Datafied medicines: for Precision Medicine

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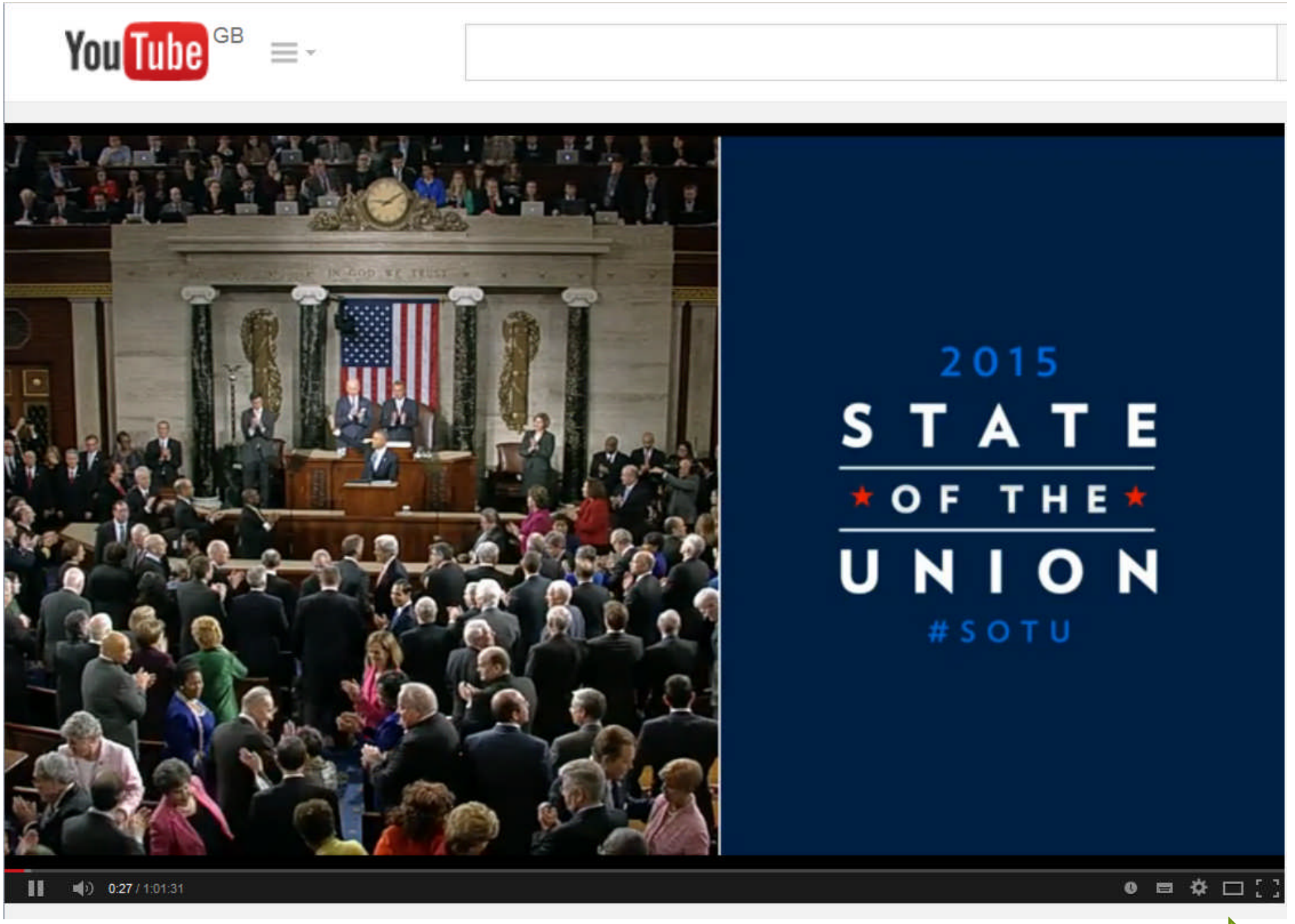

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Table 2. Examples of NNTs calculated from systematic reviews[1,2]

