal characteristics and causal links behind the onset of ADE,[21] particularly among hospitalized patients in emergency departments.[22,23]

In parallel to this approach, another instrument—initially introduced to register and manage harms within hospitals—has become a subject of interest for pharmacovigilance: the Global Trigger Tool (GTT).[24,25] In line with previous literature[26] that has shown how important it is to counteract ADEs under-reporting through the exploitation of electronic health records, we strongly believe that GTT could serve both as a secondary source of signals collection (to be juxtaposed to traditional pharmacosurveillance channels), but also—as we detail in Section 3—as a backbone itself for the collection of ADEs in smart hospitals.

Finally, this article is structured as follows: **Section 2** elaborates on the methods under consideration, specifically focusing on how the GTT, sensor data, and IoMT can be utilized to enhance ADE detection capabilities; **Section 3** provides a conceptual framework illustrating how these emerging methods might be effectively combined within a smart hospital environment to achieve superior pharmacovigilance outcomes; **Section 4** provides a comprehensive discussion addressing the opportunities presented by these integrated approaches, and acknowledging the remaining challenges and outlining potential future directions for research and implementation.

Methods

With the aim of advancing the collection of ADEs, we focus on three distinct methodologies: GTT, sensor technologies, and IoMT. The GTT, in particular, boasts an extensive reservoir of academic literature, especially concerning its application in ADE collection. Since its seminal introduction into healthcare infrastructures in the early 1990s, the GTT has become a cornerstone technique. Over the past decade, it has been systematically used for detecting ADEs, highlighting its important and lasting contribution to the development of this field. On the other end of the spectrum, research on sensor technologies and the IoMT is in its early but rapidly developing stage. These cutting-edge methods are still predominantly being evaluated in pilot settings. As such, they have not undergone validation in healthcare setting. Sensor technologies and the IoMT offer promising means to collect more precise and timely signals for ADE detection, potentially surpassing the manual methods used in the GTT approach. This shift may lead to a more efficient and integrated model of pharmacovigilance.

The IHI Global Trigger Tool: a new era in monitoring adverse events in healthcare

Healthcare systems worldwide have been plagued by adverse events (AEs) that jeopardize patient safety, leading to preventable complications, extended hospital stays, and even mortality. Traditional methods, such as voluntary reporting systems and error-tracking databases, were historically the go-to means for detecting these AEs. However, these methods demonstrated significant shortcomings: they were notorious for underreporting, and they often highlighted errors that, while concerning, did not always lead to tangible harm to the patient.

Addressing these challenges, the Institute for Healthcare Improvement (IHI) unveiled a fundamentally different approach with the IHI GTT.[27] A cornerstone of its methodology is the systematic and structured application of "triggers." These triggers, which can be thought of as red flags or early warning signals, are specific words, phrases, laboratory values, or medication orders found in patient records. Their presence may signify potential AEs that might not be immediately obvious upon a casual review. By systematically sifting through patient documentation and harnessing the power of these predefined triggers, healthcare professionals are empowered with the ability to uncover latent AEs, which would otherwise remain buried using older, less sensitive systems.[27]

Recognizing the logistical and operational challenges of implementing such a detailed approach, the IHI has complemented the GTT with a comprehensive and rich assortment of supplementary resources. These range from a curated list of AE triggers to best-practice guidelines for record selection, thorough training materials for reviewers, and a comprehensive appendix detailing trigger definitions and usage. This repository not only facilitates the tool's implementation but also empowers healthcare institutions with the means to monitor pivotal metrics, such as Adverse Events per 1000 Patient Days, Adverse Events per 100 Admissions, and the alarming Percentage of Admissions that culminate in an Adverse Event.[27]

The conceptual foundation for using triggers as indicators for adverse event (AE) detection was established by Jick in 1974.[28] With technological advancements in the digital era, electronic triggers were integrated into hospital information systems, significantly enhancing the efficiency of AE identification.[29,30] Recognizing the limitations of traditional strategies, the Institute for Healthcare Improvement (IHI) took action in 2000, forming a task force that led to the development of the Global Trigger Tool (GTT). This tool, a synthesis of multiple trigger tools, provides a comprehensive metric for harm at healthcare institutions.[27]

