ASCO Update
Georgia State Medical Oncology Society Meeting

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Financial Disclosure

- No financial relationships to disclose

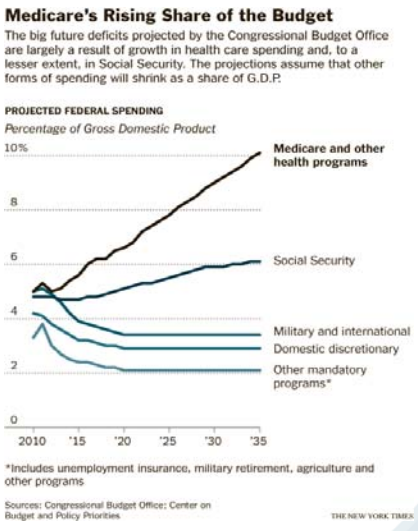
Outline of Presentation

- SGR Fix and Physician Payment Reform
- Choosing Wisely Campaign
- Update on Drug Shortages
- CancerLinQ
- Implementing Personalized Cancer Care

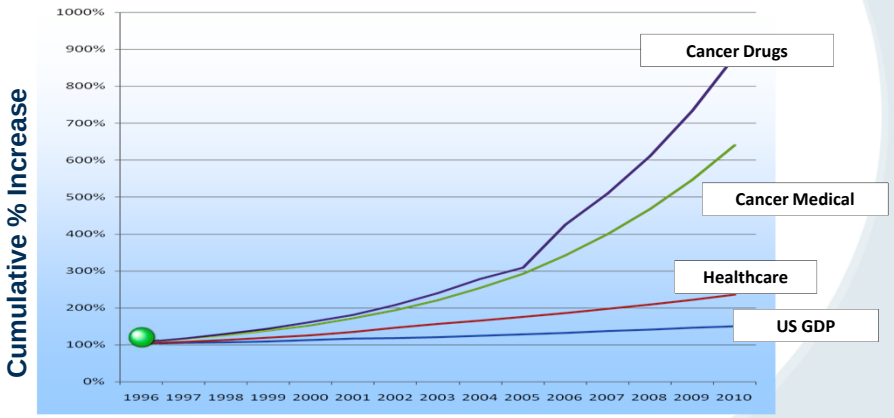
Unsustainable Trends

Medicare is a major reason for deficit projections

Cancer costs rising 15-18% annually



Costs of Cancer Care Rising Faster than Overall Healthcare



Source: Blue Cross Blue Shield Association

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Major Cost Drivers

- ER visits
- Unplanned hospitalizations
- End of life care
- Unnecessary tests, imaging
- Drugs
- Physician fees

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SGR Rollercoaster

Dec 19, 2009:	Congress freezes rates for two months.
March 2, 2010:	CMS holds claims.
April 15, 2010:	CMS advises physicians to hold claims
June 25, 2010:	Congress delays cut until November 30
Nov 30, 2010:	Congress freezes rates for one month
Dec 15, 2010:	President signs bill for one-year delay to 25 percent cut.
Feb 17, 2011:	Congress delays cut with 10-month patch
Feb 22, 2012:	Congress delays until Jan of 2013
Jan 1, 2013:	Congress delays for one year

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Current Status

- Congress has passed a 1 year patch for 2013 – 30% cut scheduled for January 2014
- One Committee has passed a bill to repeal SGR, two others working on different versions. Question is how these efforts are reconciled and how do we pay for it.
- Opportunity now because estimated price tag to fix it has recently been reduced

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ASCO Principles on SGR Fix

- Medical specialty societies play an essential role in quality assessment/improvement
- Quality measures and core competencies to be established by specialty societies
- Phased approach to new payment models (3-5 years)
- Payment stability during transition with predictable annual update

What has ASCO Been Doing?

- Engaging with members of Congress — Ways and Means, Energy and Commerce-- on SGR fixes
- Exploring payment reform alternatives
- Participating in AMA and other specialty society advocacy efforts
- Grassroots activity through ACT Network

…and working on things we can do now…

Choosing Wisely Campaign: Five Key Opportunities to Improve Value of Patient Care

- Established in 2012
- Multidisciplinary initiative led by American Board of Internal Medicine Foundation
- Charge: to identify five common, costly procedures that are not supported by evidence and that should be questioned

Stewardship of Limited Resources

Choosing Wisely™
An initiative of the ABIM Foundation

Question these things before doing them:

1. Use of chemotherapy for patients with advanced cancers who are unlikely to benefit, and who would gain more from a focus on palliative care and symptom management.
2. For early breast cancer, use of advanced imaging technologies (i.e., CT, PET and radionuclide bone scans) in cancer staging.
3. For early prostate cancer, use of advanced imaging technologies (i.e., CT, PET and radionuclide bone scans) in cancer staging.
4. Routine use of advanced imaging and blood biomarker tests for women treated with curative therapy for breast cancer and who have no symptoms of recurrence.
5. Use of white cell stimulating factors for patients who are at low risk for febrile neutropenia.

