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Integrating genomics into healthcare: prospects, professionals and publics

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The promise of genomic medicine

“Genetics offers enormous potential to improve our health and healthcare - more personalised prediction of risk, more precise diagnosis, more targeted and effective use of existing drugs, new gene-based drugs and therapies, and prevention and treatment regimes tailored according to a person's individual genetic profile.” Genetics White Paper, 2003



Realising the potential of genomic medicine

- Martin, P. and Morrison, M. (2006) *Realising the Potential of Genomic Medicine*
- Report for the Pharmacy Practice Trust of the Royal Pharmaceutical Society
- Overview of recent progress in the clinical development and adoption of new medical technologies based on genomics
 - Detailed literature review
 - Survey of industry investment and new products
 - Audit of progress in integrating genomic technologies into routine practice



Key questions

- What progress has been made in realising the promise of genomics?
- What are the main barriers to development and adoption of new genomic technologies?
- How might these be overcome?
- What is it realistic to expect?
- What role might education play in supporting the development of genomic medicine?



Systemic analysis

- The idea of entrenchment
- To become entrenched into routine healthcare a new medical technology must be:
 - safe and effective
 - available as a commercial product (some exceptions)
 - fit into established working practices
 - command the confidence of patients and professionals
 - be regulated in an enabling manner



GENETICS - BIOETHICS - SOCIETY

Criteria for successful development of new medical technologies

- Scientific proof of principle
- Demonstration of safety and therapeutic efficacy
- Successful adoption (integration into clinical practice)
- Establishment of a viable business model for their commercial exploitation
- Resolution of any important social and ethical issues
- Creation of a stable regulatory framework
- Enrolment of public support



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The changing context of medicines development and use

- Industry
- Pharmaceutical market place
- Health services
- Professional practice
- Regulation of medicines
- Government policy



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Public attitudes to genetics and biotechnology

- Widespread public support for biomedical applications
- Some anxieties around particular technologies that raise novel social and ethical issues e.g. hESCs
- Key issue is extent of public trust in science
- Little evidence that greater knowledge of biology leads to increased acceptance



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Genomic technologies that are well entrenched in the clinic

- Genetic testing for monogenic disorders
- Therapeutic proteins
- Monoclonal antibodies.

- Medium term prospects for expansion of these technologies is very promising. They raise few new social, ethical or practice issues.



Technologies that are starting to become entrenched in the clinic

- Pharmacogenomic drugs e.g. Glivec
- Pharmacogenetic drugs/tests
- Genetic tests for common conditions
- Adult stem cell therapies e.g. HSCs

- Expansion in the medium term is likely, but they have yet to be fully entrenched in a mature market or established set of clinical practices. They still face significant technical difficulties and most will also have to overcome a number of commercial, clinical, ethical and regulatory difficulties



Technologies that have yet to successfully enter the clinic

- Gene therapy
- Cancer vaccines
- Embryonic stem cell therapies
- These technologies face very significant problems at present and are unlikely to enter the market in anything other than first proof of principle products in the near future



A new framework for policy?

- In general, it is not the lack of public support, adverse media reports or excessive regulation that holds back the development of new medicines, but the very significant scientific and technical problems involved
- In order for effective public policy to be developed in the field of genomic medicine, two things need to change:
 - a more realistic set of expectations about the speed and scale of innovation needs to be adopted by all stakeholder groups
 - a different model, which views biomedical innovation as a slow and incremental process, should be used to inform public discussion and policymaking