The implementation of GTT in the global healthcare community has been remarkably positive and widespread since its inception in 2003. Its integration into prominent campaigns, such as the IHI's 5 Million Lives Campaign, highlights its success and widespread adoption, especially in countries like the USA.[31] Moreover, the GTT can be adapted to various countries and adjusted to suit diverse regional contexts, making it suitable for different healthcare landscapes and patient populations.[27]

The GTT's efficacy and demonstrated potential to detect a wider range of harm have attracted attention globally, with countries like Belgium leveraging it for pharmacovigilance and China customizing it for pediatric patients and addressing challenges related to polypharmacy.[32–35] Its versatility is evident in applications ranging from Italy's medical AE monitoring to Norway's surveillance in both general and psychiatric hospitals.[36–38] Evaluative studies, including those by researchers like Hanskamp and Sebregts,[39] have contributed to solidifying the GTT's reputation for reliability and validity under specific review conditions. Comparisons, such as the one undertaken by Sharek et al.,[24] have demonstrated the GTT's superiority over similar collection systems in identifying AEs. The tool's adaptability is further underscored by customizations tailored for specific groups, such as pediatric cohorts.[40]

Advancements in sensor technologies and their implications for healthcare and pharmacovigilance

Sensors, particularly those used to monitor biosignals such as heart rate, respiration, and biochemical markers, have significantly evolved thanks to advancements in semiconductor technology. These developments have enabled the creation of low-power, high-precision devices suitable for continuous patient monitoring in clinical settings. Coupled with intelligent wireless communication networks and increasingly sophisticated big data analytics, these advancements constitute the foundation of the Internet of Things (IoT). These sensor nodes, endowed with sensing, control, data processing, and networking capabilities, can interconnect, laying the groundwork for the IoT and considerably more sophisticated Big Data applications.[41]

Thanks to the high level of detail they provide, modern sensors are becoming increasingly important across diverse applications, including environmental monitoring, eHealth, and the broader IoT ecosystem. In healthcare, they offer high potential for collecting and analyzing data related to drug efficacy and safety, thereby enhancing precision and accelerating evaluation processes. Sensors can continuously monitor patient vital signals like heart rate, blood pressure, and body temperature, providing medical professionals with real-time data, information which is crucial in emergency departments or for detecting subtle changes. Moreover, they can oversee medication adherence and drug dosage, offering an accurate portrayal of patient compliance and medication effectiveness.

In the era of ubiquitous internet connectivity, wearable technologies have enabled collection of vast amounts of health-related data.[42] Present-day smartphones possess the capability to track myriad physiological metrics including heart rate, blood glucose levels, electrocardiographs (via connected accessories), activity levels, and more. This extensive information can be instrumental in identifying adverse drug reactions (ADRs). Wearable devices embedded with electrochemical sensors can harvest pharmacokinetic data from sweat, tears, or saliva, enriching this data pool. Furthermore, location-specific data, sourced from map histories or social media platforms (with appropriate consent), can indicate visits in healthcare services, potentially indicative of ADRs or related concerns. Investigations into drug-associated Google search trends have mirrored community drug consumption patterns.

Overall, data from wearable sensors is becoming increasingly pivotal for pharmacovigilance and clinical research.[20] The notion of a "digital biomarker," essentially a measure computed over measurements performed via a wearable sensor, equating a biological biomarker, is evolving rapidly. As mobile devices play an increasingly prominent role in clinical trials and health monitoring, the resulting influx of data presents significant challenges—comparable to those of social media analytics, but amplified by greater volume and complexity.

Delving deeper, Dorj et al.[19] present an intelligent healthcare system underpinned by nanosensors. This paradigm, involving minute sensors embedded within patients or applied externally to monitor various health metrics, can wirelessly transmit this data to an advanced data management system. However, ensuring data accuracy, maintaining sensor calibration, and handling vast datasets emerge as substantial challenges requiring robust solutions.