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Current & Future Work

- Broad educational initiatives:
  - Patients: Cancer.Net, Consumer Reports
  - Professionals: Journal articles, Commentaries, Educational Programming
  - Integration into QOPI to measure/improve behavior change
- 2013 ASCO Top Five List, to be released in October 2013

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2013 Round of Choosing Wisely

- Appropriate use of anti-emetics
- Combination chemotherapy in metastatic breast cancer
- Biomarker-directed use of targeted therapy
- Post-treatment surveillance imaging
- Routine PSA screening in men with limited life expectancy

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Physician Payment Reform…

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Is Buy and Bill a Sustainable Model?

- Currently at ASP+4.3% with sequestration
- ASP+4% proposed during debt ceiling debate
- ASP+3% proposed in President's budget
- **Every 1% reduction = ~$155 million/year**
- Even without cuts, practices are struggling

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Top Ten Medicare Drugs 2011

	In millions
Ranibizumab	$ 1,365
Rituximab cancer treatment	$ 885
Infliximab injection	$ 668
Bevacizumab injection	$ 667
Injection, pegfilgrastim 6mg	$ 623
Oxaliplatin	$ 309
Darbepoetin alfa, non-esrd	$ 307
Pemetrexed injection	$ 281
Epoetin alfa, non-esrd	$ 272
Docetaxel	$ 259

Source: Moran Company Analysis of Medicare Physician/Supplier Procedure Summary File, 2011. Includes carrier claims only (physician office and DME). Outpatient Prospective Payment System (OPPS) claims are excluded.

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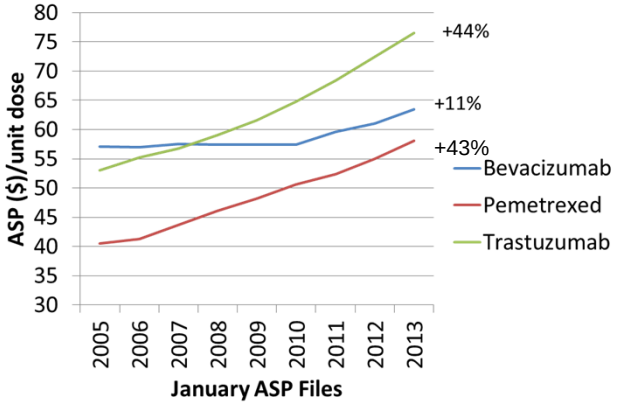
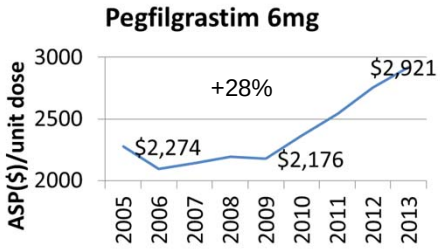
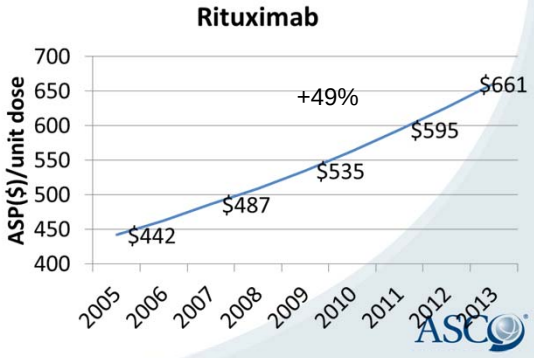
Select Branded IV Drugs, Price Increase 2005-2013







Guiding Principles For Payment Reform

- Assure every cancer patient has access to high quality, high-value care based on peer-reviewed evidence.
- Protect patients' needs and wishes through shared decision-making.
- Further develop and uphold the practice standards for the medical profession.
- Support system-wide reforms and improvements with incentives and shared savings that keep pace with the evolution of the health care system.

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Exploring Alternatives

- Cancer therapy management fee
- Bundled payments
- Episode based payments
- New practice models such as PCMH
- Aligning doctor-patient goals

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Payment Reform Workgroup Members

Member	Affiliation
Jeffery Ward, MD [CPC Chair]	Swedish Medical Center
Roscoe Morton, MD [CPC Past Chair]	Medical Oncology & Hematology Associations
Anupama Kurup, MD [CPC Chair Elect]	Providence Cancer Centers
John Cox, DO	Texas Oncology Methodist
Daniel M. Hayes, MD	Maine Center for Cancer Medicine
John Hennessy, CMPE	Sarah Cannon Cancer Services
Christian Thomas, MD	Maine Center for Cancer Medicine
Dan Zuckerman, MD	Mountain States Tumor Institute
Don Moran / Kevin Kirby	The Moran Company
Kavita Patel, MD, MS	Brookings
Eric Wong, MD	Beth Israel Deaconess Medical Center
Kerri Nottage, MD	St. Jude Children's Research Hospital
Linda Van Le, MD	University of North Carolina
ASCO Staff	ASCO

