

Contact: Keith Saunders

UNIVERSITY OF IOWA HOSPITALS AND CLINICS COMMITTEE

BOARD OF REGENTS, STATE OF IOWA
OLD CENTRAL BALLROOM, ROOMS A AND B
UNIVERSITY OF NORTHERN IOWA
CEDAR FALLS, IOWA

FEBRUARY 5, 2014
4:00 P.M.

Actions Requested: The University of Iowa Hospitals and Clinics Committee is requested to:

- Approve the minutes from the December 4, 2013, Committee meeting.
- Receive an informational report.

Executive Summary: The University of Iowa Hospitals and Clinics Committee will be provided with a report on the following topics:

- Opening Remarks (Robillard)
- Operational and Financial Performance (Kates/Fisher)
- Proposed Amendments to the Bylaws of the UIHC and its Clinical Staff (Hesson)
- Iowa Institute of Human Genetics (Dr. Richard Smith)

Contact: Keith Saunders

MINUTES OF DECEMBER 4, 2013, TELEPHONIC COMMITTEE MEETING

(host location)
ALUMNI CENTER, UELNER EXECUTIVE BOARD ROOM
IOWA STATE UNIVERSITY
AMES, IOWA

Committee Members

Nicole Carroll (Chair)
Milt Dakovich
Robert Downer

Ruth Harkin (absent)
Larry McKibben
Katie Mulholland

Bruce Rastetter
Subhash Sahai
Hannah Walsh

University of Iowa Hospitals and Clinics

Jean Robillard, Ken Fisher, Ken Kates, Debra Schwinn

Chair Carroll called the meeting to order at 1:05 p.m.

Minutes of December 4, 2013, Telephonic Committee Meeting

- MOVED by MULHOLLAND, SECONDED by SAHAI, to approve the minutes of the October 24, 2013, Committee Meeting. MOTION APPROVED UNANIMOUSLY.

Opening Remarks

Vice President for Medical Affairs Dr. Jean Robillard provided opening remarks to the Committee.

- The Committee received the remarks by GENERAL CONSENT.

Operational and Financial Performance

The Committee listened to a presentation by Chief Financial Officer Ken Fisher and Chief Executive Officer Ken Kates on operational and financial performance.

- The Committee received the presentation by GENERAL CONSENT.

Chair Carroll adjourned the meeting at 1:25 p.m.

The corresponding docket memorandum for each agenda item, an integral component of the minutes, is available on the Board of Regents website: <http://www.regents.iowa.gov/>. Copies of these memoranda can also be obtained from the Board Office by calling 515-281-3934. Audio of the meeting is also available on the web site.



University of Iowa Health Care

***Presentation to
The Board of Regents, State of Iowa***

***February 5-6, 2014
University of Northern Iowa
Cedar Falls***

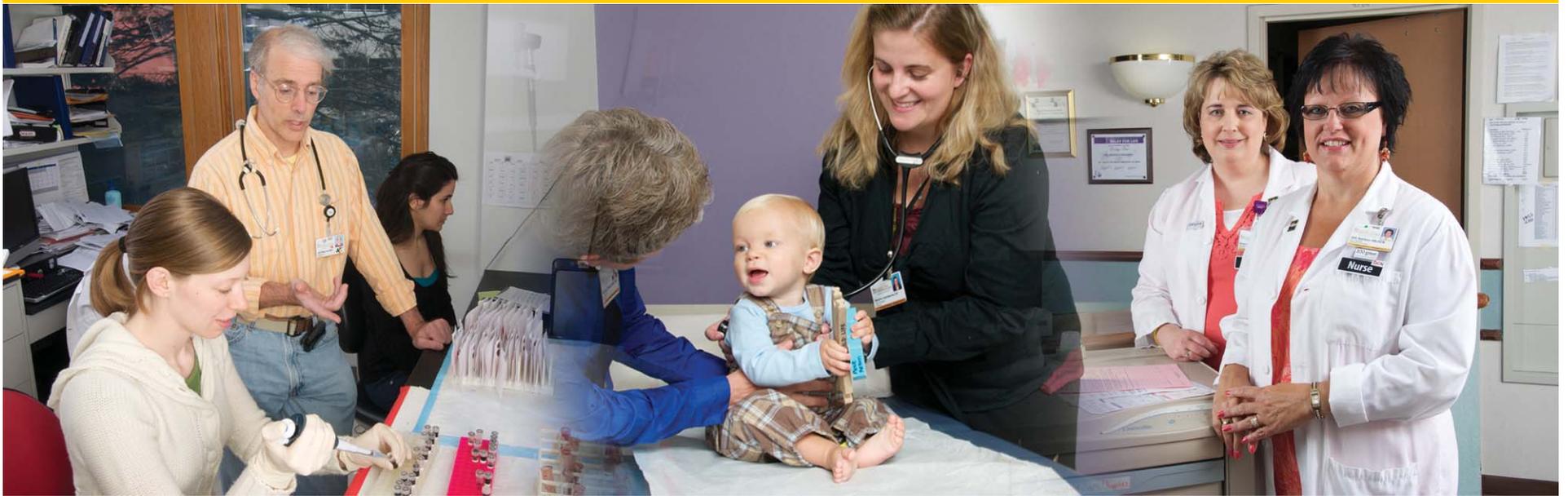
Agenda

- Opening Remarks (Jean Robillard)
- Operational and Financial Performance (Ken Kates & Ken Fisher)
- Proposed Amendments to the Bylaws of the UIHC and its Clinical Staff (Bill Hesson)
- Iowa Institute of Human Genetics (Richard Smith)



Opening Remarks

Jean Robillard, MD
Vice President for Medical Affairs



Proposed Amendments to the Bylaws of the UIHC and its Clinical Staff

Bill Hesson
Associate Vice President for Legal Affairs & Legal Counsel, UIHC



Operating and Financial Performance Update

Ken Kates, Associate Vice President and Chief Executive Officer
UI Hospitals & Clinics

Ken Fisher, Associate Vice President for Finance
and Chief Financial Officer

Volume Indicators

Fiscal Year to Date December 2013

Operating Review (YTD)	Actual	Budget	Prior Year *	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Discharges	15,748	15,960	15,454	(212)	-1.3% ○	294	1.9% ○
Patient Days	99,243	97,872	97,397	1,371	1.4% ○	1,846	1.9% ○
Length of Stay	6.27	6.20	6.37	0.07	1.2% ○	(0.10)	-1.5% ○
Average Daily Census	539.36	531.91	529.33	7.45	1.4% ○	10.03	1.9% ○
Total Surgeries	14,850	14,673	14,183	177	1.2% ○	667	4.7% ●
- Inpatient	5,943	5,947	5,742	(4)	-0.1% ○	201	3.5% ●
- Outpatient	8,907	8,725	8,441	182	2.1% ○	466	5.5% ●
ED Visits	30,476	31,339	30,689	(863)	-2.8% ●	(213)	-0.7% ○
Total Clinic Visits	410,591	402,919	382,784	7,672	1.9% ○	27,807	7.3% ●

* from ongoing operations

● Greater than 2.5% Favorable	○ Neutral	● Greater than 2.5% Unfavorable
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Discharges by Type

Fiscal Year to Date December 2013

Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Adult Medical	4,872	5,468	5,317	(596)	-10.9% ●	(445)	-8.4% ●
Adult Surgical	7,905	7,316	7,063	589	8.1% ●	842	11.9% ●
Adult Psych	706	756	737	(50)	-6.6% ●	(31)	-4.2% ●
<i>Subtotal – Adult</i>	<i>13,483</i>	<i>13,540</i>	<i>13,117</i>	<i>(57)</i>	<i>-0.4%</i> ○	<i>366</i>	<i>2.8%</i> ●
Pediatric Medical & Surgical	1,588	1,706	1,644	(118)	-6.9% ●	(56)	-3.4% ●
Pediatric Critical Care	402	436	424	(34)	-7.8% ●	(22)	-5.2% ●
Pediatric Psych	275	278	269	(3)	-1.1% ○	6	2.2% ○
<i>Subtotal – Pediatrics w/o newborn</i>	<i>2,265</i>	<i>2,420</i>	<i>2,337</i>	<i>(155)</i>	<i>-6.4%</i> ●	<i>(72)</i>	<i>-3.1%</i> ●
Newborn	747	744	730	3	0.4% ○	17	2.3% ○
TOTAL w/o Newborn	15,748	15,960	15,454	(212)	-1.3% ○	294	1.9% ○

