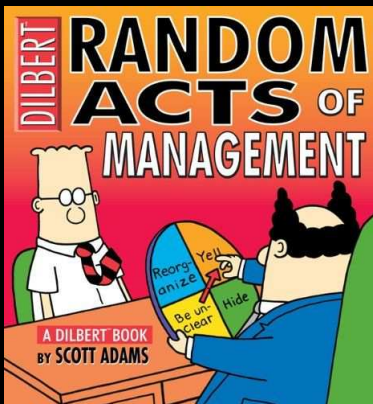


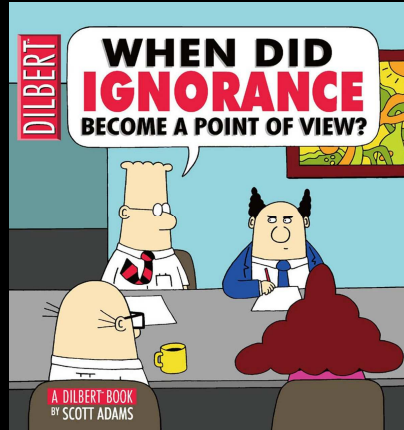
“Opportunities” in Molecular Lab Management

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Disclaimer I: Not much science in this



Disclaimer II:
I have no management training



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I have no management training



But neither does
anyone else in
medicine

Disclaimer III:
I know Management is not a hot topic



BOREDOM

But:
Management is EVERYTHING!

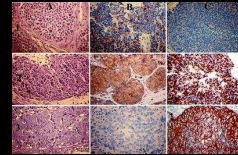


MANAGEMENT

If you think the problems we create are bad, just wait until you see our solutions.

Management is EVERYTHING

- What are the obstacles in your work?
 - Cases too difficult?
 - Science too confusing?
- NO! It's stuff like
 - Tracking down slides, samples, or paperwork
 - Waiting for someone else to do their job
 - Insufficient infrastructure or equipment
 - Needing to be in two places at once
- It's the same for everyone else



Management “Opportunities” in molecular diagnostics

- “Opportunities” = “problems”
 - Striped Pajamas
 - The Black Hole
 - A Floor Wax AND a Dessert Topping
 - Schoolyard Drug Deals
 - The Salt Mines
 - Benedict Arnold
 - Siberian Exile
 - That's so Yesterday

Striped pajamas: Regulatory environment



Striped pajamas: Regulatory environment



- Few approved IVDs
- FDA: LDTs *verboden*
 - Concerned about safety
- LDT bills introduced
 - DAIA: FDA oversight
 - VALID: FDA oversight
 - VITAL: CLIA update
- *De facto* regulation
 - reimbursement only if FDA approved
- “Opportunity” to work with Congress

The Black Hole: Finances



The Black Hole: Finances

■ Mol Dx doesn't make money

- Specialized space needs
- Specialized expertise
- Custom informatics
- Labor intensive
- Costly reagents
- Limited vendor competition
- Rapid instrument turnover
- Reimbursement is poor



Finances

- BWH Oncopanel test
- Direct costs: \$875
- Indirect costs: \$725
- Total cost: \$1600
- Does not include capital
- CMS reimbursement: \$595
- ~\$3K reimbursement for FDA cleared tests
- “Opportunity” to seek FDA approval for LDTs



A floor wax and a dessert topping: Competition with commercial labs



A floor wax and a dessert topping: Competition with commercial labs



- Aggressive marketing claims and practices
 - Direct-to-consumer testing promoted
 - Entertainment is outside regulatory oversight
- Lobbying government, payers, clinicians, patients
 - Communication “opportunity” for Pathologists

Schoolyard drug deals: Free tests for access to clinical data



Schoolyard drug deals: Exchanging clinical data for tests

- The big value is in the data
 - Valuable to Pharma
- Commercial labs: “free” tests
 - Upload clinical data to the ref lab
 - Ref lab sells clinical data
- Ref lab goal: market share, not patient care
- “Opportunity” to compete with free