Components of Comprehensive Medical Oncology Payment Reform

- Quality Oncology Practice Initiative (QOPI)
- A Cancer Therapy Management Fee
- Value Based Pathways
- Episodes of Care/Bundle Payments
- Care Coordination/Patient-Centered Medical Oncology Home

Element	Phased Approach				
	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**	**Phase 5**
QOPI	No negative adjustment Positive adjustment for participation	No negative adjustment Positive adjustment for participation	Must meet performance benchmarks for positive adjustment; no negative adjustment	Must meet higher performance benchmarks for positive adjustment; no negative adjustment	Positive and negative adjustments based on performance benchmarks; increased positive adjustment based on QOPI certification
Management Fee (Chemotherapy)	Practices choose to opt-in (must also participate in QOPI); those who do not opt-in remain in current ASP+6 environment	Management fee grows at MEI (or other suitable index)	Management fee grows at MEI (or other suitable index)	Management fee grows at MEI (or other suitable index)	Management fee grows at Medicare Economic Index (MEI) (or other suitable index)
Pathways	Positive adjustment for participation	Positive adjustment for participation	Must meet 70% concordance for positive adjustment	Must meet 80% concordance for positive adjustment	Must meet 80% concordance for positive adjustment; negative adjustment for those below
Episodes/Bundling	Practices choose to opt-in to colon cancer bundle for one year	Practices choose to continue bundle or opt out / Data analysis from first round of colon cancer bundle	Second round of colon bundle offering; breast cancer bundle opened	Practices choose to continue bundle(s) or opt out/ Data analysis from first round of breast bundle, second round of colon bundle	CMS determines, based on results, continued offering of bundle(s)
Care Coordination Fee → Patient-Centered Medical Oncology Home (based on NCQA "specialty" home criteria)	Practice receives "care coordination" fee and begins to put in place the basic elements of a PCMH	Practice receives "care coordination" fee and finalizes basic elements of a PCMH	Practice must achieve Level I Recognition from NCQA	Practice must achieve Level II Recognition from NCQA	Practice must achieve Level III Recognition from NCQA (fully-functioning medical home); higher adjustments for higher performers (whether through NCQA criteria or actual performance on ER visits, hospitalizations)

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QOPI Should Be The Underpinning of any Reimbursement System

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Alternative to ASP+6: The Cancer Therapy Management Fee

- Uncouples reimbursement from drug prices, drugs are a pass through, paid at acquisition price.
- Instead of a margin on drugs, pays a flat episodic fee for pharmacy management during active chemotherapy.
- Keeps practices “whole”; in aggregate, reimbursement very similar to ASP+6.
- Paid outside of Part B cap on physician services just as ASP+6 is today.
- Saves money by tying increases in reimbursement to performance, quality, and inflation (MEI) not to increasing drug prices.

Cancer Therapy Management Fee

- Can be calculated from CMS actuarial data
- Must be modeled and piloted in real practices
- Should be applied to both IV and oral treatment regimens
- Practices should be allowed to opt in or stay with ASP based reimbursement.
- A semblance of the current drug distribution infrastructure, must be maintained.
- Downward pressure on drug prices must be maintained or enhanced.

Value Based Pathways

- Pathways can reduce variability.
- Good pathways will, in the aggregate, reduce costs.
- ASCO will not develop pathways, there are already 7 commercial pathways in the market and NCCN/USON have announced a partnership to develop a new and comprehensive set of pathways.
- Physicians should only have to use one set of certified pathways.
- Optimal pathway adherence is not yet established, but it is less than 100%.

Episodes of Care/Bundled Payments

- Already exist: DRG, APC, Dialysis
- In 2009, ASCO proposed a colon cancer bundle demo to CMS and CMMI. In 2011 it was updated and resubmitted.
- Bundled permutations can include:

✓ drug or no drug
✓ aggregated monthly payments
✓ disease and stage specific payments
✓ supportive care
✓ hospital utilization
✓ imaging,…

Episode Based Payment (An Example)

- Specified condition, defined period of time, single payment
- Bundles drugs and administration
- Payment based on average cost of care for all patients with condition
- Theorized savings:
  - Physician as discretionary purchaser (incentive for providers to select lower-price regimens)
  - Suppliers reduce prices to remain competitive
- Sustain innovation by allowing expensive innovator drugs initial period of “pass through” status
- Protect against under-utilization through quality monitoring