●	○	●
Greater than 2.5% Favorable	Neutral	Greater than 2.5% Unfavorable

Discharge Days by Type

Fiscal Year to Date December 2013

Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Adult Medical	26,316	29,753	29,631	(3,437)	-11.6% ●	(3,315)	-11.2% ●
Adult Surgical	40,528	35,463	35,241	5,065	14.3% ●	5,287	15.0% ●
Adult Psych	10,175	10,487	10,429	(312)	-3.0% ●	(254)	-2.4% ○
<i>Subtotal – Adult</i>	<i>77,019</i>	<i>75,703</i>	<i>75,301</i>	<i>1,316</i>	<i>1.7%</i> ○	<i>1,718</i>	<i>2.3%</i> ○
Pediatric Medical & Surgical	8,523	9,047	9,005	(524)	-5.8% ●	(482)	-5.4% ●
Pediatric Critical Care	10,758	11,827	11,766	(1,069)	-9.0% ●	(1,008)	-8.6% ●
Pediatric Psych	2,418	2,305	2,298	113	4.9% ●	120	5.2% ●
<i>Subtotal – Pediatrics w/o newborn</i>	<i>21,699</i>	<i>23,179</i>	<i>23,069</i>	<i>(1,480)</i>	<i>-6.4%</i> ●	<i>(1,370)</i>	<i>-6.0%</i> ●
Newborn	1,651	1,634	1,605	17	1.0% ○	46	2.9% ●
TOTAL w/o Newborn	98,718	98,882	98,370	(164)	-0.2% ○	348	0.4% ○

●	○	●
Greater than 2.5% Favorable	Neutral	Greater than 2.5% Unfavorable

Average Length of Stay by Type

Fiscal Year to Date December 2013

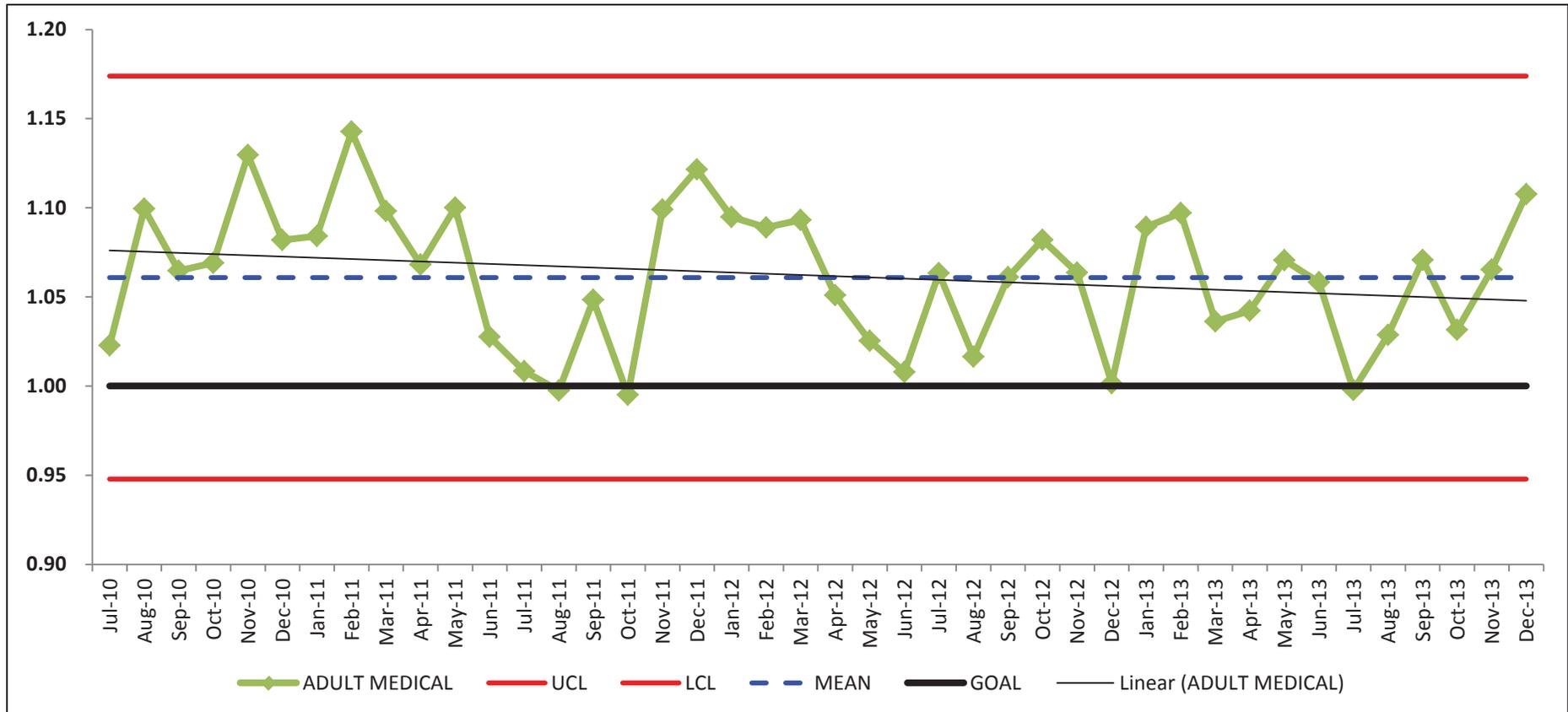


Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Adult Medical	5.40	5.44	5.57	(0.04)	-0.7% ○	(0.17)	-3.1% ●
Adult Surgical	5.13	4.85	4.99	0.28	5.8% ●	0.14	2.8% ●
Adult Psych	14.41	13.87	14.15	0.54	3.9% ●	0.26	1.9% ○
Subtotal – Adult	5.71	5.59	5.74	0.12	2.2% ○	(0.03)	-0.5% ○
Pediatric Medical & Surgical	5.37	5.30	5.48	0.06	1.2% ○	(0.11)	-2.0% ○
Pediatric Critical Care	26.76	27.13	27.75	(0.36)	-1.4% ○	(0.99)	-3.6% ●
Pediatric Psych	8.79	8.29	8.54	0.50	6.1% ●	0.25	2.9% ●
Subtotal – Pediatrics w/o newborn	9.58	9.58	9.87	0.00	0.0% ○	(0.29)	-2.9% ●
Newborn	2.21	2.20	2.20	0.01	0.6% ○	0.01	0.5% ○
TOTAL w/o Newborn	6.27	6.20	6.37	0.07	1.2% ○	(0.10)	-1.5% ○

●	○	●
Greater than 2.5% Favorable	Neutral	Greater than 2.5% Unfavorable

Length of Stay Index – Adult Medical(*)

