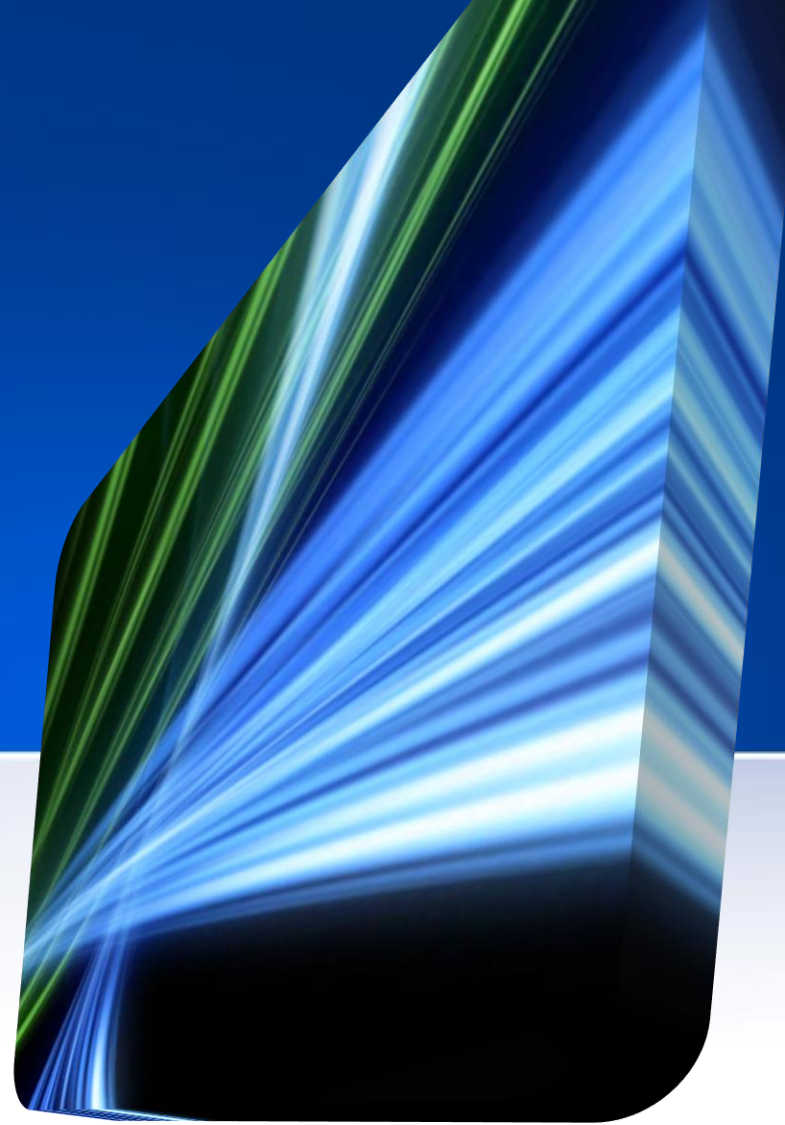


Emerging Medical Technologies



Ethical Reflections on Emerging Medical Technologies



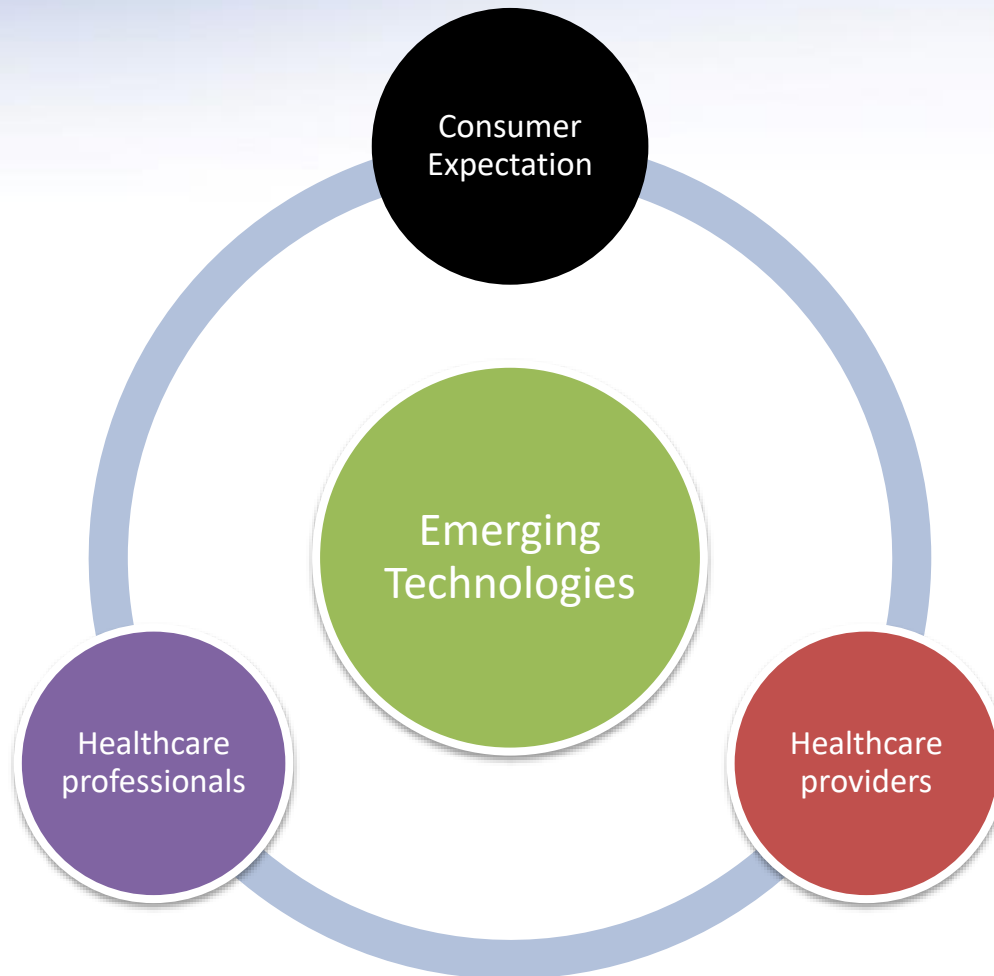
- The emergence of the digital patient
- The genetic revolution
- The development of new pharmaco-therapeutics

Medical Utopias



- Living without pain, diseases or even dying
- No more fertility or reproductive problems
- Delaying or defying the aging process
- Getting rid of physical and psychological imperfections
- Optimize and enhance normal abilities

Medical Utopias and Emerging Technologies



Problems with medical utopias



- It is often a sentiment
- Goals which at first seems to be ideal may turn out undesirable
- Goals may remain unattainable
- Ethic problems during the research and development

