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FOR HEALTH TECHNOLOGY

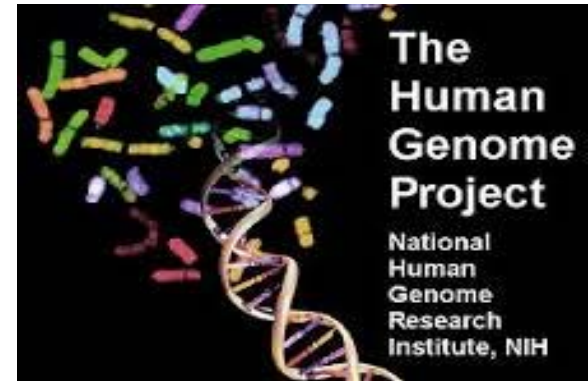
Paying for Personalized Value: Perspective of the Payers

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Overview



- Perspective of the payers
- Concerns over costs and prices
- Concerns for evidence and effectiveness
- Worries about over-diagnosis
- Focus on population health



Perspective of the Payers

- Payers respond to their clients and constituents: employers, individuals, governmental insurance programs, enrollees
- The biggest problem facing the US health system, viewed by the payers and their clients, is affordability. The average American cannot afford the average health insurance plan
 - See debate over 'repeal and replace'
- The horrendous costs of the US health care system are not the fault of genomics, Dx, and biopharmaceutical firms
 - On the contrary, the evidence base often is stronger for life sciences products than for much of what is done to patients
 - But new tests and treatments receive greater scrutiny than do established ones
- The cost crisis is not your fault, but it's your problem



We All Love Value

- For life sciences firms, value is what they sell, and 'value-based prices' are high prices
- For payers, value is what they buy, and 'value-based prices' are low prices
- Insurers and employers are besieged by genomics and diagnostic firms requesting coverage and reimbursement
- The argument is always the same: value
- The counterargument is always the same: value



Payer Concerns for **Costs and Prices**

- Advocates assert that precision medicine reduces costs
 - Target patients who are likely to respond positively to a therapy, reducing the costs of unnecessary and inappropriate treatment
 - Reduce the financial and human costs of treatment toxicity
 - Reduce the size and cost of clinical trials; improve the rate of FDA approval and payer coverage
- Skeptics assert that precision medicine increases costs
 - Screenings are done both on patients with disease and on patients without disease. Therefore, the total costs for screening can be high even if the cost per disease identified (true positive) is low.
 - Even true negatives cost money
 - Early identification of risk and illness does not always reduce cost; it may increase cost due to greater intensity of treatment, sometimes with no clinical benefit



Pricing Companion Tests and Treatments

- The clinical value of a Dx/Tx depends on the analytic accuracy of the test, its linkage to appropriate treatment, the efficacy of the treatment, patient adherence, etc.
- It is conceptually impossible, and practically difficult, to identify value, and hence a value-based price, for each
- Integrated firms that have diagnostic and therapeutic units can price the combination, but much innovation in life sciences is due to non-integrated firms with strong incentives and streamlined decision-making processes
- Payers are willing to listen to ideas on value-based pricing for precision medicine, but not if it means high prices for tests and then high prices for treatments, based on incomplete evidence of patient outcomes and without concern for budgetary impact



Payer Concerns for Evidence

- Payers in the US are hamstrung by legal and cultural objections to comparative clinical and cost effectiveness analysis, and to health technology assessment generally
- But faced with ever more 'innovation' they now are pushing for ever more evidence
- The precision medicine evidence, linking new tests to better patient outcomes, often is indirect, with many assumptions
- Life sciences firms are pushing for reduced evidentiary requirements and accelerated approval by FDA, at the same time they advocate 'value-based pricing'
- This shifts the burden of assessment onto payers
- Payers are insisting on evidence on each step in the test/treatment/outcome pathway



The Test-Treatment Pathway

1. Diagnostic test delivered
 - Appropriate timing; acceptability to patient (completion); harms inflicted by test on patient; cost of test
2. Test result produced
 - Speed of result; test accuracy (sensitivity, specificity)
3. Diagnosis made
 - Was diagnosis affected by test (definitive dx, ruling out suspected dx, confirming previous dx)? Diagnosis incorporates results of all tests.
4. Treatment decided
 - Did new dx result affect treatment plan? Was new plan implemented?
5. Effect of new treatment plan
 - Appropriate timing, efficacy of treatment; patient adherence



Payer Worries about Over-Diagnosis

- The proliferation of genomic and other tests exacerbates fears of too much, rather than too little, diagnosis
- False positives increase anxiety, follow-on tests, risky interventions
- New 'illnesses' are created based on test results with unknown significance ('disease mongering')
- Privacy is placed at risk from tests suggesting higher risk of illness
- Focus on individual variance in risk undermines social insurance
- Genomic and other diagnostic and screening tests contribute to the 'medicalization' of daily life



Causes of Over-Diagnosis

- Technological innovation: ever more sensitive tests report ever more abnormalities, which may or may not imply risk or illness
- Social enthusiasm for screening of healthy people is producing more reports of abnormalities that may or may not be related to risk
- Physician enthusiasm for diagnostic testing is producing more reports of abnormalities that may or may not be related to clinical illness
- Over-estimating efficacy. As less ill patients within a population (detected with more sensitive tests) are treated, reported success rates rise, giving an over-estimate of treatment efficacy and encouraging over-treatment



Payer Focus on Population Health

- Payers have embraced ‘population health’
 - Focus on major chronic illnesses: heart disease, obesity, diabetes...
 - Focus on causes of absenteeism, productivity loss
- Rightly or wrongly, payers are not focused on rare, poignant, expensive outliers
- It is not immediately evident whether a focus on precision medicine would impede or promote population health
- Let’s consider the possibilities



Precision Medicine Impedes Population Health

- Disease causality usually is multi-factorial. Most studies find multiple associations between genetic markers and diseases, while the strength of each association often is quite weak
- Whatever be the strength of the statistical association between genetic markers and disease in the population, the predictive power in individual patients often is very low
- The burden of illness is primarily the result of behavioral factors, not genetic variability (e.g., genetics cannot explain changes in disease prevalence over short periods)
- The hype of ‘war on cancer’, ‘moonshot’ etc. lead to unrealistic expectations, followed by disillusion and skepticism with respect to population health initiatives



Precision Medicine Promotes Population Health

- Population health requires directing resources towards sub-populations at greatest risk; genetic biomarkers can identify them. Risk stratification can improve the effectiveness and cost effectiveness of medicine and public health
 - Most payer initiatives for wellness, prevention, and chronic care management begin with risk stratification
- Some genetic markers have high value for predicting risk in individuals, and not just in populations, with consequent improvements in population health
- Some forms of precision medicine reduce cost, freeing resources for population-based initiatives
- If the ultimate payers (taxpayers, consumers) are willing to pay higher premiums in order for health plans to invest in precision medicine, insurers are happy to invest



Conclusion

It is important for innovators in the life sciences to understand the needs and perspectives of those who pay the bills

It is not necessary to agree, but it is useful to remember that, in most other sectors, the value of a product or service is how much the payer is willing to pay

You will be held to standards of economic as well as clinical value

The health care cost crisis is not your fault, but it is your problem

Help us solve it