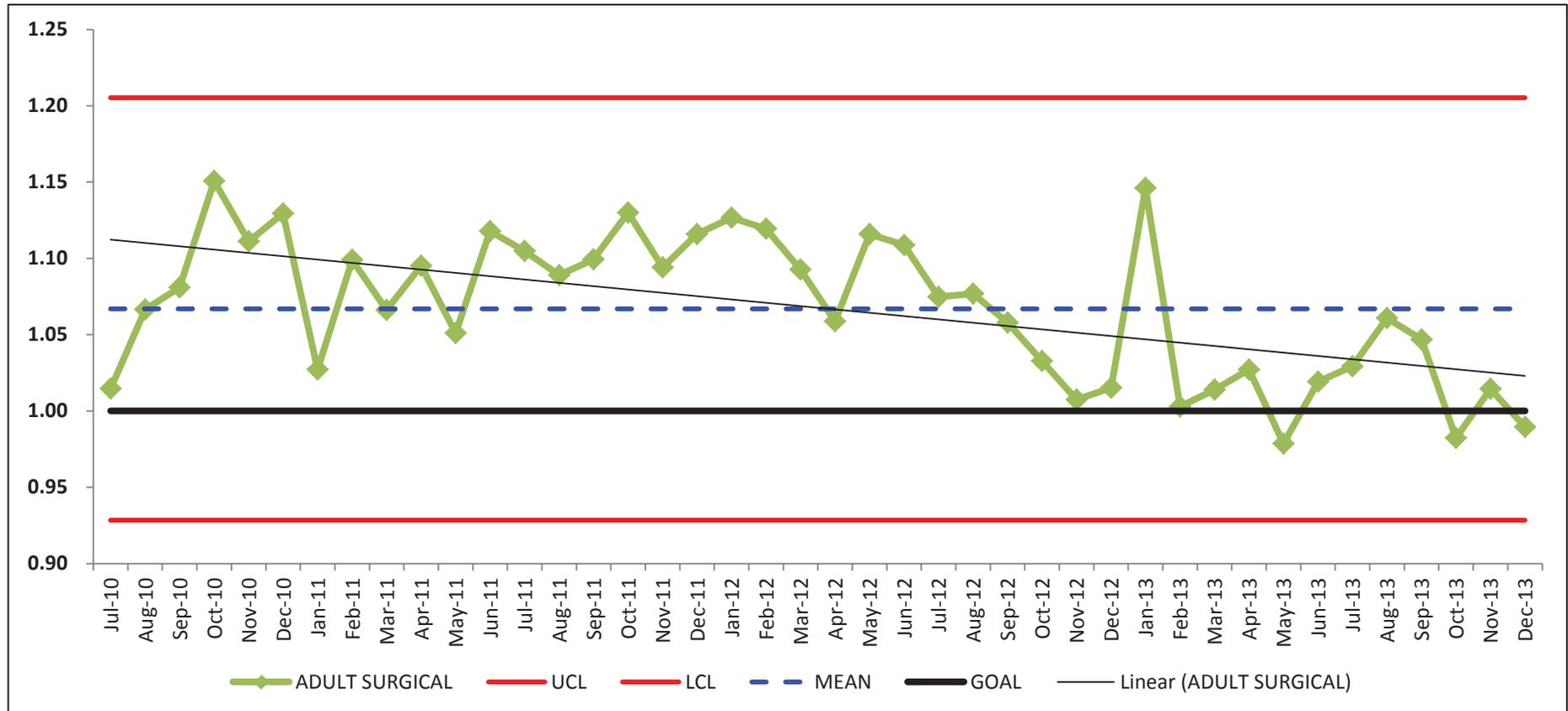
July 2010 through December 2013



(*) excludes outliers

Length of Stay Index – Adult Surgical(*)

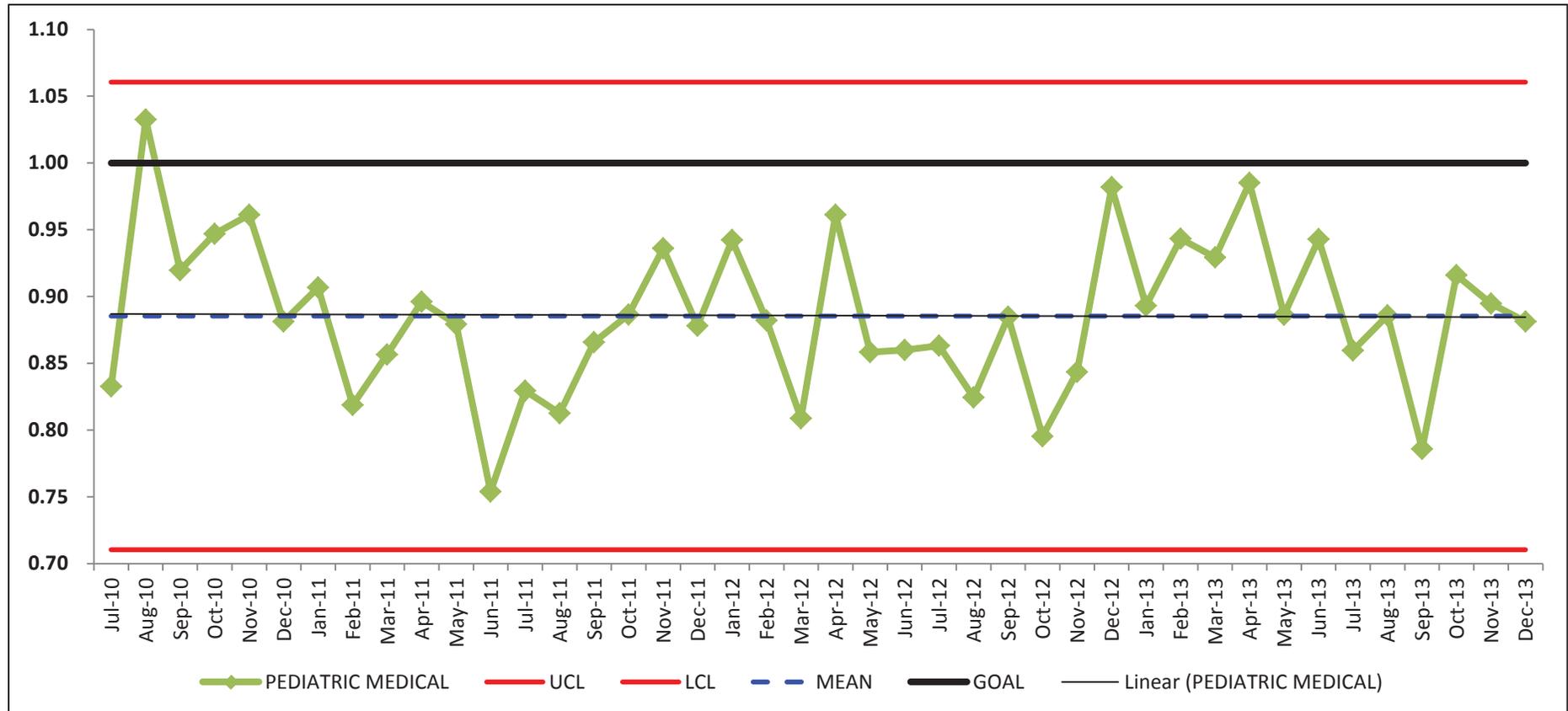
July 2010 through December 2013



(*) excludes outliers

Length of Stay Index – Pediatric Medical^(*)