Biomedical Ethics Framework



Respect for Autonomy

Beneficence

Non-maleficence

Justice

Ethical areas of concern



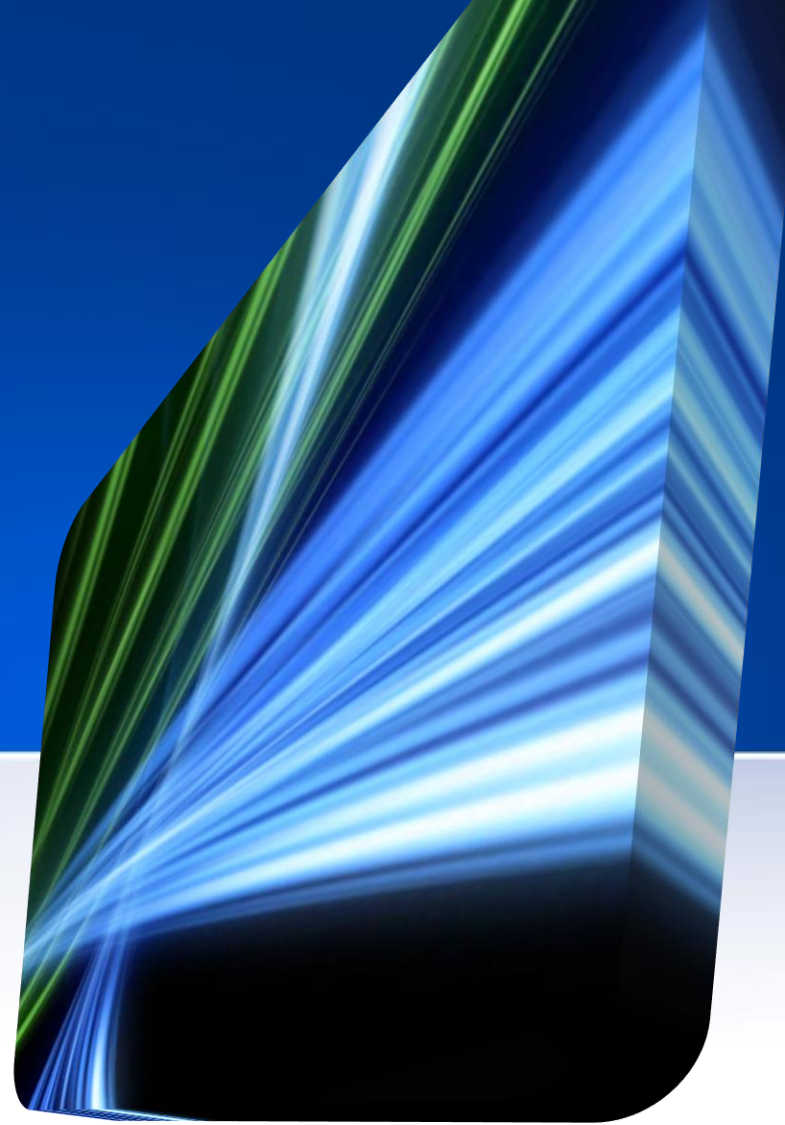
1. Already in clinical applications (include phase 3 trials)
2. Research fields at preclinical stages
3. Research fields at purely theological stages

Ethical areas of concern



1. Already in clinical applications (include phase 3 trials) – tissue engineering, bioelectronics, health IT, Internet, genetic tests, drugs testing
2. Research fields at preclinical stages - reproductive cloning, Germ line genome modification, interventions in biological aging process
3. Research fields at purely theological stages – nanotechnology, virtual digital patient

The Emergence of the Digital Patient



Ethical Reflection on the Digital Patient



Health IT and
patient care





Health IT

Administrative
Functionality

Health
Management
Functionality

Medical
Device
Functionality

Ethical Reflections: Health Management IT Functionality



- Health information and data management
- Data capture and encounter documentation
- Electronic access to clinical results
- Most clinical decision support
- Medication management (electronic medication administration records)
- Electronic communication and coordination (e.g. provider to patient, patient to provider, provider to provider, etc.)
- Provider order entry
- Knowledge (clinical evidence) management
- Patient identification and matching

Ethical Reflections: Medical Device Functionality



- computer aided detection/diagnostic software
- remote display or notification of real-time alarms from bedside monitors
- radiation treatment planning
- robotic surgical planning and control software

Health IT Sociotechnical System



Issues in health IT Sociotechnical System



- Poorly designed health IT new hazards in an already complex system of health care delivery
- Individual health IT components may meet their stated performance requirements, yet the system as a whole may yield unsafe outcomes
- Problematic events involving complex systems often cannot be ascribed to a single causative factor
- Poor human-computer interactions can contribute to serious injury and death