The Salt Mines: Sequencing as a commodity

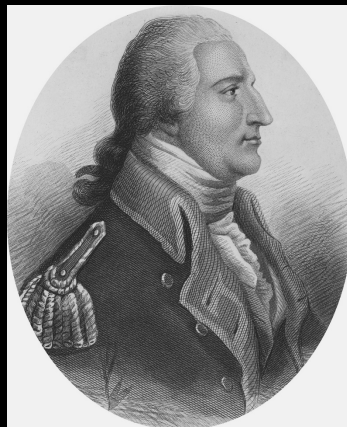


The Salt Mines: Sequencing as a commodity

- Perceived Quality
 - Menu, TAT, Client service
 - Accuracy, Consultations not valued
- Sequence mills are cheap
- Outsource technical work, insource interpretation
 - Lose ability to troubleshoot or identify artifacts
 - Lose ability to customize assay or informatics
 - Lose control over the data, and its disposition
- Really damaging when Pathologists say this!
- Opportunity to show that know-how matters



Benedict Arnold: Personnel recruiting and retention



Benedict Arnold: Personnel recruiting and retention

- General Arnold wanted a promotion and a raise.
- Molecular personnel are hard to find and keep
 - Both lab techs and informatics
 - Industry: salaries and promotions, ice cream
 - Hospitals: benefits, stability
 - This talent pool more attracted to industry perks
- Biotech aggressively recruits clinical lab personnel
 - Raises, promotions, parking spaces, nicer looking facilities
- Opportunity to compete with biotech for personnel



Siberian Exile: Off-site laboratories

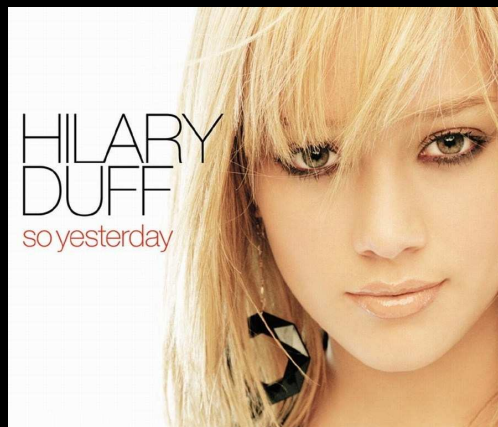


Siberian Exile: Off-site laboratories

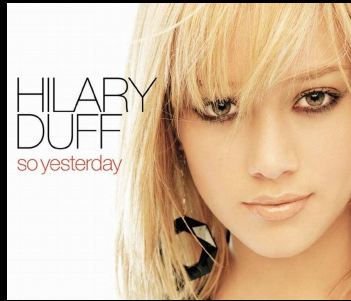


- Molecular space is expensive
 - Many instruments, but low volumes
 - Separation of steps → custom renovations
- Results not needed STAT
- Move lab somewhere else
- Pathology-wide problem
 - Isolation from clinical care and colleagues
 - Exclusion from hospital decision-making
 - Pathology as afterthought?
- “Opportunity” to zoom

That's so yesterday: Rapid pace of technology



That's so yesterday: Rapid pace of technology



- New assays every year
- New boxes every 3 yrs
- New genes constantly
- New informatics
- New applications
- Depth of expertise
 - Death of the generalist?
- Fun “opportunity”

Not all opportunities are problems



MANY things to look forward to!



- The gimping of cancer?
 - Early detection by cfDNA
 - Better treatments/ outcomes
- Response to epidemics?
 - Imagine COVID without molecular
- New molecules/technology
 - Epigenetics, transcriptome, whole genome, 3D genome structure
 - Nanopore, single cell, CRISPr
 - Artificial intelligence

CONCLUSION:



- Hopefully, greed won't ruin everything



- Many problems, but benefits still outweigh