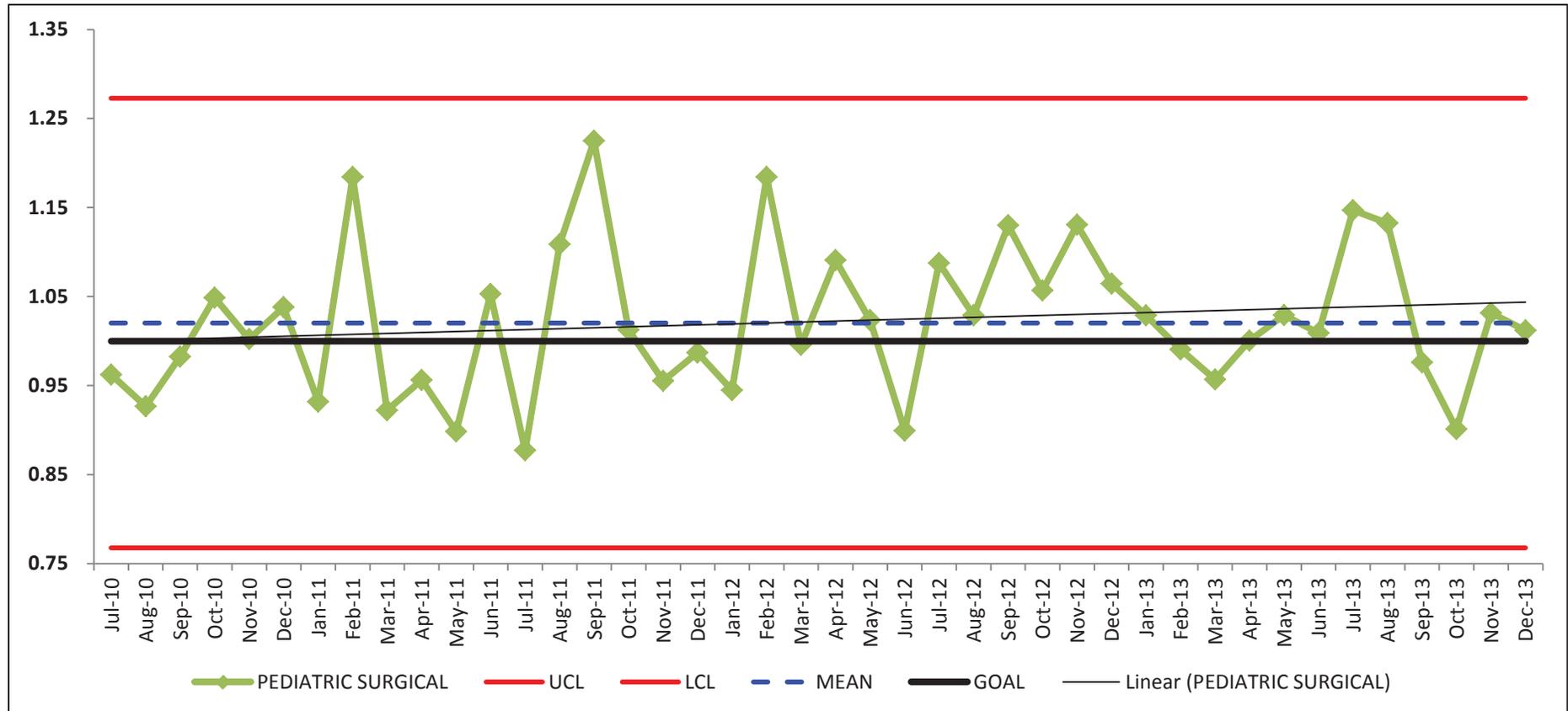
July 2010 through December 2013



(*) excludes outliers

Length of Stay Index – Pediatric Surgical^(*)

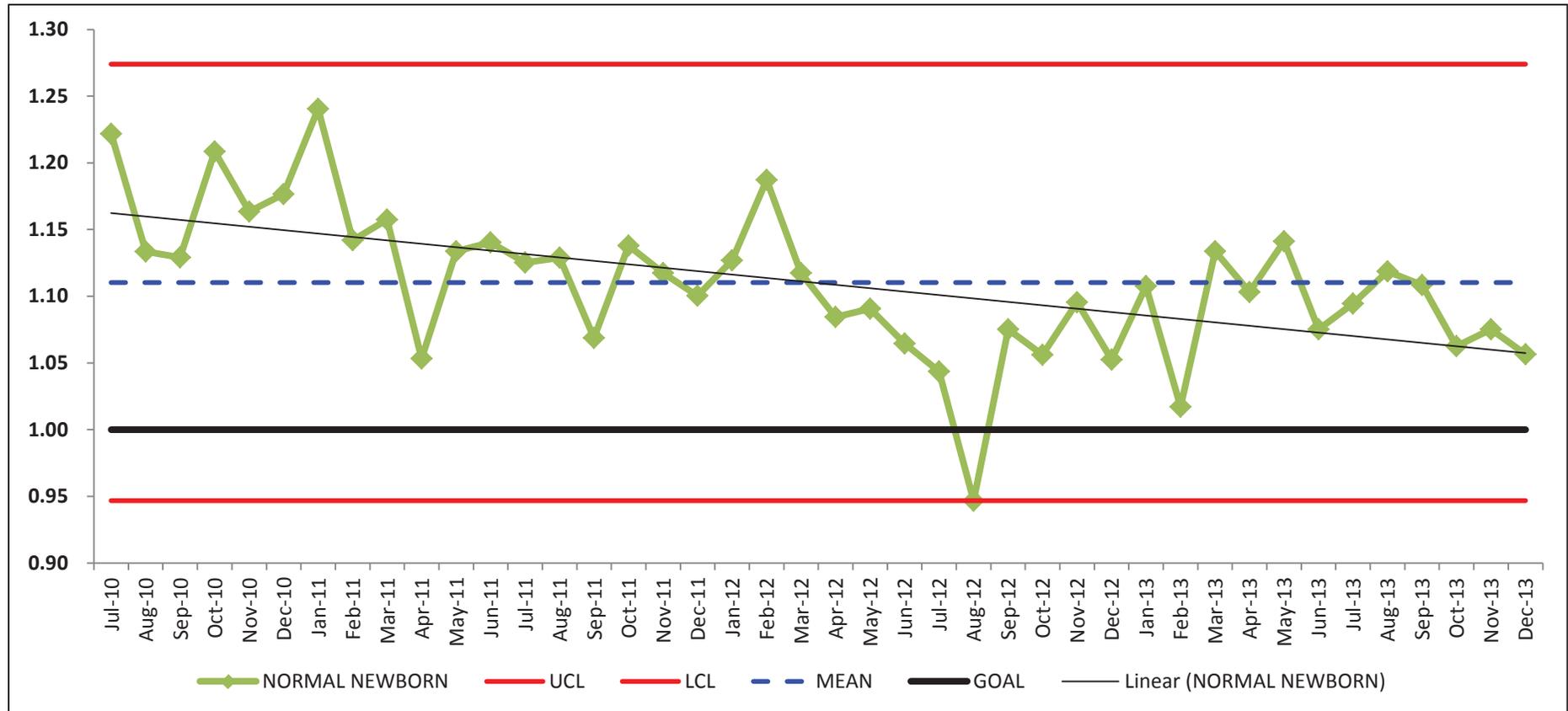
July 2010 through December 2013



(*) excludes outliers

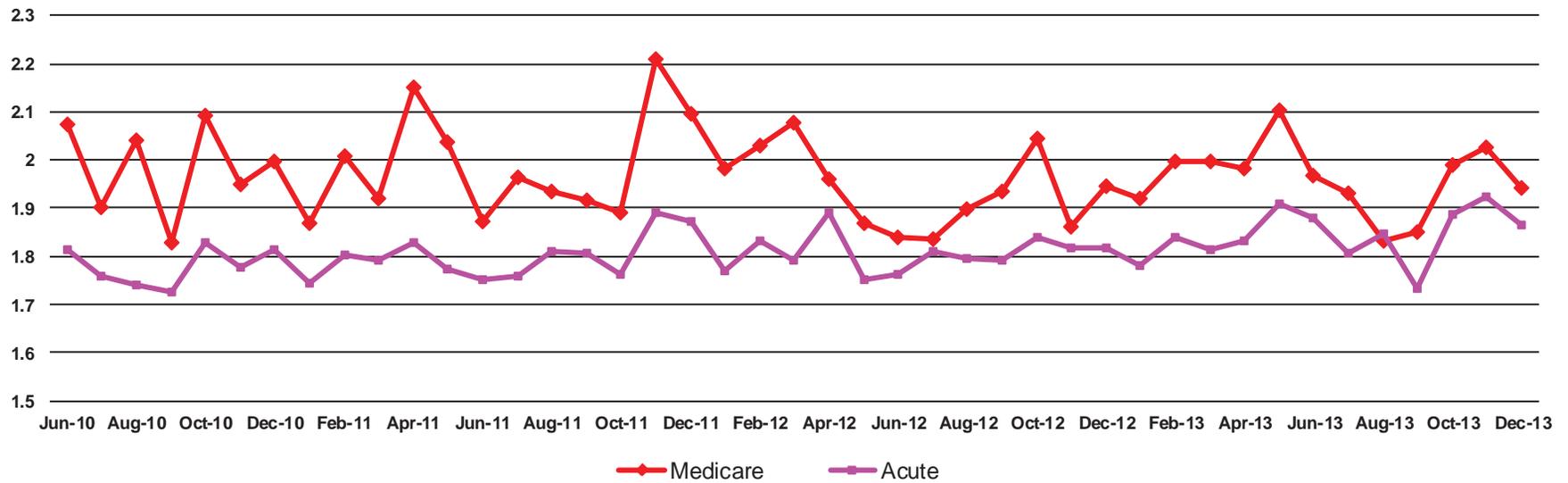
Length of Stay Index – Normal Newborn^(*)