Ethical reflection

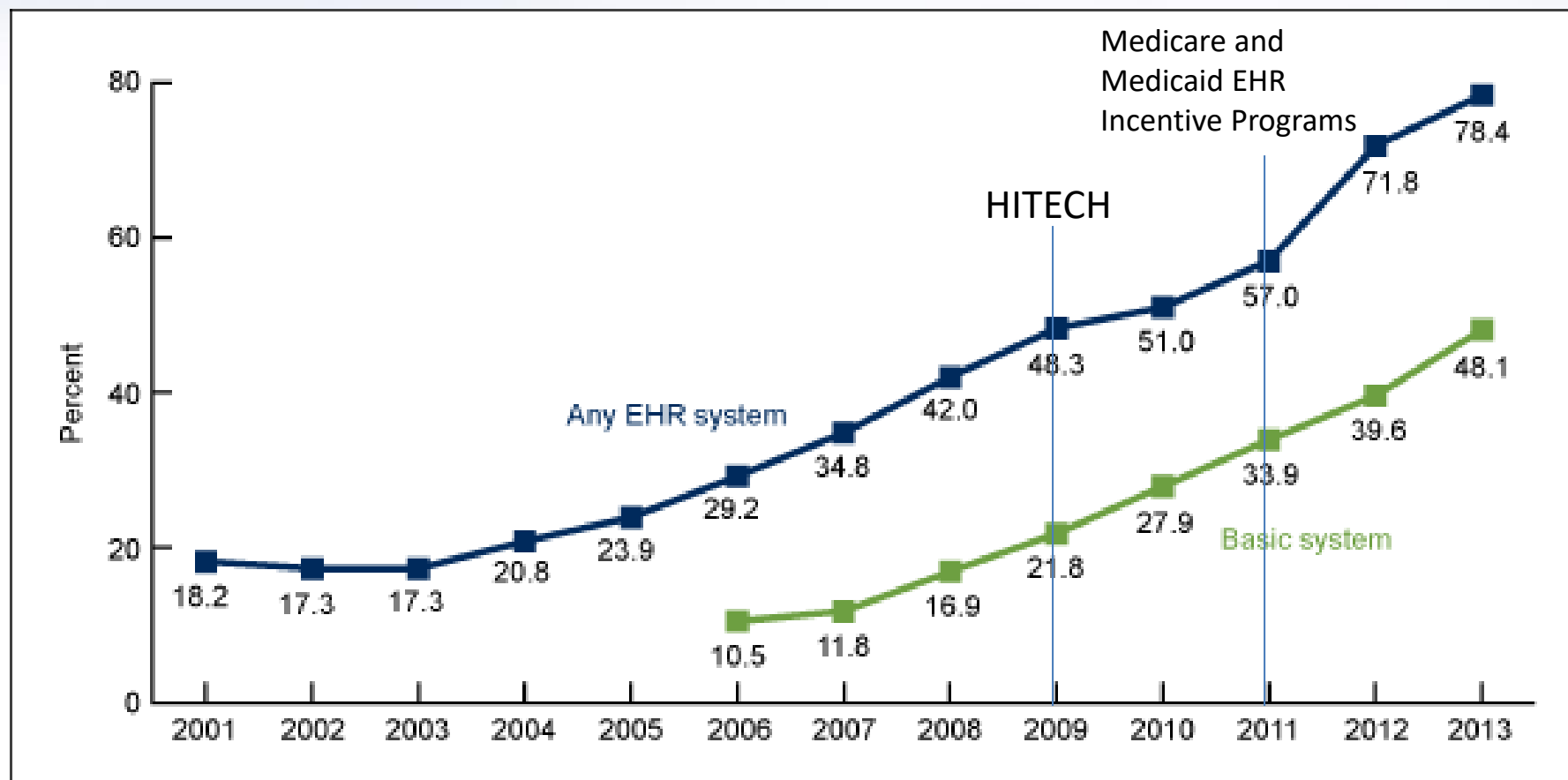


- Is health IT the panacea to better healthcare?

Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001–2013



Percentage of office-based physicians with EHR systems: United States, 2001–2013



Adverse Drug Events (ADEs) in a Highly Computerized Hospital (20 week period)

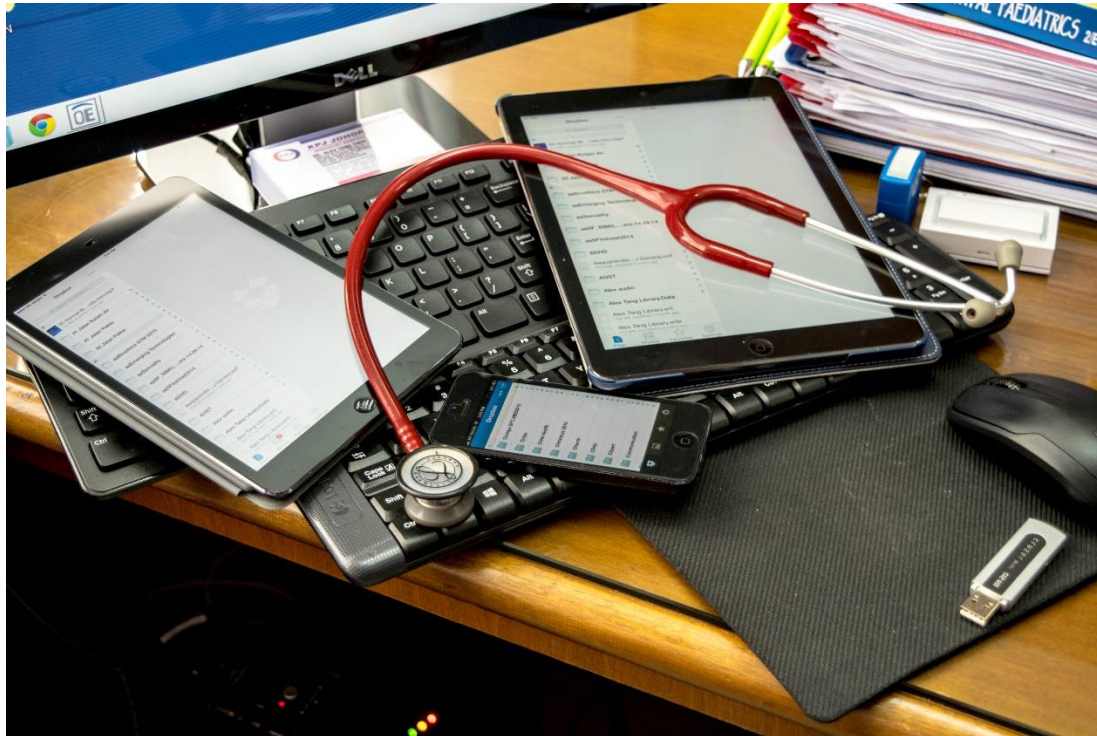


- One quarter of the hospitalizations (937 admissions) had at least 1 ADE
- 9% resulted in serious harm, 22% in additional monitoring and interventions, 32% in interventions alone, and 11% in monitoring alone
- Errors associated with ADEs: 61% ordering, 25% monitoring, 13% administration, 1% dispensing, and 0% transcription

Ethical reflection



- Is health IT the panacea to better healthcare?
- Data interoperability – will it ever be resolved?



Ethical reflection on IT online healthcare platform



- Scientific value
- User protection
- Facilitating user agency
- Trustworthiness
- Benefit
- Sustainability (funding)

Riso, Brígida, et al. 2017. "Ethical Sharing of Health Data in Online Platforms – Which Values Should Be Considered?" *Life Sciences, Society and Policy* 13, no. 1 (August 21): 12.

Ethical Reflection on the Digital Patient



Health IT and
patient care



Social Media and
Dr Google



Ethical reflection



- What is the present role of medical professionals as gatekeeper?
- Has patients respect for medical professionals decreased?

Ethical Reflection on the Digital Patient



Health IT and patient
care



Social Media and
Dr Google



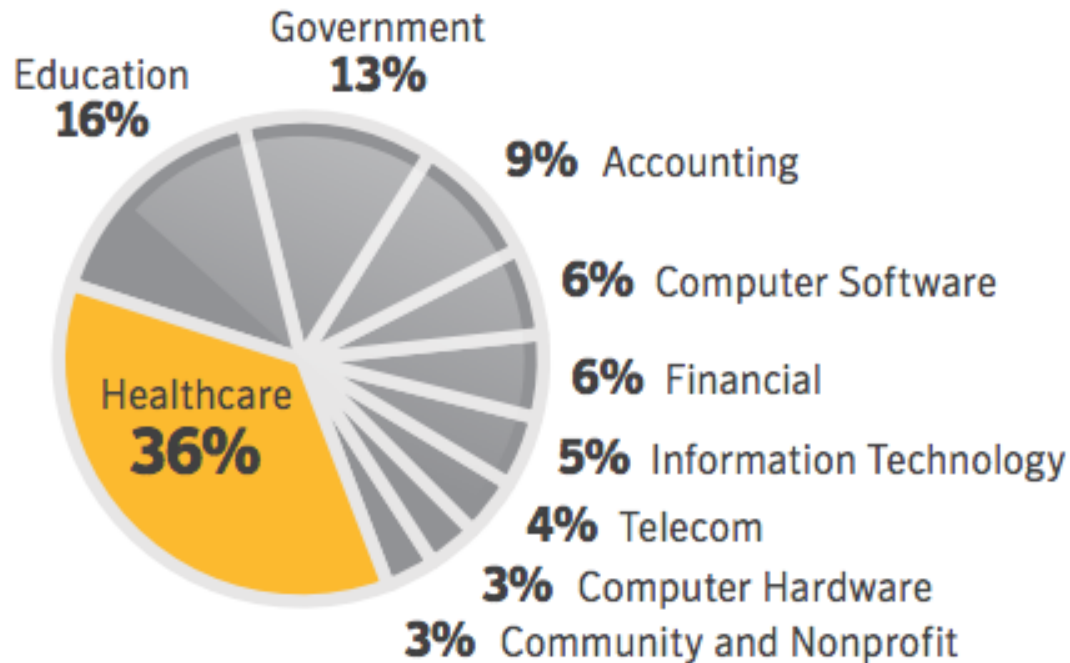
Privacy, Confidentiality,
Security

Ethical reflection



Data Breaches by Sector in 2012

Source: Symantec



At 36 percent, the healthcare industry continues to be the sector responsible for the largest percentage of disclosed data breaches by industry.