The Patient Centered Medical (Oncology) Home

- Complete coordination of care, including survivorship and hand-off to PCP
- Use of pathways
- Aggressive pre-emptive symptom management
- Extensive use of proactive telephone contact
- Continuous flow of information back to PCP via EHR
- Savings from decreased utilization of expensive services, i.e. ER visits and hospitalizations
- Model and resultant savings highly HIT dependent

CMMI Grant: Improving Quality and Reducing Cost of Cancer Care Through Practice Transformation and Patient Engagement

- Collaboration of ASCO, Oncology Management Solutions (OMS) and International Oncology Solutions (ION)
- Provides technical and financial support for practice transition to a patient centered medical home
- Aligned Patient-Engagement Program incentivizes the alignment of patient behaviors with the plan for treatment and symptom management

Aligned Health Patient Engagement Program

Patient Actions that Most Influence Quality, Outcomes and Cost
• Patient completes disease-specific education, including clinical trials options
• Patient's caregivers complete training
• Patient participates in patient distress screening
• Patient participates in discussion re: goals of therapy and written treatment plan
• Patient participates in Advance Care Planning discussions
• Patient completes medication therapy management (MTM) program with >90% compliance
• No ED visits without call to practice first (monthly reward)– unless life-threatening
• Patient understands and applies home care instructions for symptom management
• Patient establishes account on patient portal and visits weekly (monthly reward)
• Patient completes satisfaction survey

Whatever the path…

- Fee for service unlikely to remain dominant model
- Prospective payment models are the trend
  - Shifts reward from volume to efficiency
  - Risk will move from over- to under-utilization
  - Because of this, require strong quality measurement programs
- Need a national program created by - and meaningful to - oncology professionals
- First step: fiscal cliff legislation included provision to qualify registries like QOPI for reporting to Medicare
  - PQRS historically not meaningful in oncology
  - QOPI developed by oncology professionals
  - Aim is to avoid each payer creating their own

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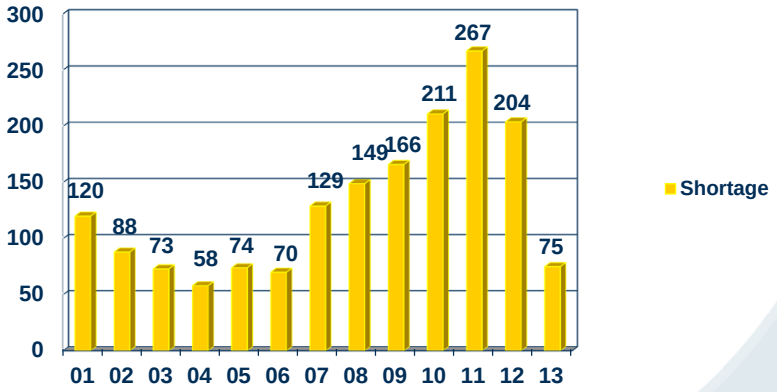
New Drug Shortages by Year January 2001 to June 30, 2013



Note: Each column represents the # of new shortages identified during that year

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Oncology Drug Shortages

- Vinblastine 01/10/08
- Mitomycin injection 07/09/08
- Etoposide injection 12/16/08
- Daunorubicin injection 01/26/10
- Cisplatin 02/09/10
- Carboplatin 05/05/10
- Fludarabine 05/12/10
- Doxorubicin 05/17/10
- Leucovorin Injection 05/20/10
- Mesna injection 05/28/10
- Dacarbazine injection 06/18/10
- Pentostatin 07/16/10
- Fluorouracil 07/20/10
- Leuprolide injection 02/08/11
- Thiotepa injection 02/11/11
- Irinotecan 02/18/11
- Daunorubicin 03/02/11
- Busulfan injection 03/03/11
- Vinorelbine 03/16/11
- Methotrexate inj 11/17/10
- Bleomycin
- Cytarabine
- Liposomal doxorubicin

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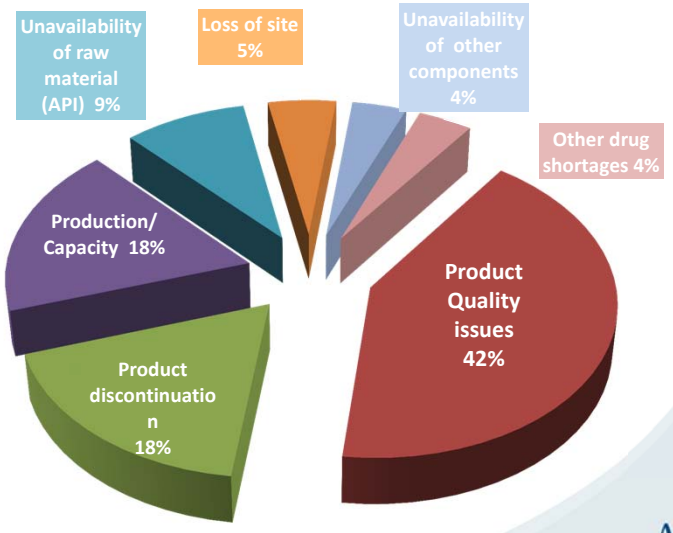
Causes of Drug Shortages