July 2010 through December 2013



(*) excludes outliers

Case Mix Index



Inpatient Surgeries – by Clinical Department

December 2013



Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Cardiothoracic	538	490	462	48	9.8% ●	76	16.5% ●
Dentistry	92	82	63	10	11.8% ●	29	46.0% ●
General Surgery	1,745	1,718	1,652	27	1.5% ○	93	5.6% ●
Gynecology	334	355	357	(21)	-5.8% ●	(23)	-6.4% ●
Neurosurgery	876	945	910	(69)	-7.3% ●	(34)	-3.7% ●
Ophthalmology	60	80	76	(20)	-25.0% ●	(16)	-21.1% ●
Orthopedics	1,503	1,437	1,395	66	4.6% ●	108	7.7% ●
Otolaryngology	311	347	333	(36)	-10.4% ●	(22)	-6.6% ●
Radiology – Interventional	43	53	64	(10)	-19.5% ●	(21)	-32.8% ●
Urology w/ Procedure Ste.	441	440	430	1	0.3% ○	11	2.6% ●
Total	5,943	5,947	5,742	(4)	-0.1% ○	201	3.5% ●
Solid Organ Transplants	139	193	179	(54)	-28.0% ●	(40)	-22.3% ●

● Greater than 2.5% Favorable
 ○ Neutral
 ● Greater than 2.5% Unfavorable

Outpatient Surgeries – by Clinical Department

December 2013



Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget		Variance to Prior Year	% Variance to Prior Year	
Cardiothoracic	38	58	32	(20)	-35.0%	●	6	18.8%	●
Dentistry	317	333	329	(16)	-4.7%	●	(12)	-3.6%	●
Dermatology	21	18	22	3	15.0%	●	(1)	-4.5%	●
General Surgery	1,399	1,350	1,353	49	3.7%	●	46	3.4%	●
Gynecology	406	380	385	26	6.8%	●	21	5.5%	●
Internal Medicine	4	5	6	(1)	-20.0%	●	(2)	-33.3%	●
Neurosurgery	350	320	292	30	9.5%	●	58	19.9%	●
Ophthalmology	1,964	1,967	1,866	(3)	-0.2%	○	98	5.3%	●
Orthopedics	2,109	1,981	1,914	128	6.5%	●	195	10.2%	●
Otolaryngology	1,231	1,297	1,214	(66)	-5.1%	●	17	1.4%	○
Pediatrics	1	2	2	(1)	-50.0%	●	(1)	-50.0%	●
Radiology – Interventional	15	19	27	(4)	-19.6%	●	(12)	-44.4%	●
Urology w/ Procedure Ste.	1,052	995	999	57	5.7%	●	53	5.3%	●
Total	8,907	8,725	8,441	182	2.1%	○	466	5.5%	●

●	○	●
Greater than 2.5% Favorable	Neutral	Greater than 2.5% Unfavorable

Emergency Department

December 2013



Operating Review (YTD)	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
ED Visits	30,476	31,339	30,689	(863)	-2.8% 	(213)	-0.7% 
ED Admits	9,256	8,911	8,717	345	3.9% 	539	6.2% 
ED Conversion Factor	30.4%	28.4%	28.4%		6.8% 		6.9% 
ED Admits / Total Admits	58.9%	56.6%	56.8%		4.2% 		3.8% 

		
Greater than 2.5% Favorable	Neutral	Greater than 2.5% Unfavorable

Clinic Visits by Specialty

Fiscal Year to Date December 2013



Operating Review (YTD)	Actual	Budget	Variance to Budget	% Variance to Budget	
Burn Clinic	1,570	2,267	(697)	-30.7%	●
Center for Disabilities & Development	4,517	4,669	(152)	-3.3%	●
Center for Digestive Disease	9,975	10,215	(240)	-2.3%	○
Clinical Cancer Center	24,786	27,318	(2,532)	-9.3%	●
Dermatology	10,953	11,201	(248)	-2.2%	○
General Surgery	7,979	8,834	(855)	-9.7%	●
Hospital Dentistry	8,495	8,297	198	2.4%	○
Internal Medicine	17,940	17,858	82	0.5%	○
Neurology	6,628	6,918	(290)	-4.2%	●
Neurosurgery	5,882	5,710	172	3.0%	●
Obstetrics/Gynecology	27,945	25,454	2,491	9.8%	●
Ophthalmology	32,497	34,151	(1,654)	-4.8%	●
Orthopedics	36,726	34,628	2,098	6.1%	●
Otolaryngology	10,125	10,262	(137)	-1.3%	○
Pediatrics	26,606	28,173	(1,567)	-5.6%	●
Primary Care (non-IRL)	87,446	79,448	7,998	10.1%	●
Psychiatry	16,136	17,004	(868)	-5.1%	●
Urology	7,022	7,861	(839)	-10.7%	●
UI Heart Center	8,101	8,845	(744)	-8.4%	●
IRL	59,262	53,806	5,456	10.1%	●
Total	410,591	402,919	7,672	1.9%	○

● Greater than 2.5% Favorable

○ Neutral

● Greater than 2.5% Unfavorable

Clinic Visits by Location

Fiscal Year to Date December 2013



Operating Review (YTD)	FY14 Actual				FY13 Actual *				Variance to Prior Year	%
	On-Site	IRL	UICMS & QuickCare	Total	On-Site	IRL	UICMS & QuickCare	Total		
Primary Care	28,394		59,052	87,446	42,809		53,679	96,488	(9,042)	-9.4%
General Internal Medicine		14,019		14,019		5,747		5,747	8,272	143.9%
Pediatrics		12,696		12,696		5,157		5,157	7,539	146.2%
<i>Subtotal - Primary Care</i>	<i>28,394</i>	<i>26,715</i>	<i>59,052</i>	<i>114,161</i>	<i>42,809</i>	<i>10,904</i>	<i>53,679</i>	<i>107,392</i>	<i>6,769</i>	<i>6.3%</i>
Burn Clinic	1,570			1,570					1,570	
Center for Disabilities & Development	4,517			4,517	4,434			4,434	83	1.9%
Center for Digestive Disease	9,975	1,897		11,872	10,584	528		11,112	760	6.8%
Clinical Cancer Center	24,786			24,786	26,239			26,239	(1,453)	-5.5%
Dermatology	10,953	2,808		13,761	11,406	642		12,048	1,713	14.2%
General Surgery	7,979			7,979	7,729			7,729	250	3.2%
Hospital Dentistry	8,495			8,495	7,753			7,753	742	9.6%
Internal Medicine	17,940	2,491		20,431	17,726	1,006		18,732	1,699	9.1%
Neurology	6,628			6,628	6,565			6,565	63	1.0%
Neurosurgery	5,882			5,882	5,294			5,294	588	11.1%
Obstetrics/Gynecology	27,945	9,737		37,682	29,478	3,380		32,858	4,824	14.7%
Ophthalmology	32,497	3,676		36,173	33,760	1,203		34,963	1,210	3.5%
Orthopedics	36,726			36,726	33,558			33,558	3,168	9.4%
Otolaryngology	10,125	3,323		13,448	10,655	1,029		11,684	1,764	15.1%
Pediatrics	26,606			26,606	25,615			25,615	991	3.9%
Psychiatry	16,136			16,136	16,361			16,361	(225)	-1.4%
Urology	7,022	2,976		9,998	8,485	966		9,451	547	5.8%
UI Heart Center	8,101	5,639		13,740	9,168	1,828		10,996	2,744	25.0%
<i>Subtotal – Specialty Care</i>	<i>263,883</i>	<i>32,547</i>		<i>296,430</i>	<i>264,810</i>	<i>10,582</i>		<i>275,392</i>	<i>21,038</i>	<i>7.6%</i>
Total	292,277	59,262	59,052	410,591	307,619	21,486	53,679	382,784	27,807	7.3%