Highlighting a specific application, Lin et al.[43] discuss nanosensors' potential in glucose detection, spotlighting their relevance in continuously tracking glucose levels and potentially improving drug safety among diabetic patients on complex regimens. The integration of these nanostructured sensors into wearable devices augurs well for drug safety and can inspire subsequent innovations in non-invasive diagnostics and chronic disease management across various conditions. In the context of orphan drugs, Price[44] accentuates the rising significance of sensors in pharmacovigilance, where continuous monitoring can provide crucial safety data for small patient populations. Mobile applications and biosensors can continuously monitor health metrics and transmit this data. Yet, the extensive and diverse data from continuous monitoring can make identifying true correlations challenging, necessitating advanced computational capabilities and careful study design. Lastly, Triantafyllidis et al.[18] postulate a framework for crafting sensor-driven health monitoring systems. The authors demonstrate the framework's feasibility and value in pervasive healthcare and project its utility in shaping future systems focusing on continuous, personalized patient care.

IoMT sensors in predicting and tracking adverse drug events

The Internet of Medical Things (IoMT) represents the convergence of medical devices, sensors, and software applications with the broader Internet infrastructure, often hailed as a fundamental pillar and core component of "Smart Healthcare." The overarching goal of IoMT is to transform the conventional healthcare paradigm by facilitating seamless, secure exchanges of medical resources, data, and services, fostering improved coordination and resource allocation for practitioners and patients alike.[45] Yet, the essence of this transformation extends beyond the mere interconnection of digital devices; it lies in leveraging the vast and diverse data generated by these devices to enhance patient care quality, predict potential health issues including ADEs, and proactively address adverse drug reactions.[46]

The role of sensors is critical in the IoMT; they have evolved significantly from basic tracking entities to sophisticated tools capturing a diverse array of patient physiological and behavioral metrics. These range from fundamental devices like blood pressure monitors and glucometers to advanced implantable devices such as life-critical pacemakers and continuous glucose monitors.[47] The applications of sensors have expanded beyond clinical settings to residential spaces, particularly those housing the elderly or chronically ill patients, where specialized sensor-based monitoring systems contribute to timely medical intervention, improved adherence, and support rehabilitation efforts, especially in mobility restoration post-injuries or surgeries.[5] These strategically positioned sensors not only collect data but also transmit and merge it, often via gateways, with centralized hospital databases or cloud platforms, enabling uninterrupted patient surveillance and much earlier identification of potential medication-related complications or deteriorations in health status.[48]

The introduction of disposable sensors holds significant promise, driven by recent advancements in plastic, paper, and textile-based electronic manufacturing techniques. Crafted from unconventional materials like flexible paper substrates or conductive e-textiles and often equipped with RFID or NFC capabilities for communication, these sensors are increasingly promising to facilitate ultra-affordable IoMT sensors, supporting point-of-care diagnostics and remote monitoring applications.[49] Their portability and lean operational blueprint enable patient monitoring beyond traditional clinical settings, providing a continuous stream of real-world data that can pinpoint potential health risks or early signs of ADEs.

These technological developments have far-reaching effects across various sectors, particularly in healthcare service delivery and management. The industry is evolving into a symbiotic nexus where physicians, patients, paramedical staff, diagnostic labs, and even family caregivers converge through the digital threads of IoMT.[45] This digital synergy extends far beyond simple data sharing; it aims to create a fluid, responsive system where patient health trajectories are dynamically monitored, analyzed, and potentially modified through timely medical interventions or adjustments to care plans. The data influx from IoMT sensors and connected devices supports a more personalized, patient-focused healthcare strategy.[50] IoMT's adaptability ensures that medical interventions, including medication choices and dosages, can potentially be tailored more precisely to each patient's unique health profile and real-time physiological response. This data-driven, personalized approach extends beyond direct patient care, for example, to clinical research and even the insurance domain. Biometric data from wearables, connected health devices, and biosensors is reshaping risk assessment, potentially enabling novel insurance pricing models based on tangible health parameters and behaviors.[47]

In summary, the IoMT—driven by its expansive and increasingly sophisticated network of sensors—is reshaping how data is collected, analyzed, and utilized in healthcare. From improving chronic disease management to enabling personalized preventive care, IoMT's connectivity and monitoring capabilities offer significant and clinically relevant advantages.[5] Enhanced by advanced analytics, including machine learning algorithms, subtle health patterns and potential risks can be discerned well in advance, steadily shifting healthcare toward a more predictive personalized setting.

Results

The modern healthcare era is witnessing an upsurge in digitization and automation across various processes. The integration of the Global Trigger Tool (GTT), advanced sensor technologies, and the Internet of Medical Things (IoMT) within the framework of "smart hospitals" is giving shape to an ambitious vision for a significantly enhanced and more comprehensive pharmacovigilance network, marking a significant stride towards the practical realization of real-time drug safety monitoring.