Privacy, confidentiality, security: how safe is the data?



- Most patients not aware of their right to privacy and confidentiality
- Cheaper and faster to develop non-privacy aware health IT software solutions
- Business models that favor data loss is more profitable
- Hackers



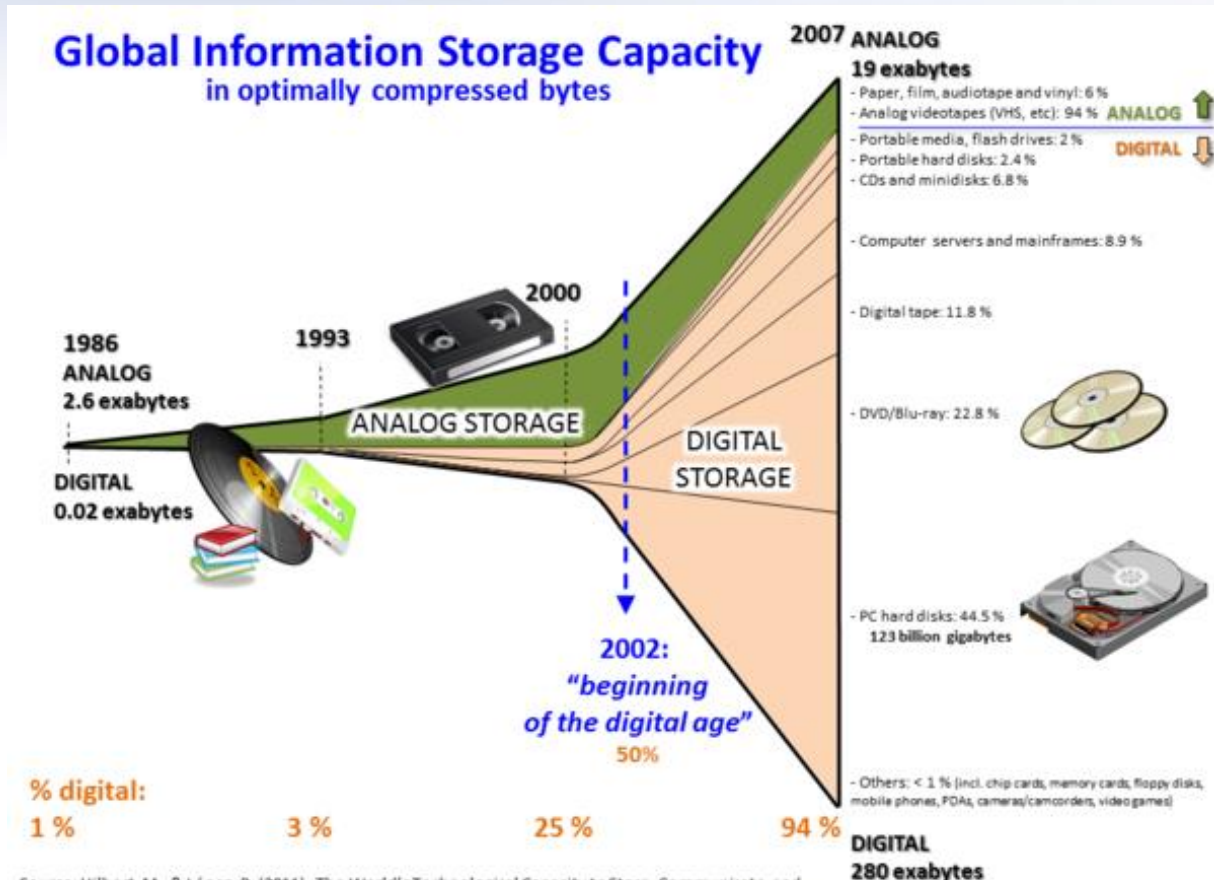
Ethical reflection



- Is our healthcare providers keeping their data secure?
- Are we educating our patients on their privacy rights?
- Do we allow patient to access their own medical records?
- Data Protection Regulation



