

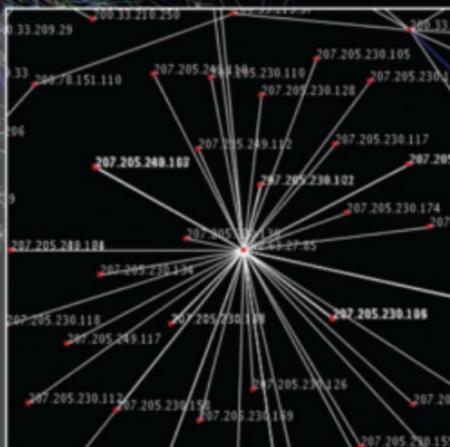
IEEE

A PUBLICATION OF THE IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY

Technology and Society Magazine

VOL. 34, NO. 4, DECEMBER 2015

BLOCKCHAIN THINKING





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Pharmaco-Electronics Emerge

Meteoritic progress in sensor, computer, and telecommunication technology has catapulted healthcare into the realm of pharmaco-electronic medicine, where increasingly we depend on automated intelligent systems to keep us well.¹ Digital technology, in nearly every corner of 21st century lives, has spawned a cornucopia of lifesaving and life enhancing products, many already adopted by the medical profession and mainstreamed into modern life. This development is in large part a result of: 1) exponential accumulation of scientific knowledge and ever-increasing computationally sophisticated computers and software, to turn that knowledge into medical technology; 2) accelerating computer processor speeds, where between 2012 and 2020,

¹Pharmaco-electronics is word coined by the author as a sub-category of mHealth, the term Robert Istepanian coined and for which a definition emerged at the 2010 mHealth Summit of the Foundation for the National Institutes of Health as “the delivery of healthcare services via mobile communication devices” (1), (2).

Digital Object Identifier 10.1109/MTS.2015.2494340
Date of publication: 17 December 2015



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engineer’s anticipate an eight-fold increase from an already astounding 40 billion flops to 330 billion flops;² 3) 4G communications networks and the planned successors, with gigabit (10^9) per second bandwidth backbones, robust networking infrastructure, and high-speed relays that provide the medium over which laptops/wireless modems,

²Flop are program cycles or operations occurring per second.

and smartphones communicate from anatomically deep seated application specific processors, directly to the cloud; 4) continuing miniaturization of computer transistors, currently smaller than a 22 nm (the size of a rhinovirus) that will soon pass into the 5–7 nm size range, employing materials such as wafer-thin graphene (carbon) and MoS₂ (molybdenum disulfide) that measure a few atoms wide, assuring us that when processors reach

micron size levels, we can virtually decouple from the traditional doctor-patient model for diagnosis.³

As in-the-body and wearable processors become commonplace within the next decade, reactive medical practices will evolve into predictive, preventive, personalized, and participatory medicine, or what has been popularly coined “P4” medicine, where devices send physiological data into the cloud so that “examinations” can proceed in real time. Expert systems, not doctors, will analyze and determine wellness and disease, and tweak personalized electronic prescriptions for treatment and anatomical enhancement. Information gathered directly from patients will be used to update charts automatically, and may also be used to alert health officials, such as the U.S. National Center for Disease Control, of impending pandemics or the potential transmission of diseases, such as Ebola and AIDS, and capable of identifying the individuals that pose the public health risk.

By 2020, The Internet of Things (3), largely RFID, will connect 100 billion identifiable objects to the Internet (4), (5), many of which will be implanted RFID-like devices, yet a significant proportion will be in the form of in-the-body application specific processors.⁴ And, beyond

³Today’s silicon-based microprocessors use 22-nm transistor technology, assembled as six-core hyper-threaded chips running at roughly 3.3 GHz. Since each core executes two threads, the theoretical processing speed is 40 billion flops. Before 2020, silicon chips will use between 5 and 11 nm technology incorporating fifty cores allowing 100 simultaneous hyper-threads to execute 330 billion flops. Although a general purpose microprocessor may measure 90 mm² and contain several billion transistors, application specific processors (ASICs) can be constructed employing fractions of the number of transistor and remain computationally powerful while reaching down into the sub-micron (smaller than blood cells) range for special processes.

⁴Products range from relatively simple devices containing medical history that are injected under the skin, to more complex devices connected to the brain (6), (7).