	Treatment	Comparator	Duration of intervention	Outcome	NNT (CI)
Peptic ulcer	Triple therapy	Histamine antagonist	6–10 weeks	*Helicobacter pylori* eradication	1.1 (1.08–1.15)
Peptic ulcer	Triple therapy	Histamine antagonist	6–10 weeks	Ulcers remaining cured at 1 year	1.8 (1.6–2.1)
Migraine	Oral sumatriptan	Placebo	Single dose	Headache relieved at 2 hours	2.6 (2.3–3.2)
Postoperative pain	Paracetamol	Placebo	1,000 mg single dose	At least 50% pain relief	3.6 (3.0 to 4.4)
Fungal nail infection	Terbinafine	Griseofulvin	12 or 24 weeks	Cured at 48 weeks	2.7 (1.9–4.5)
Painful diabetic neuropathy	Antidepressant	Placebo		At least 50% pain relief	2.9 (2.4–4.0)
Postoperative vomiting	Droperidol	Placebo	Single dose	Prevention for 48 hours in children undergoing squint correction	4.4 (3.1–7.1)
Peptic ulcer	Triple therapy	Histamine antagonist	6–10 weeks	Ulcers healed at 6–10 weeks	4.9 (4.0–6.4)
Venous thromboembolism	Graduated compression stockings	No stockings		Episodes of venous thromboembolism	9 (7–13)
Anticipated preterm delivery	Corticosteroids	No treatment	Before delivery	Risk of foetal RDS	11 (8–16)
Dog bites	Antibiotics	Placebo	Single course	Infection	16 (9–92)
Hypertension in the elderly	Drug treatments	No treatment	At least 1 year	Overall prevention of cardiovascular event over 5 years	18 (14–25)
Myocardial infarction	Aspirin alone	No treatment		Prevention of one 5-week vascular death	40
Myocardial infarction	Thrombolytic therapy 5 hours earlier	Later treatment		Prevention of one 5-week vascular death	100

CI: confidence interval; NNT: number needed to treat; RDS: respiratory distress syndrome

Andrew Moore (2009)
What is an NNT?
http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/nnt.pdf

Drugs

Science & Research (Drugs)
Additional Research Areas
Genomics
Overview of the Genomics and Targeted Therapy Group
Presentations on Genomics
Publications on Genomics

Table of Pharmacogenomic Biomarkers in Drug Labeling

Pharmacogenomics can play an important role in identifying responders and non-responders to medications, avoiding adverse events, and optimizing drug dose. Drug labeling may contain information on genomic biomarkers and can describe:

- Drug exposure and clinical response variability
- Risk for adverse events
- Genotype-specific dosing
- Mechanisms of drug action
- Polymorphic drug target and disposition genes

The table below lists FDA-approved drugs with pharmacogenomic information in their labeling. The labeling for some, but not all, of the products includes specific actions to be taken based on the biomarker information. Biomarkers in the table include are not limited to germline or somatic gene variants, functional deficiencies, expression changes, and chromosomal abnormalities.

This table does not include non-human genetic biomarkers (e.g., viral or bacterial) i.e., microbial variants that influence sensitivity to anti-invectives; biomarkers that are used solely for diagnostic purposes unless they are linked to drug activity or used to identify a specific subset in whom prescribing information differs (e.g., for genetic diseases). Therapeutic areas do not necessarily reflect the FDA review division.

Pharmacogenomic information can appear in different sections of the labeling. Relevant sections of the labeling with such information are noted in the last column of the table. For more information on the relevance of information in various parts of drug labeling (e.g. Indications and Usage, Dosage and Administration, Boxed Warning, etc.), please refer to the appropriate labeling guidance. For information on the FDA's initiative to improve prescription drug labeling, visit the FDA/CDER Learn website.

Pharmacogenomic Biomarkers in Drug Labeling

Drug	Therapeutic Area	HUGO Symbol	Referenced Subgroup	Labeling Sections
Tramadol	Analgesic	CYP2D6	CYP2D6 poor metabolizers	Clinical Pharmacology
Codeine	Anesthesiology	CYP2D6	CYP2D6 ultra-rapid metabolizers	Boxed Warnings, Warnings and Precautions, Use in Specific Populations,