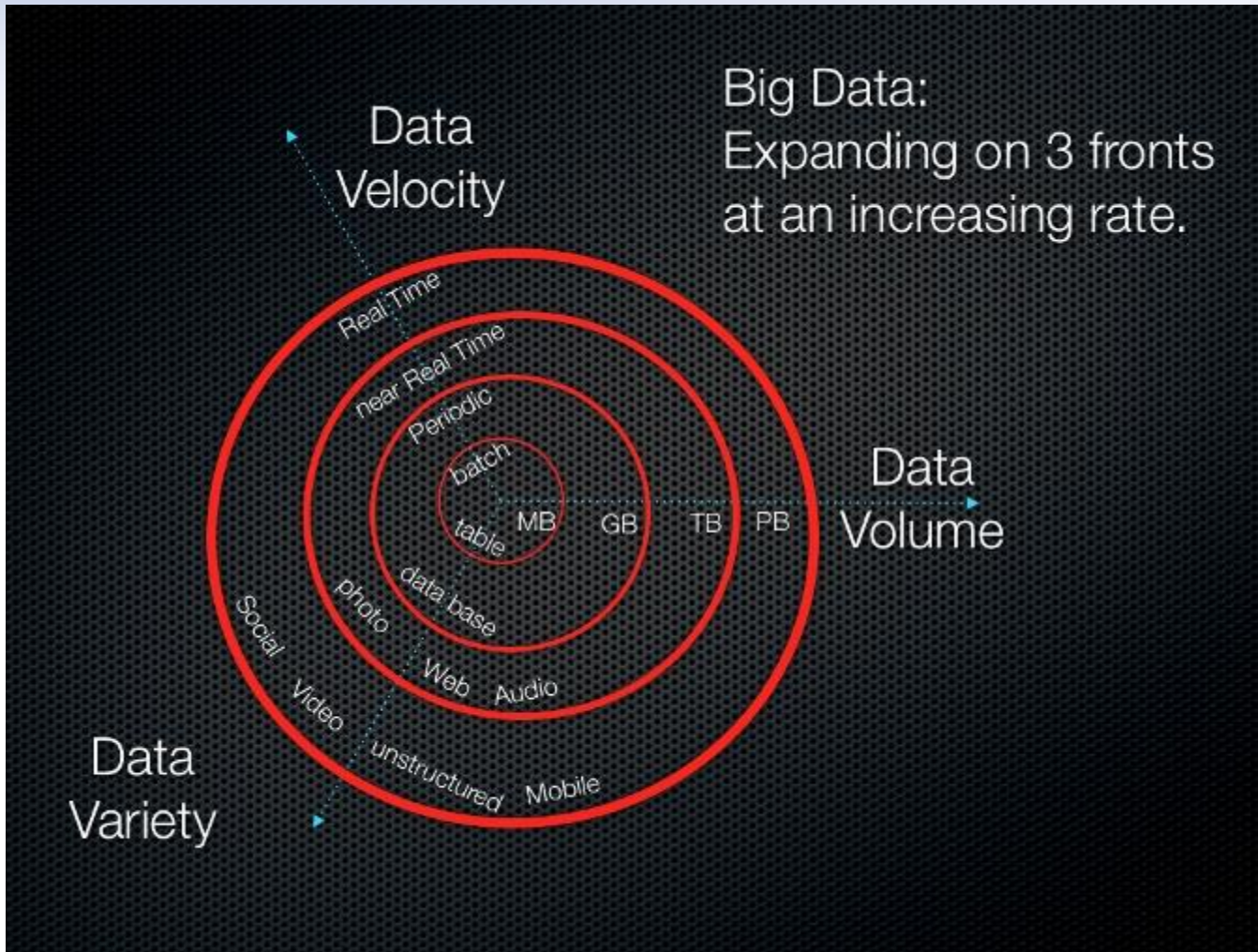
Big Data



Source: Hilbert, M., & López, P. (2011). The World's Technological Capacity to Store, Communicate, and Compute Information. *Science*, 332(6025), 60–65. <http://www.martinhilbert.net/WorldInfoCapacity.html>

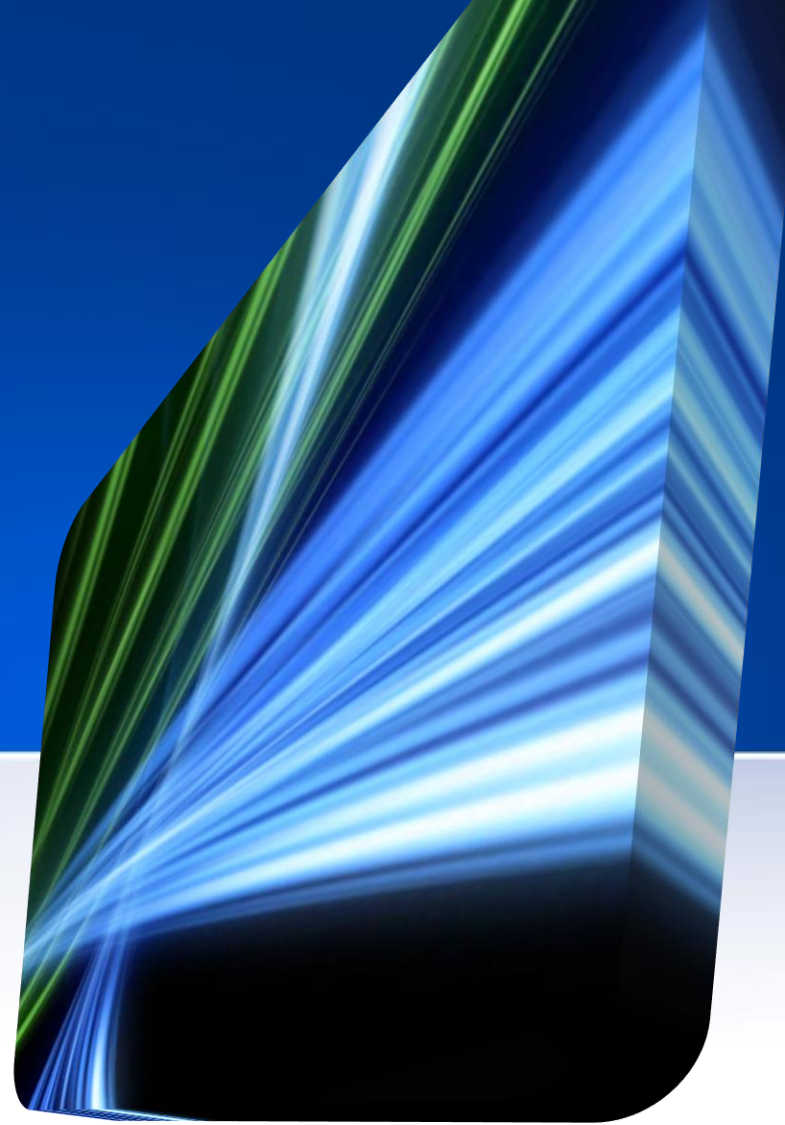
Big data is an evolving term that describes any voluminous amount of structured, semistructured and unstructured data that has the potential to be mined for information.