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Economic Issues

- Decreased demand
- Pricing issues
- Move to other-more favorable-product line
- Recalls
- Cost of plant improvements vs. profitability
- Regional issues
- Gray market
- Hoarding
- Unfavorable contract arrangements

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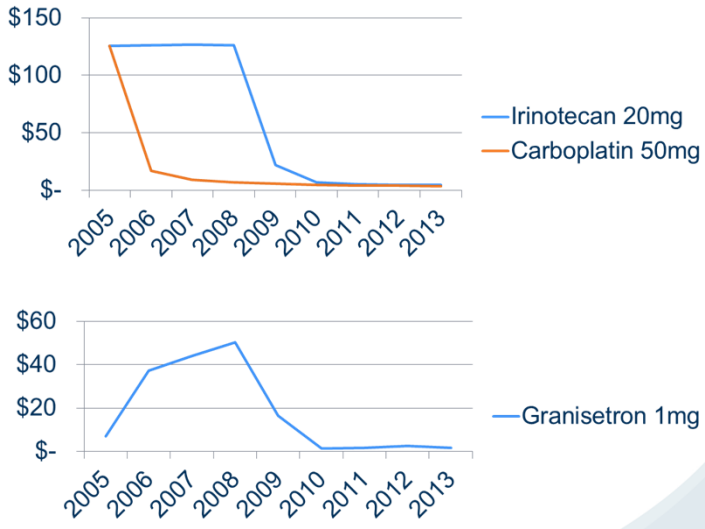
When Drugs Become Generic



Source: CMS ASP Pricing Files, January 2005-2013

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Impact on Clinical Practice

- Treatment delays and substitutions
- Treatment omissions: Doxil, cytarabine and methotrexate in particular
- Setting priorities for who gets treated
- Reducing doses
- Borrowing from other practices
- Hoarding and gray market profiteering

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Impact on Clinical Practice

- Increased patient anxiety
- Increased physician/pharmacist workload
- Decreased practice efficiency
- Decreased treatment effectiveness
- Increased risk of adverse events
- Increased cost of treatment and patient co-pays

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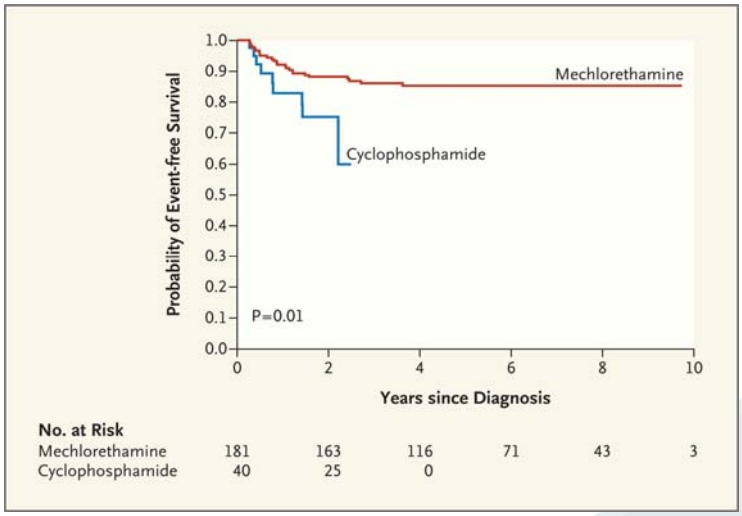
Impact of Drug Substitution on Outcome of Children with Hodgkin Lymphoma



Metzger ML et al. N Engl J Med 2012;367:2461-2463.

Impact on Clinical Research

- Decreased accrual
- Protocol “violations”
- Data confounding

Two Sequential Surveys of U.S. ASCO Members

- Survey 1: October 5 – November 2, 2012 | 390 respondents
- Survey 2: March 15 – April 8, 2013 | 462 respondents
- Identical surveys

Commonly Reported Substitutions

Drug in Shortage	Substitute
Daunorubicin	Idarubicin
Leucovorin (IV)	Leucovorin (oral)
Leucovorin (reg./high-dose)	Leucovorin (low-dose)
Magnesium (IV)	Magnesium (oral)
Sodium bicarbonate (IV)	Sodium acetate (IV)

Other Substitutions

IV to Oral

- Antiemetics (general)
- Calcium
- Dexamethasone
- Diphenhydramine
- Furosemide
- Leucovorin
- Magnesium
- Ondansetron
- Phosphorous
- Potassium
- Sodium bicarbonate