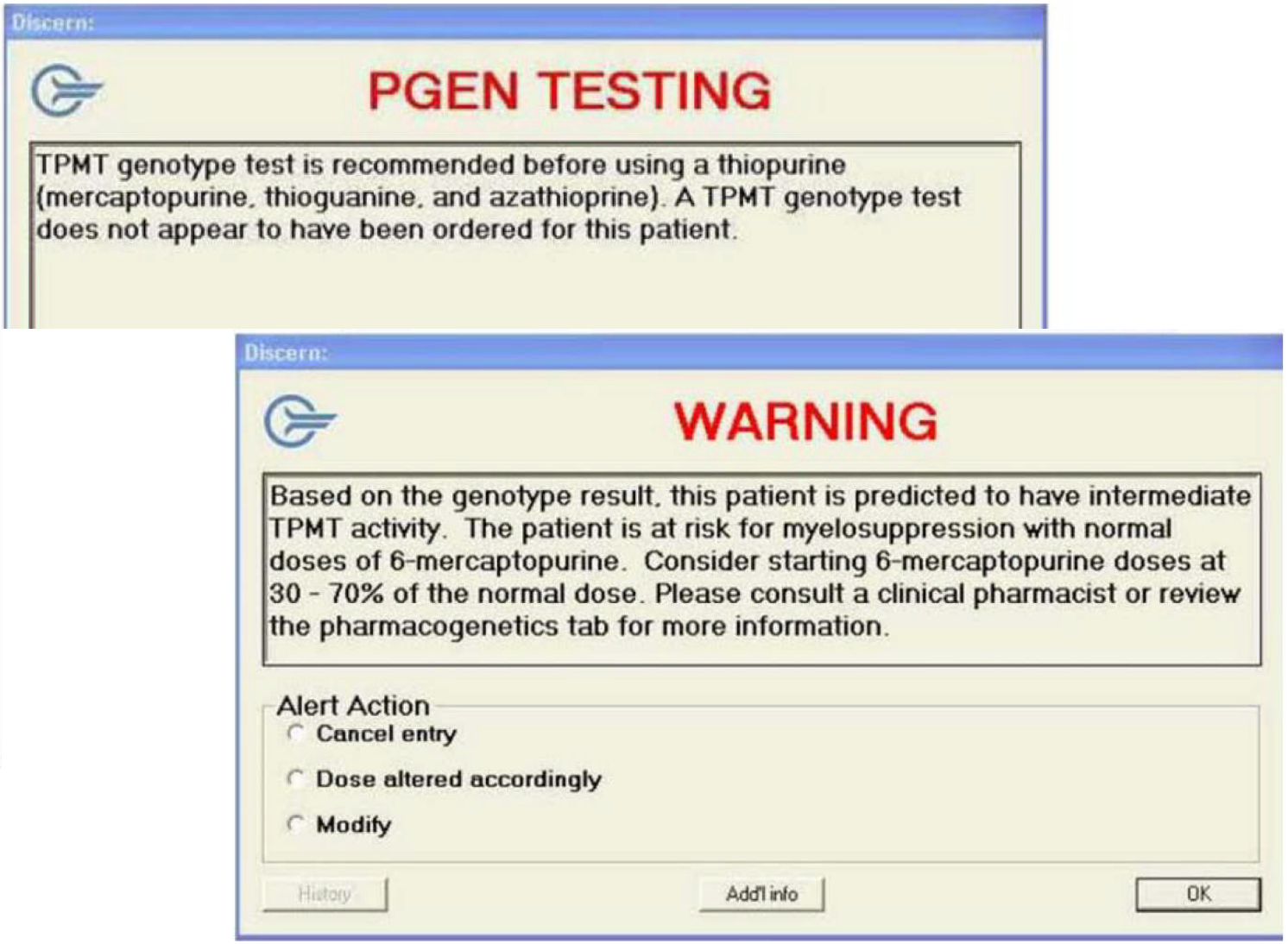
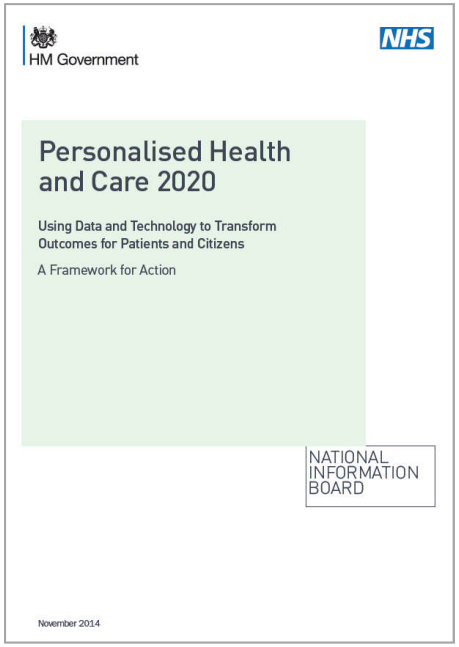


Figure 1 Example of pre-test (top) and post-test (bottom) on-screen clinical decision-support alerts for *TPMT*.