Big Data

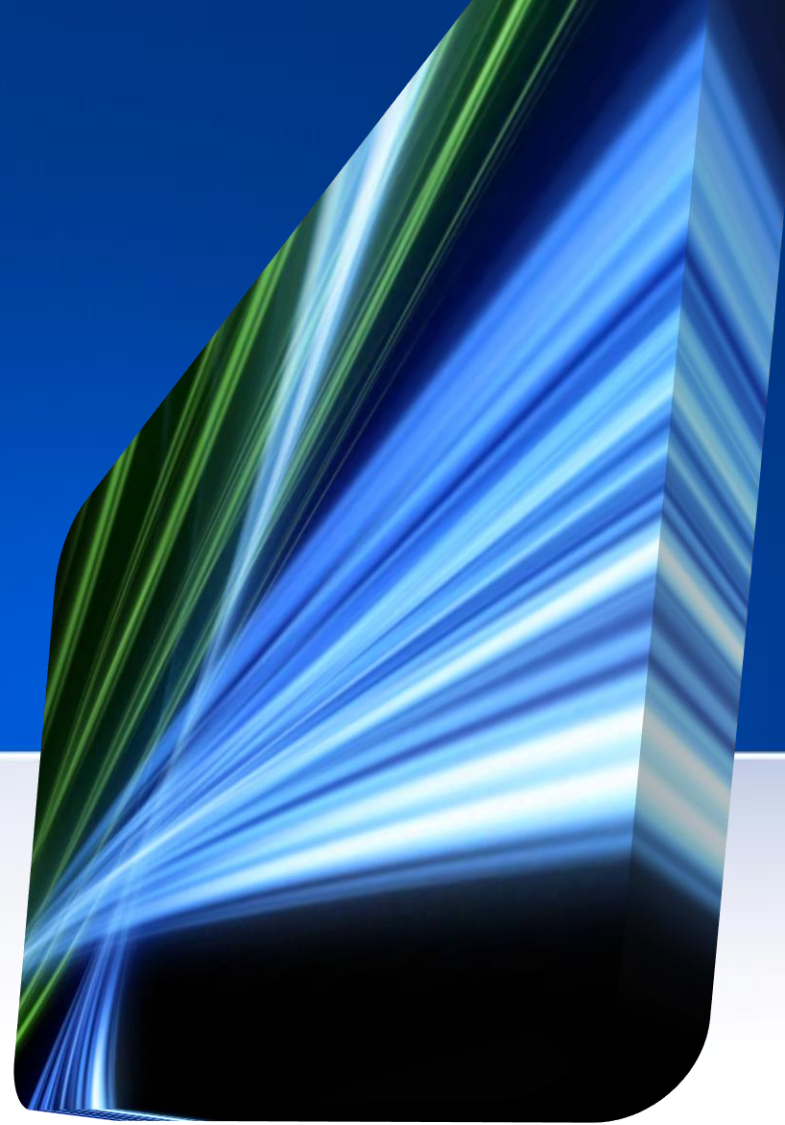


- **Volume**
terabytes,
petabytes,
exabytes
- **Velocity**
- **Variety**

The genetic revolution



Gene Editing

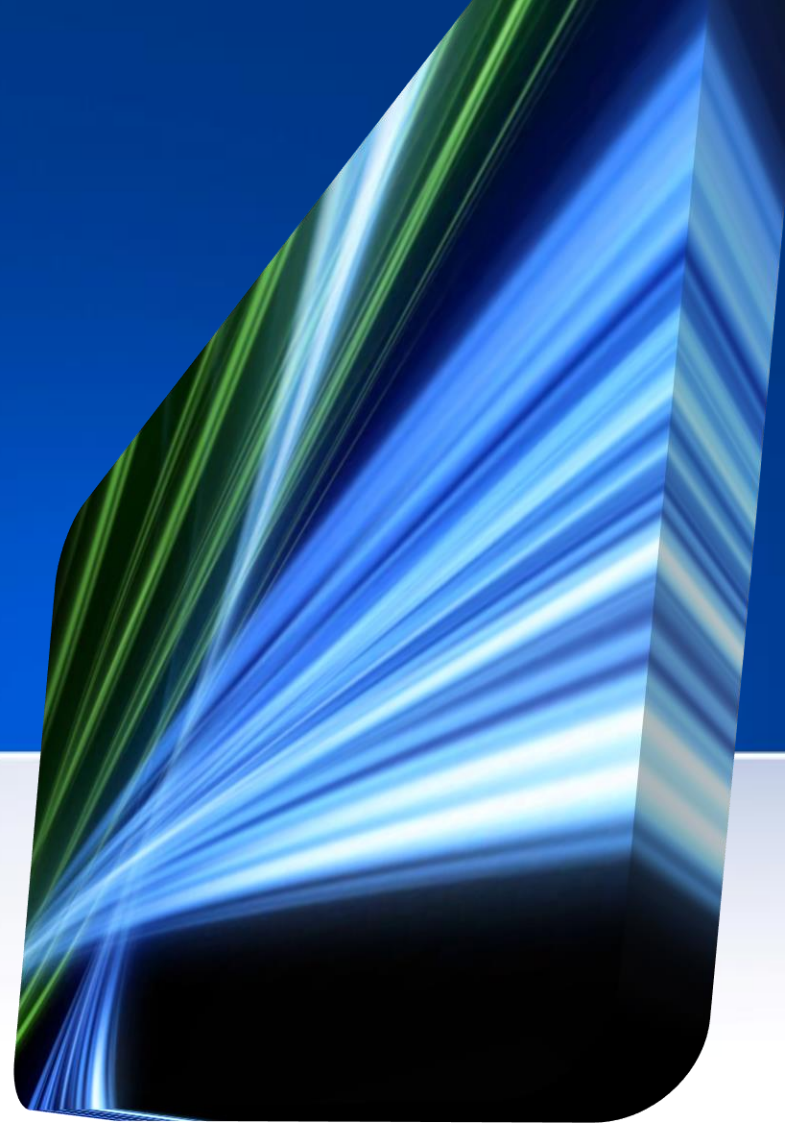


CRISPR



- CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)
- basis for the popular CRISPR-Cas9 genome editing technology

Genetic Testing





Scientists have discovered a variation in a gene that seems to affect whether a person will make it to the top of their game, at least in sports like sprinting and weightlifting that require quick bursts of powerful force. The gene is called ACTN3, but its role in athletic performance has led some to dub it the "gene for speed."

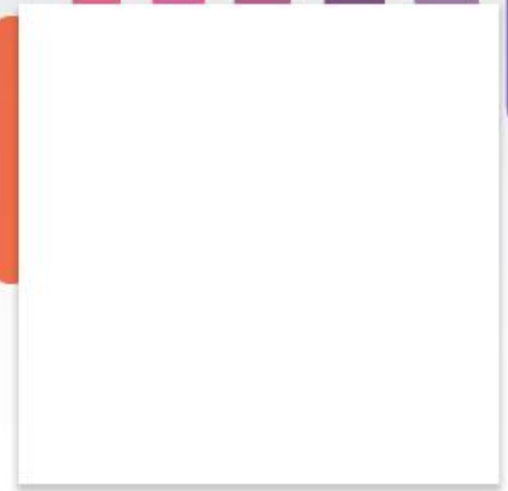
Genetic Testing



23andMe

See your genes in a whole new light.

TIME Magazine's 2008 Invention of the Year, now \$399.





- The Genetic Information Nondiscrimination Act, or GINA, is U.S. federal legislation with bipartisan support that protects Americans from discrimination (in health insurance and employment decisions) on the basis of genetic information. GINA has passed through Congress and was signed into law by the President on May 21, 2008.



American insurance companies and health plans (including both group and individual insurers, as well as federally-regulated plans) will be prohibited from

- looking at your predictive genetic information or genetic services before you enroll;
- "requesting or requiring" that you or your family members take a genetic test;
- restricting enrollment based on genetic information;
- changing your premiums based on genetic information.



GINA also prohibits U.S. employers (including employment agencies, labor organizations, and training programs) from:

- discriminating against who they hire or how much they pay on the basis of genetic information;
- "requesting or requiring" that you or your family members take a genetic test;
- disclosing your genetic information in their possession except under specific and specially controlled circumstances.

Direct To Consumer (DTC) Screening Tests



Direct To Consumer (DTC) Screening Tests



- Scientific accuracy, clinical validity and utility of genetic tests
- Absence of and/or quality of pre- and post-test counselling
- Absence of individualized medical supervision
- Lack of adequate consent procedures
- Respect for privacy and confidentiality

Ethical Reflections



- What is to be done about direct to consumer (DTC) genetic screening tests?
- Role of regulating direct to consumer medical tests?

Personal Genome Service™

Get to know your DNA. All it takes is a little bit of spit.

