The Medicine Safety Code Initiative

Towards a Global IT System for Personalized Medicine

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Drug safety and effectiveness vary drastically between patients with different genetic profiles.

Up to 100,000 deaths and 2 million hospitalisations per year in the United States.

Many therapeutics in development eventually fail to reach patients and costs of bringing a new drug to market are now > 1 billion Euros.
Pharmacogenomic assays and treatment algorithms are becoming more and more numerous.
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Pharmacogenetic assays and treatment algorithms are becoming more and more numerous

Sequencing-based:
PGRNseq
...

Microarray-based:
23andMe
Affymetrix DMET chip
Florida/Stanford chip
...
We are creating framework for representing pharmacogenomic knowledge and providing clinical decision support.
Matching patients to guidelines while minimizing potential for errors is non-trivial.
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We are actively maintaining an ontology-based knowledge base

- Knowledge of approx. 300 decision support rules for 60 drugs, >400 markers associated with 58 genes
- Enabling decision support, KB analysis and consistency checking

- Current side project:
  - Technology assessment and analysis of medical impact, e.g., in Germany, drugs covered by system account for 123 M prescriptions costing 3,7 billion € in private practice per year
How to anchor pharmacogenomics in clinical routine?

• Data not easily available at point of care
  o Pre-emptive testing for several markers at once is probably more effective than ad-hoc testing \(^1\)
  o Keeping genetic data in patient record might not even be legally allowed!

• Even when data is available, medical practitioners report they do not have enough knowledge to interpret the data!

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We are creating a barrier-free system for storing and interpreting personal pharmacogenomic information: The **Medicine Safety Code**

Current version contains data on ~15 pharmacogenes with clinically actionable variants
We are creating a barrier-free system for storing and interpreting personal pharmacogenomic information: The Medicine Safety Code
Technology

• Compressed pharmacogenomic data in QR codes
• Can be readily decoded and interpreted with common mobile devices
  o QR code readers come pre-installed on most devices; installation of dedicated apps not required
  o Web-based decision support service gives dosing recommendations based on up-to-date clinical guidelines
• All data are inside the QR code
  o No central database required
    (patients have full control over their data)
  o Optionally, client-side decoding without web access possible
• Data remains anonymous
• Backed by a sophisticated knowledge base we created
Matching treatment recommendations are displayed

<table>
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<tr>
<td>+ Azathioprine (!)</td>
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<tr>
<td>+ Codeine (!)</td>
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<tr>
<td>+ Mercaptopurine (!)</td>
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<td>+ Thioguanine (!)</td>
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<tr>
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<tr>
<td>+ Abacavir</td>
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<td>+ Acenocoumarol</td>
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<td>+ Allopurinol</td>
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Matching treatment recommendations are displayed

Clinical Pharmacogenetics Implementation Consortium guideline

Reason: TPMT poor metabolizer
For malignancy, start with drastically reduced doses (reduce daily dose by 10-fold and reduce frequency to thrice weekly instead of daily, e.g., 10 mg/m²/d given just 3 days/week) and adjust doses of MP based on degree of myelosuppression and disease-specific guidelines. Allow 4-6 weeks to reach steady state after each dose adjustment. In setting of myelosuppression, emphasis should be on reducing mercaptopurine over other agents. For nonmalignant conditions, consider alternative nonthiopurine immunosuppressant therapy.

Last guideline update: December 28, 2011

Dutch Pharmacogenetics Working Group guideline
Alternatively, you can select drugs for which treatment recommendations are required and enter data manually.
Goal

• Creating a barrier-free system for putting personalized medicine into the pockets of patients
• Making pharmacotherapy safer, more effective and less costly
• Cooperation of stakeholders
  o Clinical institutions and medical professionals
  o Health insurance providers
  o Pharmaceutical companies
  o Genetic testing providers
  o Health IT companies
  o Patient organisations
• Enable bringing stratified/personalized therapeutics to market
LET'S MAKE DATA ON ESSENTIAL PHARMACOGENES AVAILABLE FOR EVERY PATIENT EVERYWHERE!

The MSC is a technologically-simple and intuitive system that could address many of the barriers that limit the ability to share and utilize pharmacogenetic test results in clinical practice, but the true potential of this project will not be realized until the MSC is tested in different scenarios. Partnerships with clinical institutions, researchers, pharmaceutical companies, genetic testing providers, health IT companies and governmental organizations are needed. If you are interested in making personalized medicine a reality, please visit the contact page on this website.

COORDINATOR

- Matthias Samwald (Medical University of Vienna, Vienna, Austria)

ACTIVE PARTICIPANTS

- Robert R. Freimuth (Mayo Clinic, Rochester, MN, USA)
- Richard D. Boyce (University of Pittsburgh, Pittsburgh, PA, USA)
- Michiel Dumontier (Stanford University, Stanford, CA, USA)

Join us on

http://safety-code.org/
Next steps / Important discussion points

• Evaluate in clinical settings, incorporate feedback
  o Preliminary evaluations currently conducted by participants at the University of Pittsburgh, USA

• Integrate with guidelines for drug-drug interactions
Next steps / Important discussion points

Food for discussion:
How could super-institutional IT systems for clinical pharmacogenomics be established in Austria?

• Safety Code system a viable option?
• Practical considerations?
• Legal considerations?
• (Pharmaco-)genetic data in ELGA??
Thanks!

Local team (Medical University of Vienna)

PI: Dr. Matthias Samwald
Dr. Jose Antonio Miñarro-Gimenez
Kathrin Blagec
Prof. Dr. Klaus-Peter Adlassnig

International participants & supporters
Robert R. Freimuth (Mayo Clinic)
Richard Boyce (University of Pittsburgh)
Michel Dumontier (Stanford University)
Simon Lin (Marshfield Clinic)

Web
http://safety-code.org/

Funding
Austrian Science Fund (FWF): [PP 25608-N15]