2020, as computers downsize, their increasing ubiquity among the population will extend lifetimes, enhance intellect, and assist in adapting to our environments. The consequences of wearable and in-the-body technology are far reaching, and perhaps aside from potential liability and distributive justice issues, matters of autonomy, which relate directly to privacy, will become a foremost concern to the legal community.

Overview of Available Technology

Systems of medical devices, diagnostic and therapeutic, that interoperate in the single-person environment can be divided into three categories: 1) wearable and embedded computer/transmitters, sensors, electrodes, stimulators, actuators, and pumps that deliver therapy and make and transmit measurements; 2) network architecture, including telecommunications that interconnect the devices, both within the body and to the outer world; and 3) mechanisms to program and re-program applications using interoperability architectures. Combined, these systems will allow for sharing of information throughout networks both wired and wireless. Diagnostic/therapeutic devices will be tailored to a range of specialized clinical situations, home care, hospitals, the battlefield, portable applications and doctor visits. Apple Computer’s HealthKit (app installed on iPhone 6) and the Samsung Digital Health Platform are but a two examples of smartphone technology that have health and fitness apps to collect physiological data. The data inform the user of wellness; help combat medical disease such as diabetes; and potentially send the data directly to hospitals, insurance

companies, and doctors, which can update, in real-time, an individual’s medical record.⁵

The latest embedded medical gear often connects through Bluetooth or other technology to both local and remote computers,⁶ including smartphones, such as Apple’s iPhone 6, special phone equipment,⁷ and local general purpose Internet modems that transmit medical data to central sites, where a patient’s condition is analyzed.⁸ We see the emergence of sensors and stimulators telecommunicating with varying degrees of sophistication: a) to monitor the wellness of otherwise symptom free individuals, who desire to have their health monitored; b) to track the occurrence of illnesses extant within a population; c) to diagnose, for example the onset of a heart attack; d) to diagnose the state of the electronic device, e.g., the functioning of the battery life for a pacemaker or a prosthetic; e) to adjust an anatomical process, e.g., to alleviate pain, depression

⁵By way of example, Samsung’s commercial partners for digital health currently include: Nike, Aetna, Cigna, Cleveland Clinic, dacadoo, Edamam, Humana, Fitbug, Lark, Merck, Preventice, Skimble, and WellDoc. Samsung’s research partners include UCSF, imec, Bloom Technologies, EarlySense, Elfi Tech, Stanford University, LifeBeam, Sensifree, and SleepRate.

⁶Presently in-the-body medical devices, such as the pacemaker, maintain a bi-directional radio communication with a remote albeit local computer in the Medical Implant Communication Service frequency band between 401 MHz and 406 MHz. The maximum power transmission is 25 μ W, providing a range of a couple of meters. The maximum bandwidth is 300 kHz, which limits these devices to low bit-rates compared with WiFi or Bluetooth.

⁷The CareLink® Network for pacemakers allows patients to have their devices checked remotely by telephone connection rather than what had previously required a doctor’s office visit: a full parameter summary, battery voltage and longevity, lead impedance and trends, automatic capture thresholds, episodes, percent pacing, histograms, real-time and magnet egms, stored egms, arrhythmia summary with mode switch duration (8).

⁸See (9), reporting on a system that detects an arrhythmia and informs the patient’s condition by automatically sending an alerting SMS to the mobile phone of the doctor and caretaker.

or neurological diseases, such as Parkinson's disease; f) to transmit physiological data, such as obtained from electrocardiograms⁹ and ultrasonic devices at the point-of-emergency with telecommunication (11).

The pacemaker represents the most widely deployed example of an implantable/telecommunicating medical device. It comprises a working silicon-based computer, with sensors, memories, and a stimulation device with telecommunications to the outer world. Doctors install the conventional product beneath the flesh above the outer chest with leads that fix to the inner heart wall. The device paces the heart and may be combined with a cardioverter/defibrillator. The latest innovation bypasses the outer chest wall. The size of a large antibiotic capsule, physicians insert the pacer through the femoral artery leading to the heart's cavity. The device requires no interconnecting wires, but lodges via a "grappling hook" to the heart's inner wall where it stimulates the heart. Technologists project an eventual downsizing on the order of a grain of rice and diminution in power requirements to the point where energy scavenged from the body's metabolic processes someday will keep the pacemaker's micro-circuitry powered indefinitely.