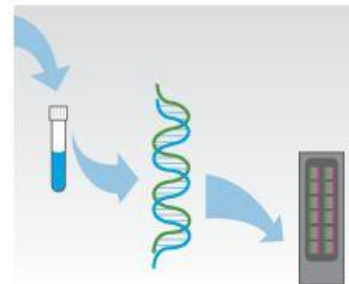
Here's what you do:



1. Order a kit from our [online store](#).



2. [Register your kit](#), spit into the tube, and send it to the lab.

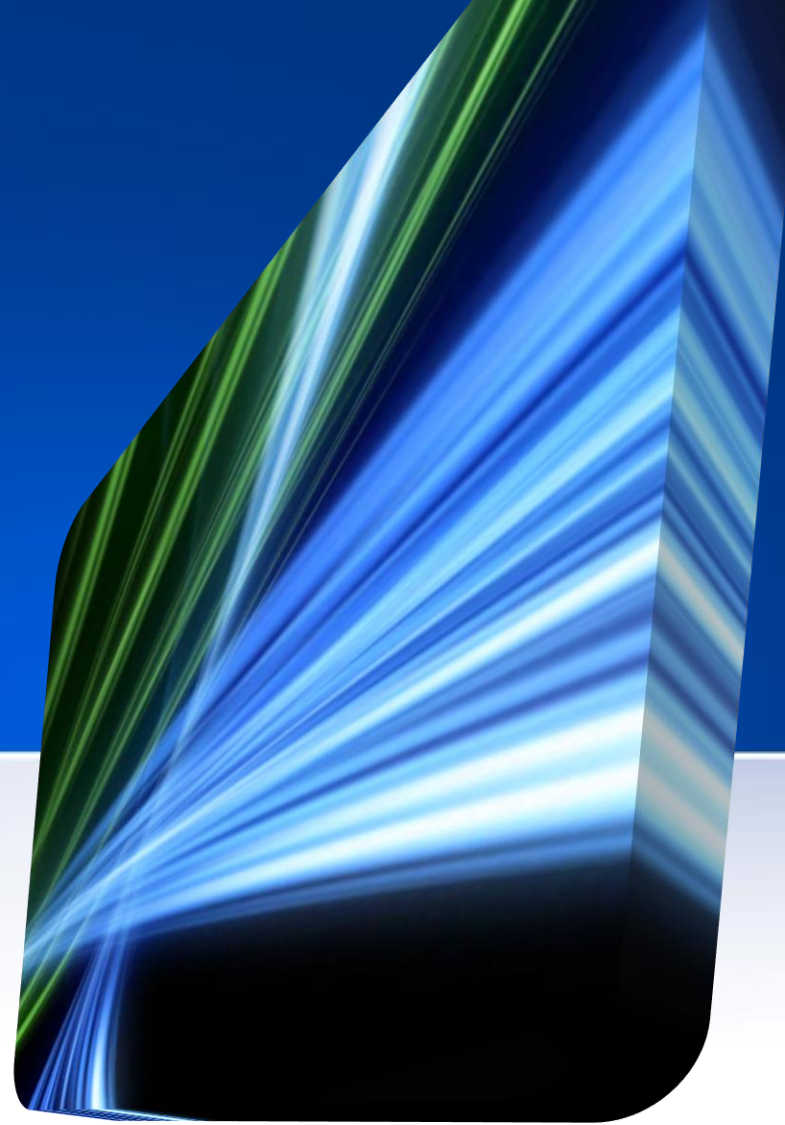


3. Our CLIA-certified lab analyzes your DNA in 6-8 weeks.



4. [Log in](#) and start exploring your genome.

Development of new pharmacotherapeutics



Ethical Concerns on Pharmacotherapeutics



Testing for carcinogenicity



Testing of new drugs



- Test for carcinogenicity
 - Short term *in vitro* mutagenicity test
 - Lifespan *in vivo* tests in rodents (two species)
 - 12-24 months
 - expensive

Short term lifespan rodent studies



- **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)** approved using genetic engineered rats for one species short term lifespan studies in 1997
- The validation was done in the 2000s by **International Life Sciences Institute (ILSI)**

Ethical Reflections



- How accurate are these studies using genetically engineered rats?
- How safe are the new drugs?

Ethical Concerns on Pharmacotherapeutics



Testing for carcinogenicity

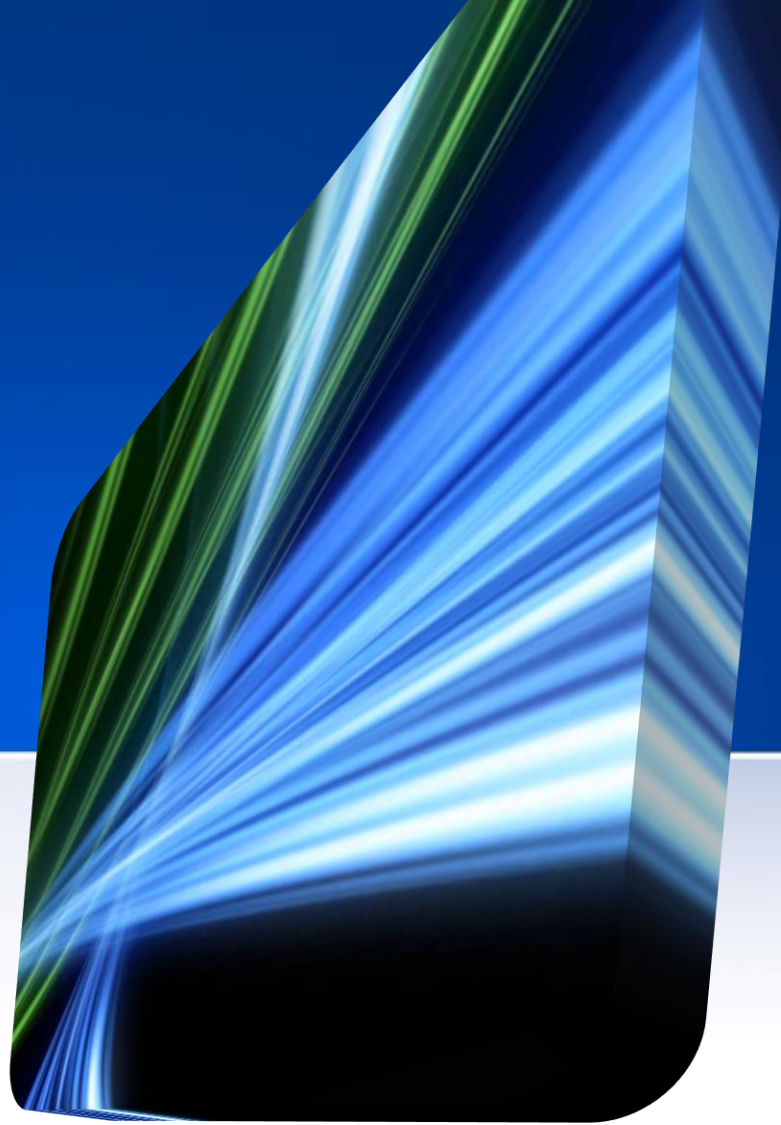
Pharmacogenomics

Ethical Concerns on Pharmacogenomics



- Design of clinical trails
- Cost as a barrier to access
- Professional standards of care
- Patenting of human cells
- Chimera research