Supportive Care

Drug in Shortage		Substitute(s)
Acyclovir	→	Ganciclovir
Atropine	→	Lomotil
Dexamethasone	→	Methylprednisolone Prednisone
Droperidol	→	Haloperidol
Furosemide	→	Bumetanide
Mannitol	→	Glucose Furosemide

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But the MOST Commonly Reported Substitutions:

Leucovorin
⇩
Levo-leucovorin

5-FU / Leucovorin
⇩
Capecitabine

- Of the 261 respondents who reported they were aware of ongoing substitutions, 202 gave specific examples
- Of those 202, **38%** mentioned substitution of levo-leucovorin for leucovorin; **12%** mentioned substitution of capecitabine for 5-FU/leucovorin
- Cost implications are *significant*

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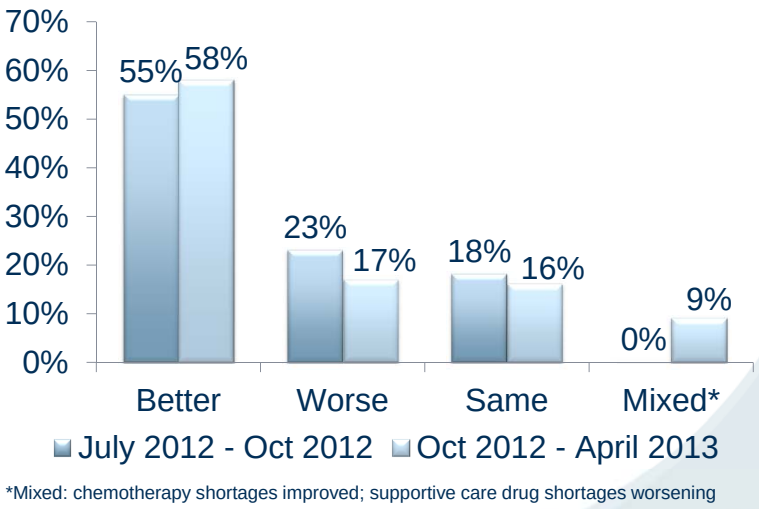
Shortages Better, Worse, or the Same?



*Mixed: chemotherapy shortages improved; supportive care drug shortages worsening

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Summary

- Drug shortages have a significant negative impact on clinical care and research
- Slight improvements recently
- Patient anxiety increased and outcomes jeopardized
- Provider efficiency reduced
- Clinical trials at risk, costs to the system increased
- Current FDA authorities enable stop-gap measures
- Permanent solutions will require enhancing the business model of generic drug manufacturing

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ASCO's Approach to Health IT & Rapid Learning Systems

Origins

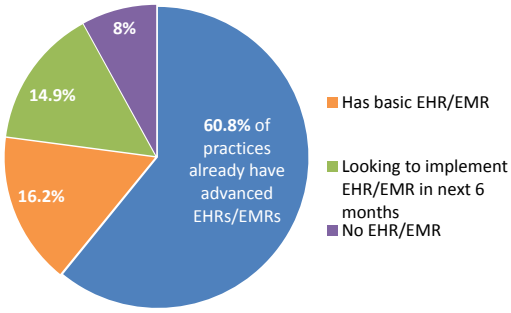
"We seek the development of a learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES
Advising the nation / Improving health

The HIT Revolution in Cancer Care

- **Widespread adoption of EHRs by physicians and hospitals**
- **Improved data processing and storage capacities**
- **Rapid analysis tools**
- **Advances in natural language processing**

2012: EHR/EMR Use in U.S. Oncology Practices



Source: Forte, GJ, et al. "American Society of Clinical Oncology National Census of Oncology Practices: Preliminary Report." JOP January 2013 vol. 9 no. 1 9-19

Foundation

What is ASCO's Rapid Learning Healthcare System?

Origins

The primary purpose of CancerLinQ is to improve the QUALITY of care and to enhance outcomes

- Many other secondary benefits will be realized
  - For Patients:
    - Highest quality care with best outcomes for EVERY patient
    - Clinical Trial Matching
    - Safety Monitoring
    - Evidence based education materials
    - Real time side effect management
    - Patient Portals to interact with providers and provide patient reported outcomes (PROs)

Origins

The primary purpose of CancerLinQ is to improve the QUALITY of care and to enhance outcomes

- Many other secondary benefits will be realized
  - For Providers:
    - Ability to scan the system for real time "second opinions"
    - Observational Clinical Decision Support (CDS)
    - Guideline driven CDS
    - Effectiveness Monitoring
    - Ability to access research, literature, guidelines, etc. in real time at the point of care
    - Quality reporting and benchmarking to avoid prior authorizations
    - Many others