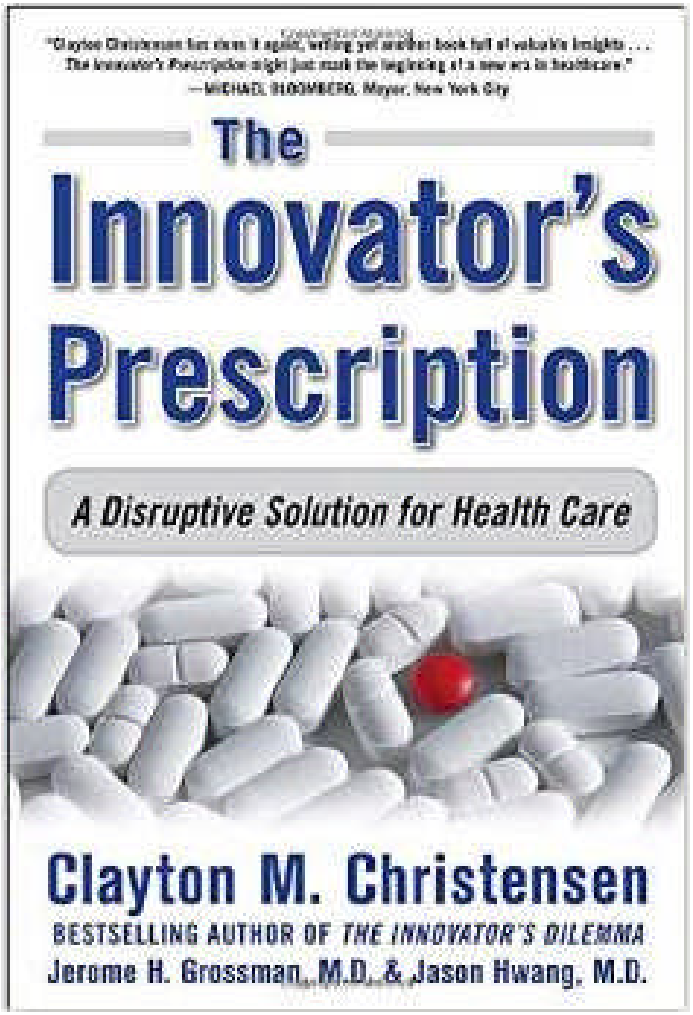
Bell, G.C., et al., Development and use of active clinical decision support for preemptive pharmacogenomics. *Journal of the American Medical Informatics Association, 2014. 21(e1): p. e93-9.*

Personalised health 2020

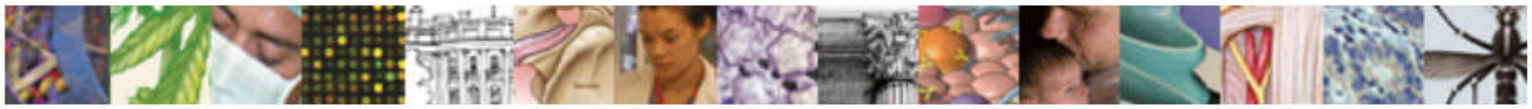
> Clinical decision support systems have been prominent in health and care for some time. Current advances in the field of cognitive computing, coupled with the ubiquity of smart technology that records and transmits medical grade biomedical data through digital media and smartphones, indicate that we are on the edge of radical change. The potential to transform remote healthcare assessment and interaction now exists. The NHS needs to explore these advances to fully understand the potential opportunity they present for faster, more accurate diagnosis, patient safety, empowerment and experience, and to transform how remote channels can be used to deliver care. The ability for clinical decision support to be auto-populated with my existing healthcare information (my past), to take real-time feeds of my biometric data (my present), to consider my genome (my future) and to configure the questions that I need to be asked based on this information is all technically possible today. We need to gain a greater understanding of this potential opportunity and be clear as to how we will realise the benefits.



- The impact of precision on the future of healthcare systems and business models – *disruptive innovation*



The NEW ENGLAND JOURNAL of MEDICINE



Perspective

Preparing for Precision Medicine

Reza Mirnezami, M.R.C.S., Jeremy Nicholson, Ph.D., and Ara Darzi, M.D.

N Engl J Med 2012; 366:489-491 | February 9, 2012 | DOI: 10.1056/NEJMp1114866

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will change how medicine is practiced and taught
and how healthcare is delivered and financed

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References

1. Bell, G.C., et al., Development and use of active clinical decision support for preemptive pharmacogenomics. *Journal of the American Medical Informatics Association, 2014. 21(e1): p. e93-9.*
2. Mirnezami R, Nicholson J, Darzi A. Preparing for Precision Medicine. *New England Journal of Medicine.* 2012;366(6):489-491FDA. Table of Pharmacogenomic Biomarkers in Drug Labeling. 2014; http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm
3. Department of Health and National Information Board, *Personalised health and care 2020: a framework for action,* 13 November 2014, p28 https://www.gov.uk/government/news/introducing-personalised-health-and-care-2020-a-framework-for-action
4. Christensen, CM, (2009) The Innovator's Prescription, McGrawHill