Patenting of Human Cells

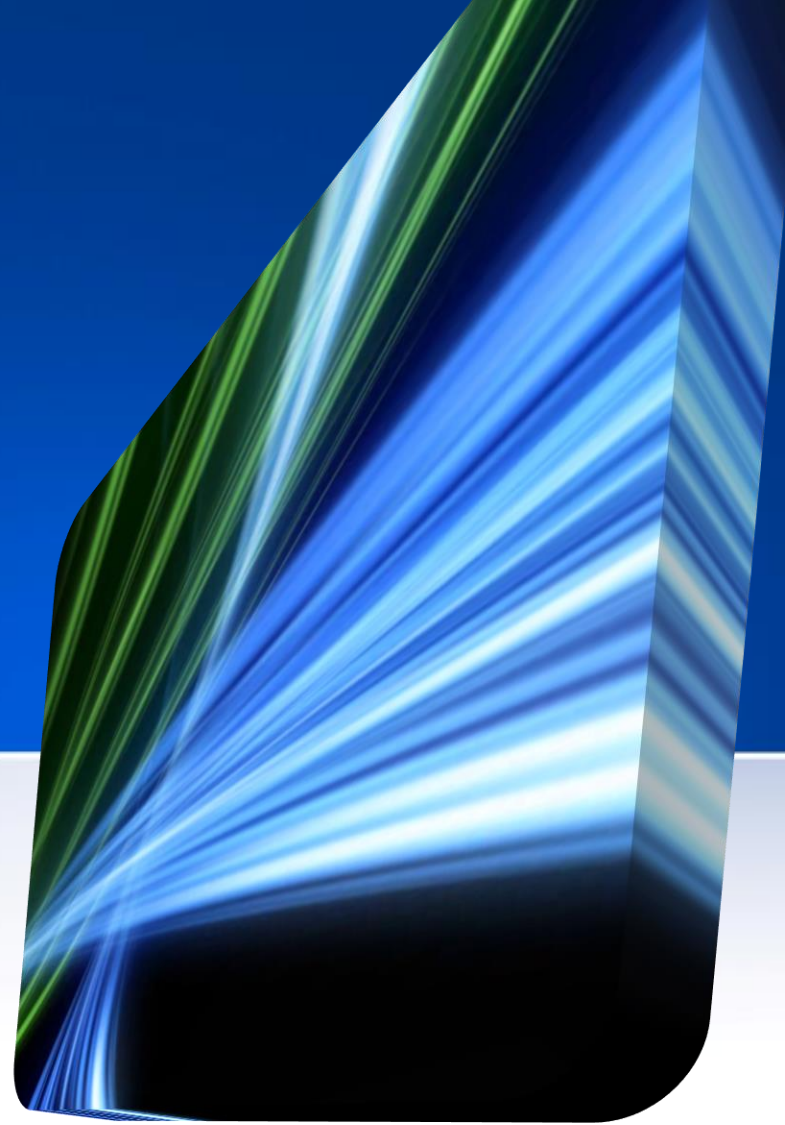


Patenting of Human Cells



- patent a part of the human body ?
- limits the opportunities for other researchers
- the rich reaping the benefits

Chimera Research



Chimera Research



- Transplantation of hESCs into early non-human embryos
- Such embryos would comprise of both human and non-human cells

Why Chimera Research?

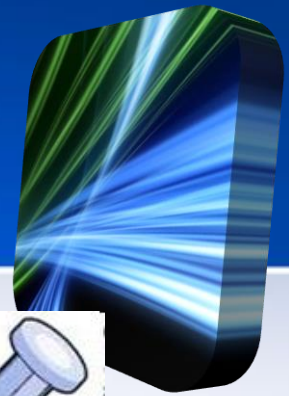


- In vivo studies yield more data than in vitro studies
- hESCs cannot be authentic cells without testing
- Prove proof that it is possible to regenerate human tissues using hESCs
- Data on how hESCs differentiate into embryonic lineages within the nascent fetus

Benefits of Chimera Research



- Testing of new drugs
- Testing of gene therapy technologies
- Production of hormones and antibodies
- Genetic enhancement



CUSTOM-MADE STEM CELLS

After discovering a reliable method for transforming human stem cells into nerve cells in rats, researchers have proved that those neurons can reach targeted muscles.

Embryonic cells



Fertilized egg

Researchers use human eggs fertilized in vitro.



Zygote

The embryo starts dividing into multiple cells.



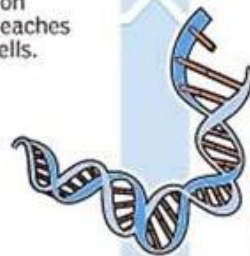
Morula

Up to 4 days after the fertilization the embryo reaches a size of 16 cells.



Blastocyst

When the embryo reaches 200 cells or more its inner mass can be cropped for small groups of 30 stem cells.



Differentiation

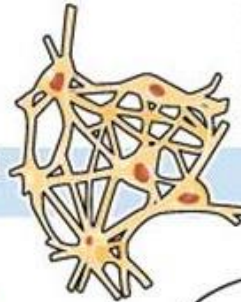
Embryonic stem cells can give rise to almost any kind of specialized cells by changing the chemical or thermic environment of the culture, or inserting specific sequences of genes into their nucleus.



Culture

Over the course of several days, the cells proliferate and begin to crowd a culture dish.

Neural cells



Blood cells



Muscle cells



Treatment

Neural stem cells are treated with a cocktail of proteins that makes them functional.



Implantation

Once inserted in rats, these primed cells can develop into neurons or functional nerve cells attached to muscular tissue.

Cold storage

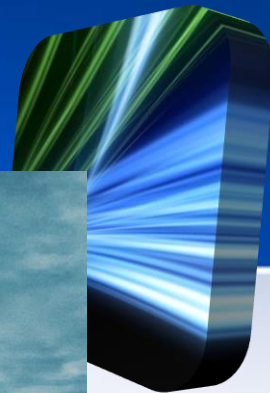
Unspecialized cells can be kept in liquid nitrogen for long periods of time for further use.



Issues with Chimera Research



- Health and safety risks (zoonosis)
- Playing God (creating)
- Repugnance argument (“yuk” factor)
- The Imago Dei argument
- Moral and social confusion (eating meal and monkeys with human blood)
- Identity problem and moral status of Chimeras



A Pastoral -Theological Approach to Christian Biomedical Ethics



1. Is the practice/principle clearly ***supported*** by well-grounded biblical teaching?
2. Is the practice/principle ***compatible*** with well-grounded biblical teaching?
3. Is there a biblical/theological ***rationale*** for or against the practice/principle?
4. Is there ***extra-biblical support*** of the practice/principle from the study of general revelation or society?
5. Is there ***widespread historical acceptance and endorsement*** of the practice/principle within the history of the Christian church?
6. What can we ***do about it*** as Christian faith communities?