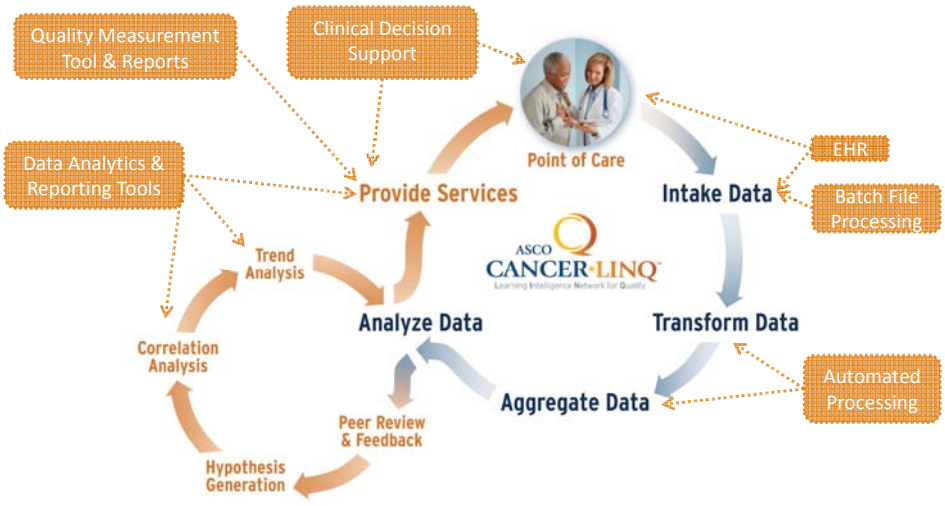
Origins

The primary purpose of CancerLinQ is to improve the QUALITY of care and to enhance outcomes

- Many other secondary benefits will be realized
  - For Research/Public Health:
    - Ability to mine "big data" for correlations that could never be identified without aggregate data
    - Comparative Effectiveness Research
    - Hypothesis generating exploration of data could lead to better use of current products
    - Identifying patients available for clinical trials
    - Identifying early signals for adverse events
    - Identifying early signals for effectiveness in "off label" use
    - Using "omics" to identify best treatment options

The Prototype

Goals of the Prototype



The Prototype

Goals of the Prototype

Demonstrate value-added tools, s
as the ability to measure a clinici
performance on a subset of QOPI
measures in real-time

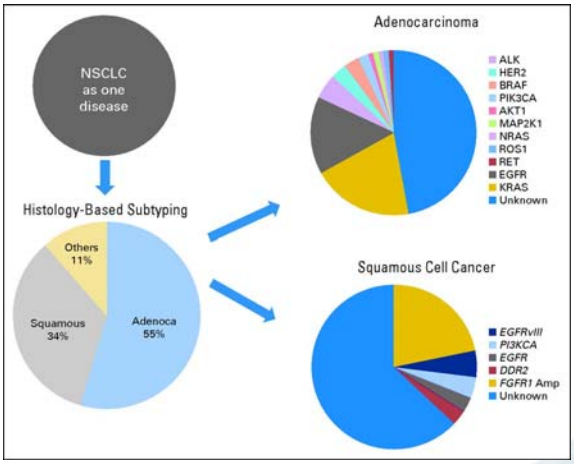
monstrate ASCO's capability t
velop rapid, real-time, clinical
decision support based on clinical
guidelines and integrate them
into a demonstration EHR
m

Provide "lessons
learned" about tl
technological an
logistical challeng
involved in a full-s
CancerLinQ
implementation

Create new ways of
exploring clinical data
and hypotheses generati

Demonstrate the ability to
capture and aggregate
complete longitudinal pa
records from any source, in a
format, and make use of the data

Implementing Personalized Cancer Care



JCO 2013;31:1039-1049

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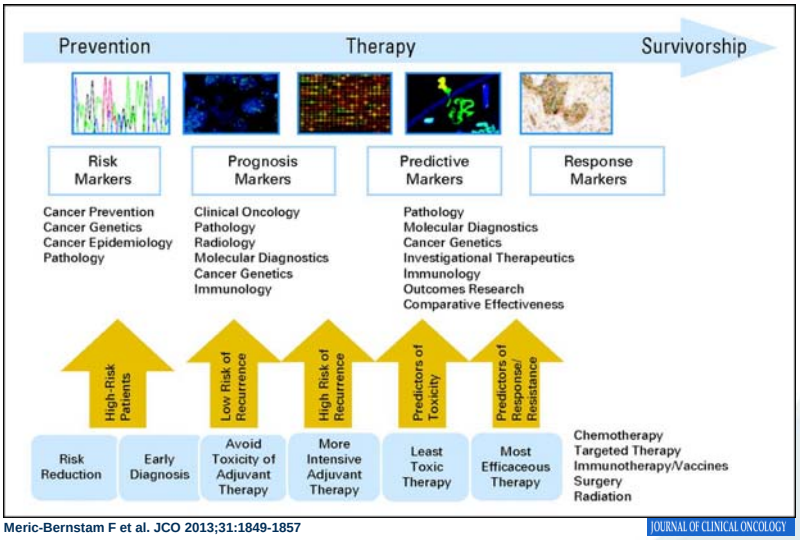
Increasing Reliance on Biomarkers