The integration of GTT, sensors, and IoMT

The GTT, a widely recognized and well-established tool for identifying and classifying adverse events including ADEs, has been an invaluable asset in the healthcare domain for improving safety measurement. It holds an unparalleled reputation for its meticulousness in recording ADEs when applied consistently.[21] Historically, the GTT's limitation was the manual, labor-intensive, and somewhat passive nature of data collection, often relying on retrospective chart reviews. Now, sensors and IoMT devices, proactively furnish a constant stream of health metrics in real-time. The seamless assimilation of data from these devices, ranging from continuous vital sign monitoring to tracking medication adherence via smart dispensers, synergizes with the IoMT infrastructure. This facilitates a robust and continuous update potentially feeding into, or crossvalidating alerts related to, the GTT trigger monitoring system. This represents a marked departure from earlier GTT applications, which depended solely on infrequent, manual updates based on retrospective chart reviews.

Furthermore, the evolution of the healthcare industry through technology is evident in the way it has embraced the potential of IoMT and sensors. The emergence of connected health devices has made remote patient monitoring a staple in contemporary medical practice for certain conditions. With the GTT's potential integration with data streams from these devices (e.g., using sensor data as automated triggers), there's a potential for a more streamlined and timely change in how ADE-related data is collected, analyzed, and acted upon, ensuring a more complete, 360-degree view of patient health and response to treatment. Specifically, this integration could manifest in several ways:

- *Automated Trigger Identification*: Sensor outputs (e.g., sustained abnormal heart rate, significant drops in blood pressure below a defined threshold, low oxygen saturation levels) could automatically flag potential issues corresponding to specific GTT triggers (like hypotension or respiratory distress), prompting immediate clinical review and reducing the need for manual chart searching for specific triggers.
- *Real-time Analytics Integration*: IoMT platforms can connect these automated sensor-based triggers to the patient's EHR, allowing for rapid retrieval and correlation with relevant medication administration records, recent lab results, existing comorbidities, or known allergies, providing basis for assessing a potential ADE.
- *Streamlined Event Logging and Reporting*: Once a potential ADE is flagged (either through automated triggers or manual GTT review) and clinically assessed, the integrated system could facilitate semi-automated logging of the event details for internal quality improvement, pharmacist review, and, where appropriate, expedited reporting to regulatory authorities, thereby minimizing manual data entry and confirming reporting.

A practical example illustrating this potential lies in the enhanced monitoring of antihypertensive treatment, drawing parallels with studies like those emerging from the Finnish research environment focused on leveraging integrated health data.[12–14] In such a scenario, continuous blood pressure data streamed from wearable sensors could be automatically matched with electronic medication administration records within the hospital's system. If a patient's readings consistently fall outside pre-defined safety thresholds (e.g., persistent severe hypotension shortly after administration of a new antihypertensive dose), an automated trigger linked to ADE monitoring could prompt an immediate check by clinical staff. Integrated approaches like this show how timely, data-driven notifications can potentially mitigate risks associated with medication side effects, such as serious hypotensive episodes, ultimately contributing to improved patient care and safety.[9]

Revolutionizing data collection

Truly proactive pharmacovigilance hinges on a dynamic, potentially automated, and comprehensive data collection procedure.[18] Previously, medical personnel often had to manually update records retrospectively for GTT reviews, the envisioned integrated system potentially benefits from an uninterrupted inflow of relevant data points. Wearable sensors, capable of detecting subtle physiological variations indicating ADEs (such as changes in heart rate variability, respiratory patterns, or electrodermal activity), could transmit this data in real-time, potentially serving as inputs to automated GTT trigger detection algorithms. Furthermore, the IoMT infrastructure, acting as an overarching network that encompasses a myriad of medical devices from infusion pumps to patient monitors, ensures that this data is channeled coherently and securely into the central hospital information system.[19]