In the family of pacemaker-like devices, the science of neurological stimulators has emerged, such as bone growth stimulators, and drug delivery systems for insulin or pain medication, which additionally typically include a pump, which stores and infuses a drug at a selected rate through a catheter to the desired

⁹See (10), Tele-diagnostic device, for collecting diagnostic information and transmitting the diagnostic information to a remote location.

location.¹⁰ Other neurological stimulators provide for "deep brain stimulation," to treat depression and bradykinesia (slow movement) associated with Parkinson's disease, where electrodes are implanted in the subthalamic region of the brain. The wire ends are placed beneath the scalp and an impulse generator placed in the chest. These treatments address not only tremors, but the full range of the symptoms, including: rigidity, slow movement, stiffness, and walking concerns. Medical technicians can adjust the device parameters remotely, via a telecom link.

Intelligent medicines, or chip-in-the-pill technology, offer yet another family of devices, roughly the size of a grain of sand. In the early 1960s, the Konigsberg telemetry pill was first ingested by patients to record their temperature and transmit the data to a receiver for analysis. In 1991, Jerome Schentag invented a pill that when swallowed was tracked as it progressed through the alimentary tract, and upon reaching a specific site, was remotely triggered to release medication. More recently, the FDA approved a pill that when swallowed transmits to a receiver (a sensing patch on the patient's shoulder) to report when a prescription has been ingested. Such chip-in-the-pill products can also measure heart rate and respiratory patterns using circuitry run on a charge generated by a patient's stomach acid. The data, transmitted through the patient's mobile phone or tablet, allows a caregiver or patient to view when the patient ingested a chip and when the medication started to metabolize. Other similar technolo-

¹⁰Medtronic, Inc., developed the IsoMed Constant-Flow Infusion System for bodily implantation that provides intrathecal infusion of morphine sulfate solution in the treatment of chronic intractable pain, or the intravascular infusion of floxuridine for the treatment of primary or metastatic cancer.

gies contain cameras capable of revealing colon tumors.

Legal Corollaries of Systems of Pharmaco-Electronics

Unlike pharmaceuticals, in-the-body electronic medicine deals with a complex system of distributed elements: an embedded device, a communications network that includes a local intermediary receiver/transmitter (e.g., smartphone, modem, and telephone line interface), a remote computer, software at every level, databases (often in the "cloud"), automated decision making, and, finally, the all-important pharmaco-electronic prescription.

Although impossible in this space to discuss the rights, duties, obligations and liabilities associated with pharmaco-electronic prescriptions, the compendium of torts, actions in contract, including medical malpractice, and product liability for pharmaceuticals and medical devices generally apply to in-the-body medical devices.¹¹ Electronic medicine is related to pharmacology generally and more directly to medical devices as goes its intended effects, and we look to legal precedent as developed in these areas. For example, The U.S. Federal Food, Drug, and Cosmetic Act, 52Stat. 1040, as amended, 21 U. S. C. §301 et seq. (Medical Device Amendments of 1976 ("MDA")), requires FDA approval for the introduction of new drugs and medical devices. In 2008, the U.S. Supreme Court considered whether the pre-emption clause enacted in §360k of the MDA prohibited common-law claims challenging the safety and effectiveness of a medical device after premarket approval by the

¹¹For example, in January, 2007 Medtronic, a leader in pacemaker technology, reported five patient deaths. The FDA has 599 reports of malfunctions and injuries associated with fractured leads. Suits followed and Medtronic settled most of the cases.

FDA (11). The Court held that state common law claims of negligence, strict liability, and breach of implied warranty against a device's manufacturer were preempted by the MDA, and that states cannot establish requirements that are different from, or add to, any federal requirement applicable to the device (13). The Court indicated that "State tort law that requires a manufacturer's (device) to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." Plaintiff's claims were preempted because they attempted to establish state requirements for safety that were "different from, or in addition to" the federal requirements, although the Court indicated that the federal law "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements" (12, *supra* note 122, pp. 322–323).

As a population becomes increasingly dependent on electronic medicine for its state of health, ownership and control of the pharmaco-electronic prescriptions will need fresh consideration. For example, who will decide availability, price, performance/warranty, safety, personal security, and ownership of data, and who will control the intellectual property, such as patent/copyright licensing, which may affect access for upgrading device hardware/software or repair. Although some of these issues currently run through pharmaceuticals and medical devices, many of them, such as ownership of data, security, and software updates, will raise issues unique to pharmaco-electronic prescriptions.