Meric-Bernstam F et al. JCO 2013;31:1849-1857

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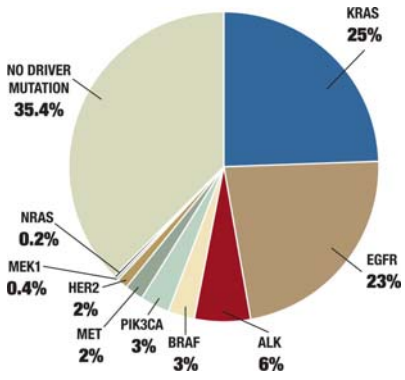
Matching Drugs to Mutations



Genotypes of NSCLC

Clin Cancer Res 18 (Suppl 1) S67. Nov 1, 2012

Potential Treatments

- Crizotinib (ALK TKI)
- Erlotinib (EGFR TKI)
- Lapatinib, Afatinib (EGFR/HER2)
- Onartuzumab (MetMAb)
- Tivantinib (cMET TKI)
- Selumetinib (MEK1/2)
- Trametenib (MEK1/2)
- Vemurafenib (BRAF)

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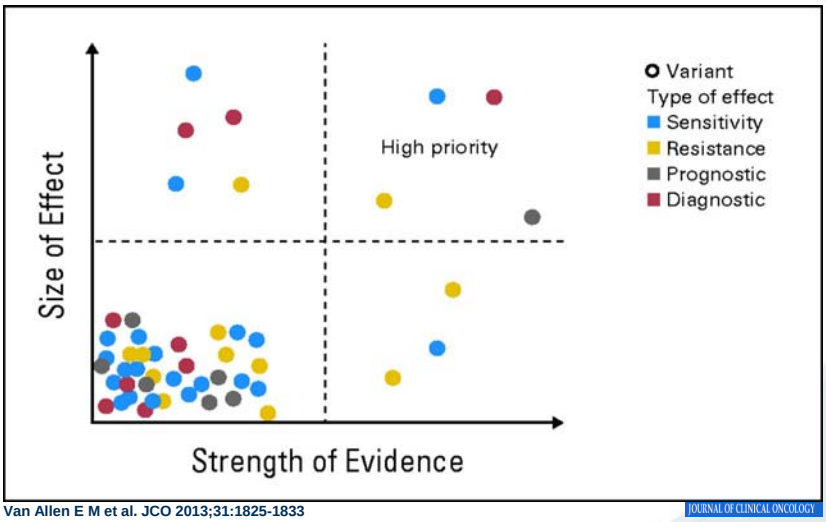
What is "Actionable"?



Van Allen E M et al. JCO 2013;31:1825-1833

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Potential Drug Sources

- Commercial drug used within indication
- Commercial drug used off label (reimbursement?)
- Clinical trial participation
- Expanded access program (company sponsor or individual patient IND)

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Proposed Solution: A National Expanded Access Program

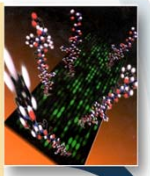
- Create a “national formulary” of targeted agents against common aberrations
- Create a registry of administered treatment and patient outcomes
- Participants: Patients, physicians, pharma, payers, FDA

How Might It Work?

National formulary stocked with representative targeted agents against common mutations.

Patient is registered in national registry.

Physician submits validated test result from certified lab and drug request.



Formulary reviews request against pre-determined guidelines and dispenses drug.

Patient receives drug treatment. Outcomes entered in registry.

What's Required?

Pharma provides drugs.

Patient agrees to data collection.

Physician submits required follow-up data.

CMS/commercial payers reimburse treatment costs (Coverage with Evidence Development).

Third party (ASCO?) hosts the outcomes registry as honest broker.

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Who Benefits?

- **Patients** receive targeted agent matched to molecular profile; become "cancer information donors"
- **Physicians** receive guidance in treatment recommendations and access to drugs
- **Pharma** receives data on drug use and outcomes to inform R&D plans and life cycle management
- **Payers** receive data on drug use and outcomes to inform future coverage decisions
- **Regulators** receive data on extent and outcomes of off label drug and test use and real world safety data

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Summary

- ASCO continues to work on many fronts to insure that all cancer patients have access to high quality cancer care and that all oncologists are well-equipped to deliver that care.
- State societies play a vital role in formulating and implementing ASCO policy and activities and we want to hear from you!