* from ongoing operations



Greater than 2.5% Favorable

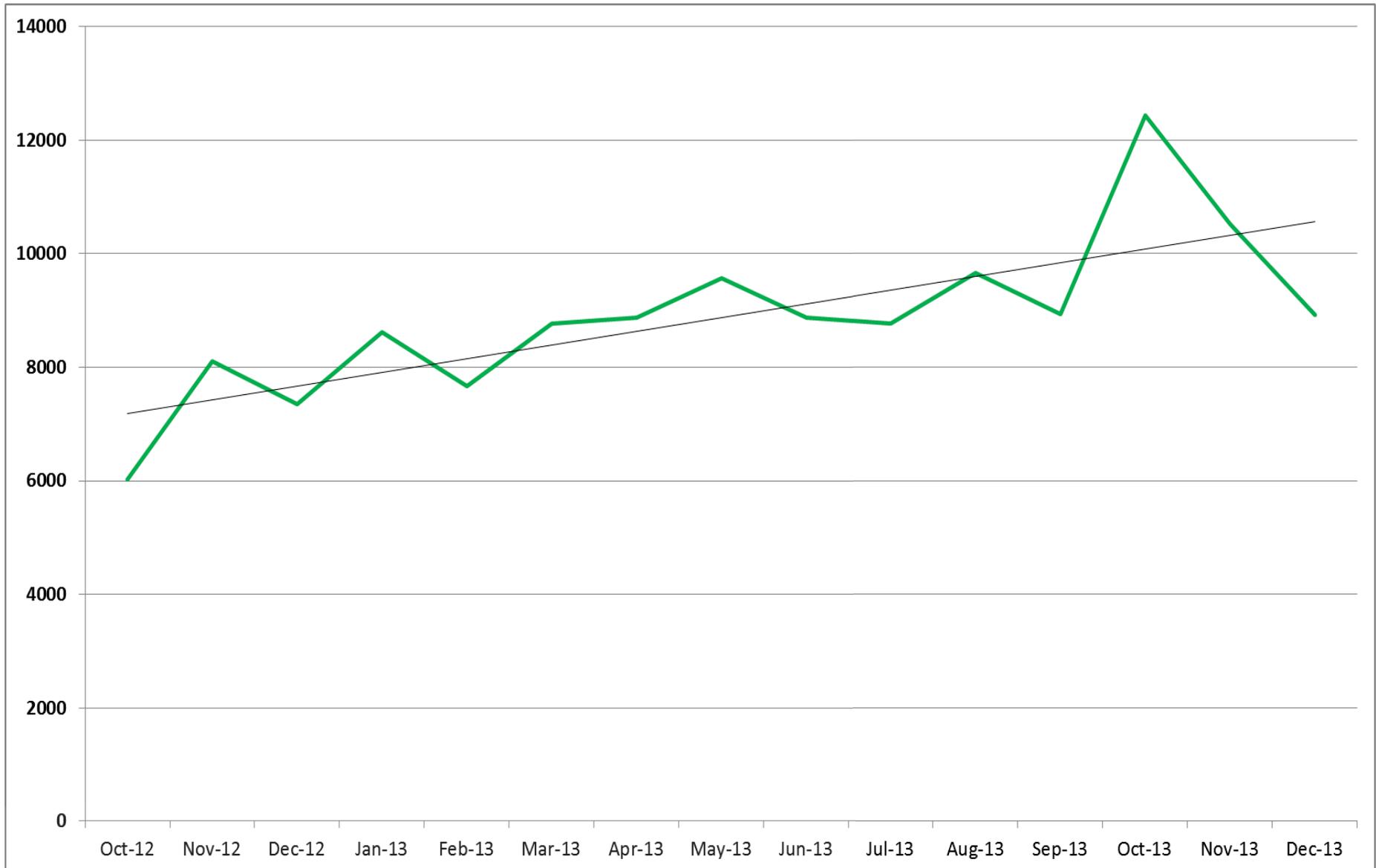


Neutral



Greater than 2.5% Unfavorable

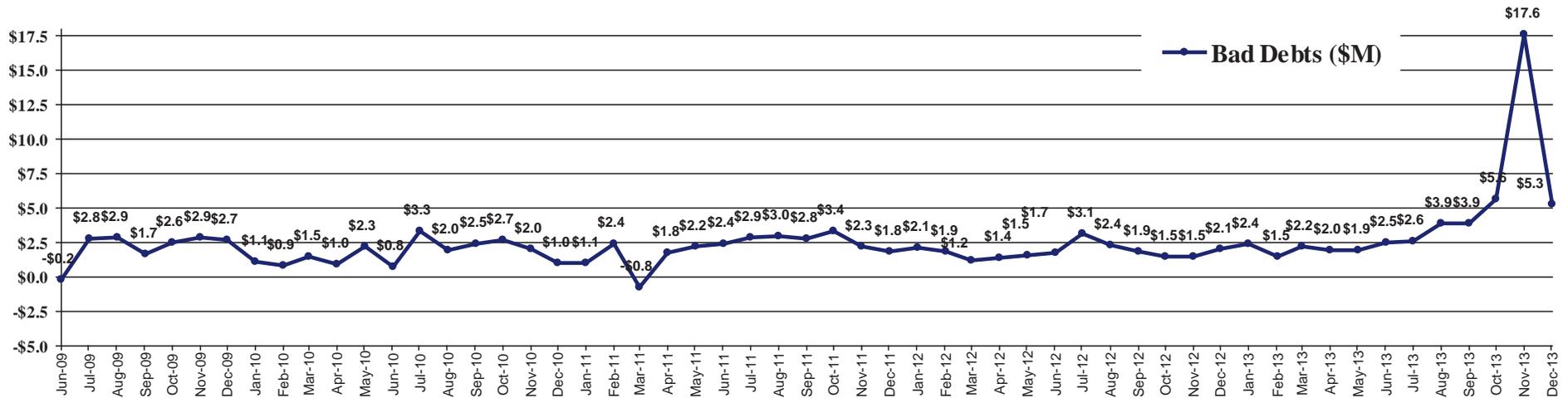
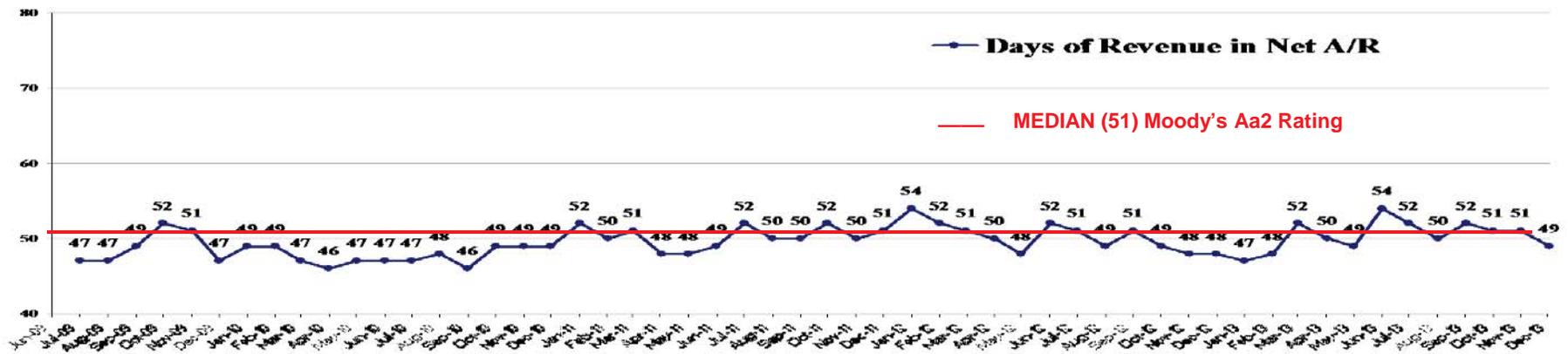
Iowa River Landing Ambulatory Visits