Two chief concepts in medical ethics relate to autonomy and non-

maleficence, which together serve as the basis for the right to privacy and to one's liberty interest. Personal ownership, which is complete interest and title to medical data, and the power to enforce those rights, assures that the data will be used for its intended purpose. Medical data, in contrast to medical information, consists of electronic data representations directly related to a patient (e.g., heartbeats or doses of a prescription) as acquired through a sensing device (e.g., pacemaker) or controlled through a transducer. Medical data at the patient level also includes transmission protocols, such as device addresses, packet control data, hash codes, and encryption keys. The data may be parsed, so it exists in various places, where medical professionals can obtain access, albeit that the charts authored by doctors will remain medico-legal records, and typically "owned" by the medical professional.¹² The difference between medical data and medical information is more than semantic. Although valid arguments might be made as to the right of a doctor to own a patient's medical record, our attention is drawn to medical data, because it further differentiates itself on the basis of: 1) the potential for non-medical uses, 2) the seriousness of harm that may occur in its misuse, and 3) lack of present day protection for its integrity, privacy and security."

The FDA monitors recalls on products that contain errant components, including software, but few instances have been reported of Internet and software related

¹²It will be interesting to see how this ownership question develops. Medical providers typically have claimed to own the information, because they created it, use it, store it, and control it. As this information goes to the "cloud," and both storage and control belong to a third party, with potentially liability for its release increasing, medical professionals may not want to "own" those records.

willful misconduct or malfeasance resulting in bodily injury or death (14). Criminal activity, through the use of computers including the Internet, takes many forms that will be applicable to in-the-body/telemetry devices and systems (15)–(24). Unlike most computer hacking, which generally invades privacy or wrecks economic damage, hacking an in-the-body device is potentially lethal, as for example slowing down or halting a pacemaker or commanding a defibrillator to deliver a 800-V deadly shock from a mobile device several feet away (25)–(27). However, currently little enforcement (state or federal) is apparent, if an individual is a victim of software piracy, knockoff, unlawful upgrade, hacking, or virus.

In addition to drugs and devices, the U.S. FDA and the European Medicines Agency (EMA) deals with combination products, which include, among other things, products largely comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and marketed as a single product¹³ (28). The FDA must

¹³A combination product resides in the body in the form of a computer control system for: drug infusion, electrical excitation, or electronic sensing as coupled to one or more of an electrical circuit, mechanical device, or drug delivery apparatus.

¹⁴There are numerous recalls related to malfunctions in medical devices with software for example, on Mar. 6, 2013, the FDA Medical Recall Division, recalled the Alaris PC Unit (Model 8015) with Software Version 9.12 manufactured by CareFusion Corporation. The Alaris PC unit (model 8015) is part of the Alaris electronic infusion pump. An electronic infusion pump delivers controlled amounts of medications or other fluids to patients through intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration. The reason for the recall was that the company received reports of a communication error on the Alaris PC unit (model 8015) with software version 9.12 when the Alaris EtCO₂ module or Alaris SpO₂ module is attached. It reported that the use of the product may cause serious adverse health consequences, including death. See, <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm348983.htm>.

position itself to address the world of implantable/telemetry devices integrated into an external world of telecommunications on a large scale, for devices used for medical prescription and for non-medical enhancement.¹⁴ Regulatory schemes must consider that, unlike implanted medical devices that today run primarily in a closed system, the future implanted/telemetry device will be connected to remote servers that will play an operational role in updating software and even making adjustments, much as occurs in personal computing, today.

Government agencies, presumably the FDA and EMA in the case of combination medical devices, must consider regulation of implantable/telemetry related software, controlling who will supply medical device software, software updates, or who decides when software subscriptions can run out. These matters invariably implicate insurance, health care, patents, copyrights, licensing, product safety, and other consumer laws. In the future the U.S. Congress may consider empowering a new Federal office to police viruses, bots, spam, and other evils and ills that befall the average computer user today, but that in the future may endanger the health of many people who use vital, life-preserving apparatuses, potentially causing a malfunction and even death.