Governance, quality control, human oversight, and regulatory compliance

While the integration of GTT methodologies with automated data streams from sensors and IoMT offers significant potential, it requires robust governance structures, rigorous quality control, and human oversight to ensure reliability and clinical validity.[2,3] Although automation can accelerate the initial detection of potential ADE signals, the clinical judgment of healthcare professionals remains indispensable. A "human-in-the-loop" governance model is crucial; this ensures that clinical experts, such as pharmacists and physicians, rigorously validate any automatically generated signals or triggers, confirm the underlying causality by reviewing the complete clinical data, differentiate true ADEs from other clinical events, and provide feedback to iteratively refine the detection algorithms or trigger thresholds. Quality control (QC) protocols must be established and regularly executed. These protocols should involve periodic audits of how triggers (both manual and automated) are identified and applied, assessments of the appropriateness of any automated alert thresholds, evaluations of inter-rater reliability for manual reviews, and tracking the rate at which flagged events are confirmed as actual ADEs upon expert review. This essential combination of AI-driven or automated data processing coupled with expert clinical review minimize false positives, reduce alert fatigue, and cultivate clinical trust in the advanced pharmacovigilance system.

Furthermore, ensuring patient privacy and data security is paramount when handling sensitive health information collected through sensors and IoMT devices. Smart hospitals must implement state-of-the-art cybersecurity measures, including strong data encryption both at rest and in transit, secure network architectures, robust access controls, and regular vulnerability assessments to safeguard patient information against unauthorized access, breaches, or misuse.[51] Compliance with data protection regulations (such as GDPR in Europe) is non-negotiable.

It is also important that these emerging methodologies for ADE detection and reporting comply with the evolving landscape of health data and AI regulations within the EU and globally.[2,3] This includes alignment with initiatives such as the forthcoming European Health Data Space (EHDS), which aims to establish clear rules and infrastructures for the primary and secondary use of health data across member states.[52] By designing and implementing smart hospital data infrastructures in accordance with anticipated EHDS requirements for data quality, interoperability, security, and ethical secondary use, institutions can ensure that the valuable insights derived from enhanced ADE detection are shared effectively and appropriately. This alignment facilitates the flow of validated safety information not only to internal clinicians and hospital administrators for immediate patient care improvements but also to national regulatory bodies (like Fimea in Finland) and pharmaceutical companies to fulfill mandatory reporting obligations and contribute to broader public health surveillance.[2,3,52]

Automated pre-analysis leveraging artificial intelligence and machine learning

The GTT framework, potentially enriched by a continuous flow of high-granularity data from sensors and IoMT devices, becomes amenable to advanced analytics. Artificial intelligence (AI) and machine learning (ML) algorithms, specifically designed for pre-analysis or signal detection support, can sift through extensive, multidimensional datasets.[53] Employing techniques such as pattern recognition, anomaly detection, time-series analysis, and predictive modeling, these algorithms might identify potential ADE signatures or deviations from expected patient trajectories with a level of speed and potential sensitivity that could complement or potentially exceed purely manual analysis in certain contexts.[54] Through the careful and validated integration of AI and ML methodologies, the pharmacovigilance system becomes more powerful and efficient in ADE detection, concurrently decreasing manual workload of the healthcare professionals. This allows highly trained professionals to focus on validating complex signals, investigating causality, and recommending interventions, with the AI-supported system handling aspects of the initial data sifting and analysis.

Reporting to regulatory and industry stakeholders

An essential outcome of enhanced ADE detection within smart hospitals is the timely and accurate reporting of relevant safety signals to key external stakeholders. In Finland, the national regulatory authority (Fimea) mandates the prompt reporting by healthcare professionals and institutions of any suspected serious adverse reactions.[2,3] Simultaneously, pharmaceutical companies (Marketing Authorization Holders) have a stringent legal responsibility to systematically collect, assess, and report ADE information associated with their products to regulatory agencies as a cornerstone of ongoing pharmacovigilance.[2,3] Consequently, pharmacovigilance systems within smart hospitals, leveraging integrated data from GTT, sensors, and IoMT, should be designed to facilitate this reporting process. Ideally, once a potential ADE signal has been identified and rigorously validated by designated human experts (e.g., clinical pharmacologists, pharmacists, or safety officers), the system should enable the efficient, standardized forwarding of necessary report details to both the national competent authority and the relevant pharmaceutical manufacturer(s). This streamlined reporting pathway ensures that improved detection capabilities at the point of care translate effectively into broader risk assessment, signal management, and potential regulatory actions (like updating product information) across the wider healthcare ecosystem.