Comparative Accounts Receivable at December 31, 2013



	June 30, 2012	June 30, 2013	December 31, 2013
Net Accounts Receivable	\$153,061,293	\$161,942,694	\$159,172,752
Net Days in AR	52	54	49



UIHC Comparative Financial Results

December 2013



Dollars in Thousands

NET REVENUES:	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Patient Revenue	\$92,437	\$94,123	\$83,568	(\$1,686)	-1.8%	\$8,869	10.6%
Other Operating Revenue	3,997	4,225	4,127	(228)	-5.4%	(130)	-3.2%
Total Revenue	\$96,434	\$98,348	\$87,695	(\$1,914)	-1.9%	\$8,738	10.0%

EXPENSES:

Salaries and Wages	\$48,349	\$49,246	\$47,035	(\$897)	-1.8%	\$1,314	2.8%
General Expenses	38,657	39,625	35,583	(968)	-2.4%	3,074	8.6%
Operating Expense before Capital	\$87,006	\$88,870	\$82,618	(\$1,864)	-2.1%	\$4,388	5.3%
Cash Flow Operating Margin	\$9,428	\$9,478	\$5,078	(\$50)	-0.5%	\$4,350	85.7%
Capital- Depreciation and Amortization	6,541	6,603	6,192	(62)	-0.9%	349	5.6%
Total Operating Expense	\$93,547	\$95,473	\$88,810	(\$1,926)	-2.0%	\$4,737	5.3%

Operating Income	\$2,887	\$2,875	(\$1,114)	\$12	0.4%	\$4,001	359.1%
Operating Margin %	3.0%	2.9%	-1.3%		0.1%		4.3%
Gain (Loss) on Investments	521	2,157	5,111	(1,636)	-75.8%	(4,591)	-89.8%
Other Non-Operating	31	(879)	(1,435)	909	103.5%	1,464	102.1%
Net Income	\$3,439	\$4,153	\$2,562	(\$714)	-17.2%	\$877	34.2%
Net Margin %	3.5%	4.2%	2.8%		-0.7%		0.7%

* Gain/(Loss) on Investments based on information available at close. Final investment return for this period is reflected in Fiscal Year to Date returns in the subsequent reporting cycle.

UIHC Comparative Financial Results

Fiscal Year to Date December 2013



Dollars in Thousands

NET REVENUES:	Actual	Budget	Prior Year	Variance to Budget	% Variance to Budget	Variance to Prior Year	% Variance to Prior Year
Patient Revenue	\$561,782	\$572,726	\$534,766	(\$10,945)	-1.9%	\$27,015	5.1%
Other Operating Revenue	24,875	25,353	25,553	(478)	-1.9%	(678)	-2.7%
Total Revenue	\$586,657	\$598,080	\$560,319	(\$11,423)	-1.9%	\$26,338	4.7%

EXPENSES:

Salaries and Wages	\$288,506	\$297,159	\$282,470	(\$8,653)	-2.9%	\$6,037	2.1%
General Expenses	243,076	245,745	227,870	(2,669)	-1.1%	15,205	6.7%
Operating Expense before Capital	\$531,582	\$542,904	\$510,340	(\$11,322)	-2.1%	\$21,242	4.2%
Cash Flow Operating Margin	\$55,075	\$55,176	\$49,979	(\$101)	-0.2%	\$5,096	10.2%
Capital- Depreciation and Amortization	37,085	39,616	35,771	(2,530)	-6.4%	1,314	3.7%
Total Operating Expense	\$568,667	\$582,520	\$546,111	(\$13,852)	-2.4%	\$22,556	4.1%

Operating Income	\$17,990	\$15,660	\$14,208	\$2,430	15.6%	\$3,780	26.6%
Operating Margin %	3.1%	2.6%	2.5%		0.5%		0.6%
Gain on Investments	16,812	12,939	13,639	3,873	29.9%	3,174	23.3%
Other Non-Operating	(5,502)	(5,273)	(4,257)	(229)	-4.3%	(1,245)	-29.2%
Net Income	\$29,300	\$23,226	\$23,590	\$6,074	26.2%	\$5,710	24.2%
Net Margin %	4.9%	3.8%	4.1%		1.1%		0.8%

* Gain/(Loss) on Investments based on information available at close. Final investment return for this period is reflected in Fiscal Year to Date returns in the subsequent reporting cycle.



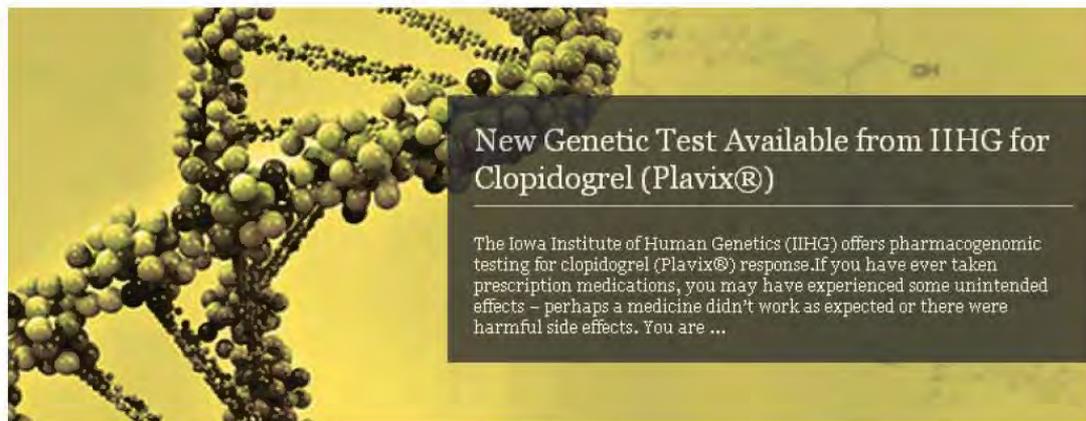
Iowa Institute of Human Genetics

Richard Smith, MD
Director, Iowa Institute of Human Genetics
Sterba Hearing Research Professor
Professor of Otolaryngology, Internal Medicine, Pediatrics and Molecular
Physiology and Biophysics

Carver College of Medicine >> Research >> Iowa Institute of Human Genetics

Iowa Institute of Human Genetics

Ways to give



New Genetic Test Available from IIHG for Clopidogrel (Plavix®)

The Iowa Institute of Human Genetics (IIHG) offers pharmacogenomic testing for clopidogrel (Plavix®) response. If you have ever taken prescription medications, you may have experienced some unintended effects – perhaps a medicine didn't work as expected or there were harmful side effects. You are ...