Future Implications

Both wearable and anatomically installed computer processors with telecommunications for medical applications at the point-of-patient have crossed the threshold that once separated the experimental from approved forms of electronic medicine. Although the combination of computer-based diagnostic or therapeutic tools and telecommunication technology has been in existence for at least two decades, only now has it begun to show up in

devices that are widely deployed to patient populations-at-large.

Without regulation, commercial interests might well run counter to bioethics. This situation raises issues of autonomy, for example when data security is breached because necessary safeguards may prove expensive, and issues of distributive justice, primarily when lack of affordability restricts access. This last point may not play out much differently from the experience some have when they discover they cannot afford a medical treatment or needed medication. Deprivation of an in-the-body pharmaceutical prescription may mean the difference between life and death.

Finally, once implantable technology goes beyond medicine and into the realm of physiological enhancement (e.g., increased physical and mental agility), it may affect those who would come to depend on its access to maintain their standing in a community of peers, for example, affecting equal opportunity, because an enhanced ability may decide the candidate better able to fulfil the requirements for employment.

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Acknowledgment

This article contains commentary, data, and conclusions, some of which is original and other material that has been disseminated in some significant manner in the author's recent publications: a) *The Techno-Human Shell-A Jump in the Evolutionary Gap* (Sunbury Press, 2012); and b) "Who should own in-the-body medical data in the age of electronic medicine?" (*IEEE Technology and Society Mag.*, Sum. 2014).

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- (22) 18 U.S.C. § 2701 Unlawful Access to Stored Communications.
- (23) 18 U.S.C. § 2702 Disclosure of Contents.

(continued on page 87)

INTERVIEW (continued from page 16)

to ban it. All in all, I haven't had any problem with law enforcement, as a truck driver anyway. A personal vehicle ... I don't know if they're going to – because, I drive down the road and every car that passes me – every car, some days – they're on the cell phone, or they're texting or changing their music. I see police officers passing me with their laptop computers – on Google – driving. And this (Glass) is – it's so much safer, having it right there. And I just think, well, I don't know, if it's the lobbying, or if it's the Congressmen not getting enough money – I don't know why they are trying to do this.

Alexander Hayes: Well what is your view on what happened to Cecilia Abadie who has connected us here. I mean, with the police – are we likely to see laws perhaps universally that change because of the rollout of Google Glass or is this just yet another technology?

Rick Sare: It's another technology. I don't even find it as useful. There is a lot of people that say it's safe to drive with and a lot of people who say it's not safe to drive with. I don't even have my glasses on right now but I still reach for them because I think they are there. And I keep looking up even though they are not

on. That's how unobtrusive they are as I don't even know if they are there or not there. What Cecilia got pulled over for, from all the articles I've read...I've never talked to her about it specifically...we just kind of chat periodically on Google Plus. The officer just noticed that she had Glass on, and with that law that California has about "no screens" and the driver's view. He figured he would write her up for it. Well I am glad she was the first person and not me, because I wouldn't know what to do. I don't know how to hire a lawyer. And me, I would be out of state so I am glad it was her – she's kind of our hero. Like she's – what a great person, an app developer and everything else. I'm glad it got thrown out. I think the law is going to change. They are working on the old GPS laws and stuff. The laws have not been updated for the technology that is getting ready to come. The technology changes every day. I mean we are getting, we will go from the Pebbles (Smart Watch) and new Motos, the LGs, and watches coming out, and the Sony glasses. It's going to change, and in five years who knows where we are going to be, and we are going to have to change the laws again.

Alexander Hayes: Speaking about laws and change...and things

that are happening in your industry...if we focus on your industry side of things...what are the unions that you are part of saying about this technology...or....has it been mentioned anywhere within your key areas of contact?

Rick Sare: No....actually...they don't even....they're focused on other things. I'm the only truck driver that has them that I can find. I've been searching and I've been searching the Internet and all over Google Plus. I don't think they are focused on it because there is only one of us right now. I live in a non-union state, a (right-to-work) state so we really don't have unions. But the rest of the United States – I go to the truck stops – or anywhere – they just look at me funny, and don't know what it is. They think it is a Bluetooth for your ear. They just think it is a new type of Bluetooth. So nobody really knows what is.

My employer knows. My boss – he didn't know what it was at first, but he's pretty much embraced it. And he is letting me go with it as I have over 75 000 safe miles right now, and I'm trying to break the 100 000 mile mark safe driving with Glass and he supports me 100 percent.

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COMMENTARY (continued from page 40)

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