Aligning with these regulatory and industry expectations, pilot programs and research initiatives, such as those explored within the Finnish context, are investigating ways to integrate automated or semi-automated pharmacovigilance findings and dashboards with national health databases or reporting portals.[2] Such integration aims to provide regulators and pharmaceutical companies with more timely and comprehensive access to emerging, validated ADE information derived from real-world clinical practice. These initiatives underscore the significant potential for localized, technologically enhanced detection systems within smart hospitals to scale up and contribute meaningfully to national and potentially international vigilance frameworks. This is particularly valuable for monitoring the safety profiles of newly introduced medicines or therapies that require close observation in the post-marketing phase.

Driving patient engagement through real-time feedback

Another potential and valuable aspect of this integrated system is its ability to facilitate real-time feedback and increased engagement for patients. With continuous monitoring capabilities and data streaming accessible via patient portals or dedicated applications, patients could potentially be apprised of certain relevant health metrics instantaneously (depending on clinical appropriateness and system design). This not only ensures patients are potentially better informed but may also foster a greater sense of empowerment and active engagement in their own healthcare journey.[55] By creating secure platforms where patients can access their own data (appropriately contextualized), understand trends, and healthcare professional based on this real-time feedback, healthcare service providers can cultivate a more genuinely collaborative and participatory framework with patients regarding their treatment and well-being.

Enhancing clinical processes

Beyond potentially improving patient safety and outcomes, the thoughtful fusion of the GTT methodology (perhaps partially automated) with sensor data and IoMT connectivity could also significantly streamline certain clinical processes. With more timely data flow and AI-driven pre-analysis identifying potential issues earlier, redundant tasks might be reduced, and healthcare practitioners could spend more time with patients and on complex decision-making.[56] Moreover, with automated alerts and notifications (appropriately filtered to avoid fatigue), medical personnel could potentially prioritize critical cases more effectively, ensuring that patients in dire need receive timely interventions. This not only improves the efficiency of healthcare services but also positively contributes to the overall patient experience and perceived quality of care.

Pharmacovigilance: the road ahead

We propose that smart hospitals employing an integrated GTT-sensor-IoMT system may embody the promising future direction in modern pharmacovigilance. The potential for real-time detection, coupled with predictive analytics, possesses the capacity to significantly enhance patient safety and improve clinical outcomes related to medication use. Moreover, as these systems evolve and become standardized, creating a collaborative pharmacovigilance network across hospitals becomes increasingly feasible. This would support a more proactive, data-driven response to ADEs across institutions and patient populations.[57]

Discussion

As outlined in Section 2, the GTT has established its position as a pivotal instrument within healthcare for measuring harm.[58] Historically, ADE data collection, even using GTT, leaned heavily towards manual input and retrospective review by healthcare professionals. However, the integration of sensors and IoMT has catalyzed a shift toward automated systems capable of continuously monitoring patients for signs of ADEs.[59] The design and realization of such an integrated system demand expertise from multifarious domains, including health informatics,[60] information engineering,[59] clinical pharmacology, and hospital pharmacoepidemiology.[61]

The challenge lies not only in the aggregation of diverse data types (structured EHR data, GTT review findings, high-frequency sensor streams) but also in ensuring seamless and meaningful integration with existing hospital data management systems. This integration is particularly crucial for systems geared towards internal quality improvement and mandatory external data sharing with regulatory agencies. As discussed in the Results section, data privacy and security remain paramount, necessitating robust encryption, stringent access controls, and ongoing privacy-preserving protocols.[62] Given the sensitivity of healthcare data, rigorous validation procedures for any new automated detection algorithms or integrated systems, benchmarked against current digital medicine standards and clinical expert judgment, are imperative before widespread adoption.[2]

The seminal work of Amalberti et al.[21] offers a glimpse into the inherent complexity and profound importance of understanding and preventing adverse events, lending support to the need for more precise pharmacovigilance methods. With this respect, the focus on localized, high-fidelity data gathering within the controlled environment of a smart hospital resonates with the paradigm outlined by De Pretis et al.[2,3] Concurrently, studies on sensor applications, IoMT frameworks, and advanced data analytics in healthcare[18,19,58] have expanded the knowledge base. Together, they contribute to the ongoing development of proactive and personalized pharmacovigilance models for smart hospitals.

The potential fusion of traditional healthcare methodologies, embodied by tools like the GTT, with burgeoning technological advancements including sensors, IoMT, AI, and ML points to a potentially transformative new level in patient care and medication safety. These integrative systems are not just about improving the efficiency of cataloging ADEs; they underscore a fundamental transition from largely reactive post-event analysis to potentially preventive setting, where ADE risks might be anticipated based on individual patient profiles and real-time monitoring, and when possible, preemptively mitigated through timely intervention.

As technology advances rapidly, it’s imperative to consider its implications within a broader societal and regulatory context. Industry stakeholders are actively assessing these innovations in healthcare. For example, the position paper on AI in pharmacovigilance by the EUCROF PharmacoVigilance Working Group[iv,v] discusses both the opportunities and challenges. Moreover, major technology industry giants like Amazon are manifesting keen interest in applying cloud computing and AI to streamline pharmacovigilance workflows, as highlighted by their public discussions and service offerings.[vi] This growing industry interest signifies the perceived value but also necessitates careful consideration of data governance and ethical implications when commercial entities become involved in processing sensitive health data for safety monitoring.

Seminal works by legal and bioethics scholars[63–65] have delved into the multifaceted ethical and legal quandaries associated with the IoT and Big Data in healthcare, including issues of consent, data ownership, algorithmic bias, liability, and the potential for over-regulation stifling innovation versus under-regulation leading to harm. There might be critiques suggesting that relying solely on real-world evidence (RWE) from broader, less controlled population datasets and existing large-scale data collection methodologies should surpass the potentially more resource-intensive, focused framework of smart hospitals for pharmacovigilance. Nonetheless, the work of researchers like White et al.[66] highlights the importance of diverse data sources. Controlled environments such as hospitals are especially valuable for pioneering and validating new technologies before they are deployed more broadly. Smart hospitals can offer a valuable testbed for developing and refining these complex integrated systems.

Beyond the present perspective, various factors can further refine this integrated system and its outputs. Inclusion of detailed information such as individual genomic backgrounds (pharmacogenomics), other relevant OMICS data (e.g., proteomics, metabolomics impacting drug response), precise drug dosages administered, comprehensive tracking of concomitant medications, and documentation of comorbidities might set the stage for more advanced and granular patient stratification for ADE risk. Adopting such a thorough methodology would necessitate leveraging both conventional statistical methods and novel computational techniques specifically adapted for complex pharmacovigilance data analysis, potentially leading towards more personalized risk prediction, as discussed conceptually by La Russa et al.[67]

As we embark on this rapidly expanding and complex terrain of multi-modal data gathering, a rising need emerges for innovative and validated techniques related to data amalgamation, rigorous statistical examination, and meaningful data fusion from heterogeneous sources. The work of Zhuravleva et al.[68] on improving pharmacovigilance systems, along with methodologies for evidence synthesis and data fusion explored by De Pretis et al.[69,70] and Streit and Silver,[71] collectively helps to illustrate and underscore this critical point. This trajectory of ongoing study and technological progress will shape the future implementation and effectiveness of preventive and personalized pharmacovigilance within smart hospitals.[2,3]

Eventually, the effective and ethical confluence of GTT principles, advanced sensor technologies, and robust IoMT infrastructure signifies a major and crucial evolution in established healthcare paradigms for monitoring patient safety. As we venture further into this technologically driven era, the potential of such integrative systems in enhancing patient care and preventing medication-related harm is increasingly evident and compelling. While significant challenges undeniably exist, especially concerning data security, interoperability, algorithmic validation, regulatory compliance,[2,3,52] and ensuring equitable access, the potential benefits of substantially strengthened, preventive pharmacovigilance and consequently improved healthcare processes appear likely to outweigh them, provided these challenges are addressed thoughtfully and rigorously. In the short to medium term, we do expect pharmaceutical companies, regulatory agencies, healthcare providers, and technology developers to engage collaboratively worldwide to further explore and refine this kind of integrated perspective for enhancing drug safety.

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Data availability statement

Not applicable, as no datasets were generated or analyzed during the current study.

Notes

i. Suomen sosiaali-ja terveysministeriö (Finnish Ministry of Social Affairs and Health). *Secondary use of health and social data*. https://stm.fi/en/secondary-use-of-health-and-social-data [Retrieved 2025-08-01].

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