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- Clinical
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'Genome Wide Analysis Study of Idiopathic Intracranial Hypertension' by Benjamin Deonovic (Advisor: Janet Pendergast) 12/2/2013 3:30 PM - So30 CPHB ◀

[BIOINFORMATICS Seminar by Krishna Kalari](#)

A Statewide Resource



The Iowa Institute of Human Genetics (IIHG) is dedicated to promoting clinical care, research and education focused on the medical and scientific significance of variation in the human genome. The IIHG serves as a statewide resource

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http://www.medicine.uiowa.edu/humangenetics/

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Iowa Institute of Human Genetics

 Ways to give

ITS MISSION

1. To promote clinical care focused on **personalized (precision) genomic medicine**
2. To promote research and education focused on the medical and scientific significance of variation in human genome
3. To provide state-wide outreach on issues related to understanding the extent and meaning of human DNA sequence variation



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Iowa Institute of Human Genetics

 Ways to give

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3. To provide state-wide outreach on issues related to understanding the extent and meaning of human DNA sequence variation

ITS VISION

1. To develop a culture of innovation in human genetics
2. To support clinicians and researchers with shared and integrated interests in human genetics
3. To capture the imaginations of the next generation at the pre-professional level



Clinical

(Advisor: Janet Pendergast) 12/2/2013 3:30 PM -
So3o CPHB ◀



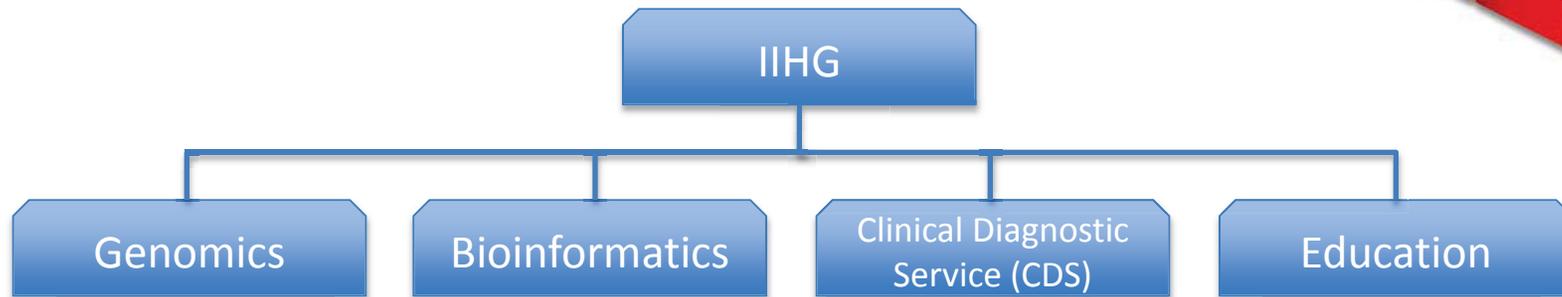
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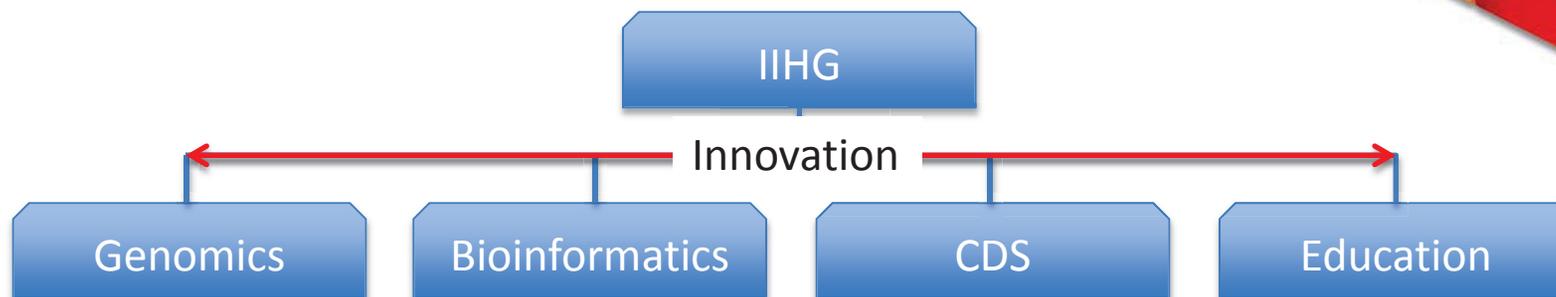
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IIHG

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Bioinformatics

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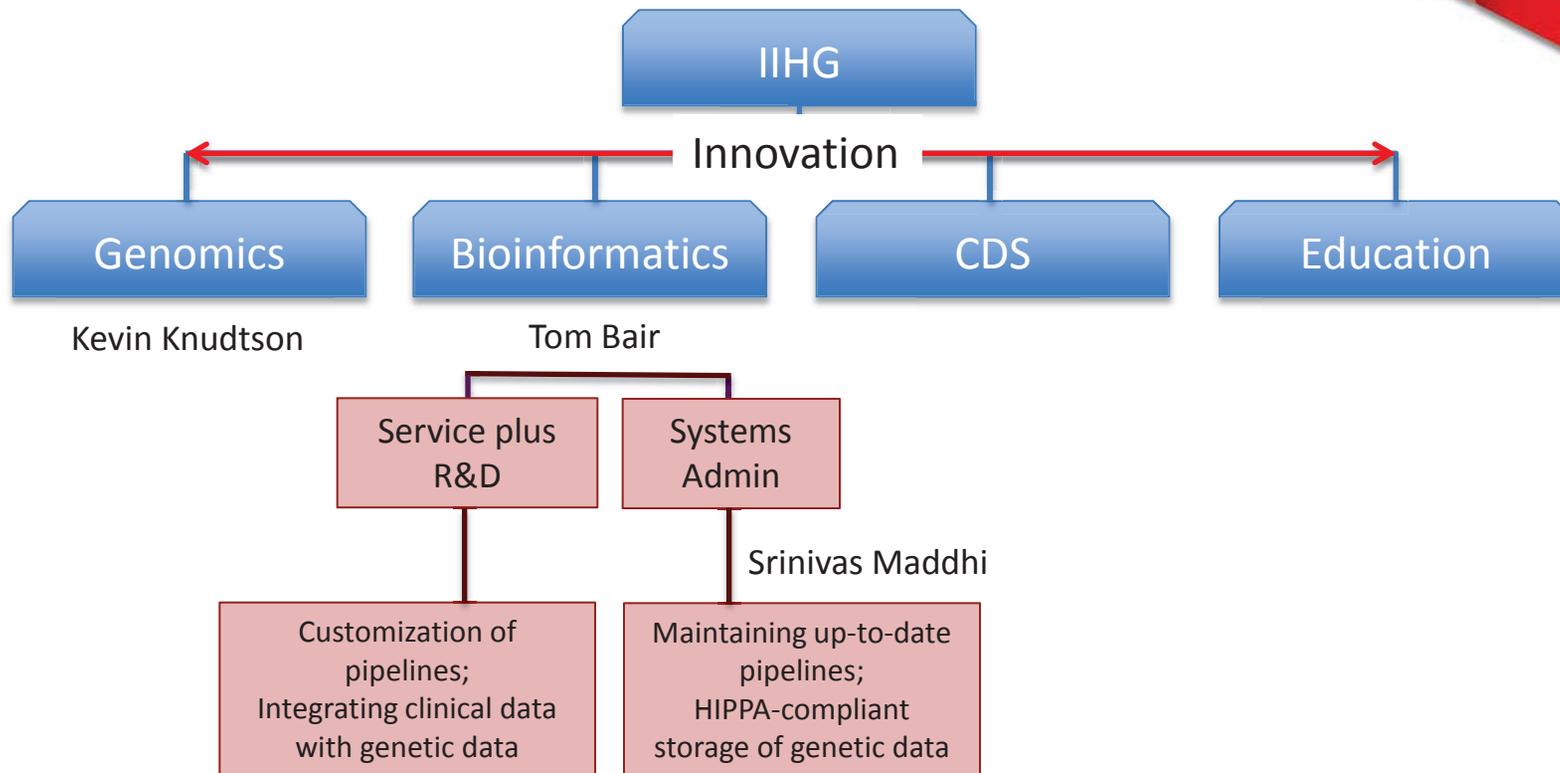
Kevin Knudtson

NGS Pipelines

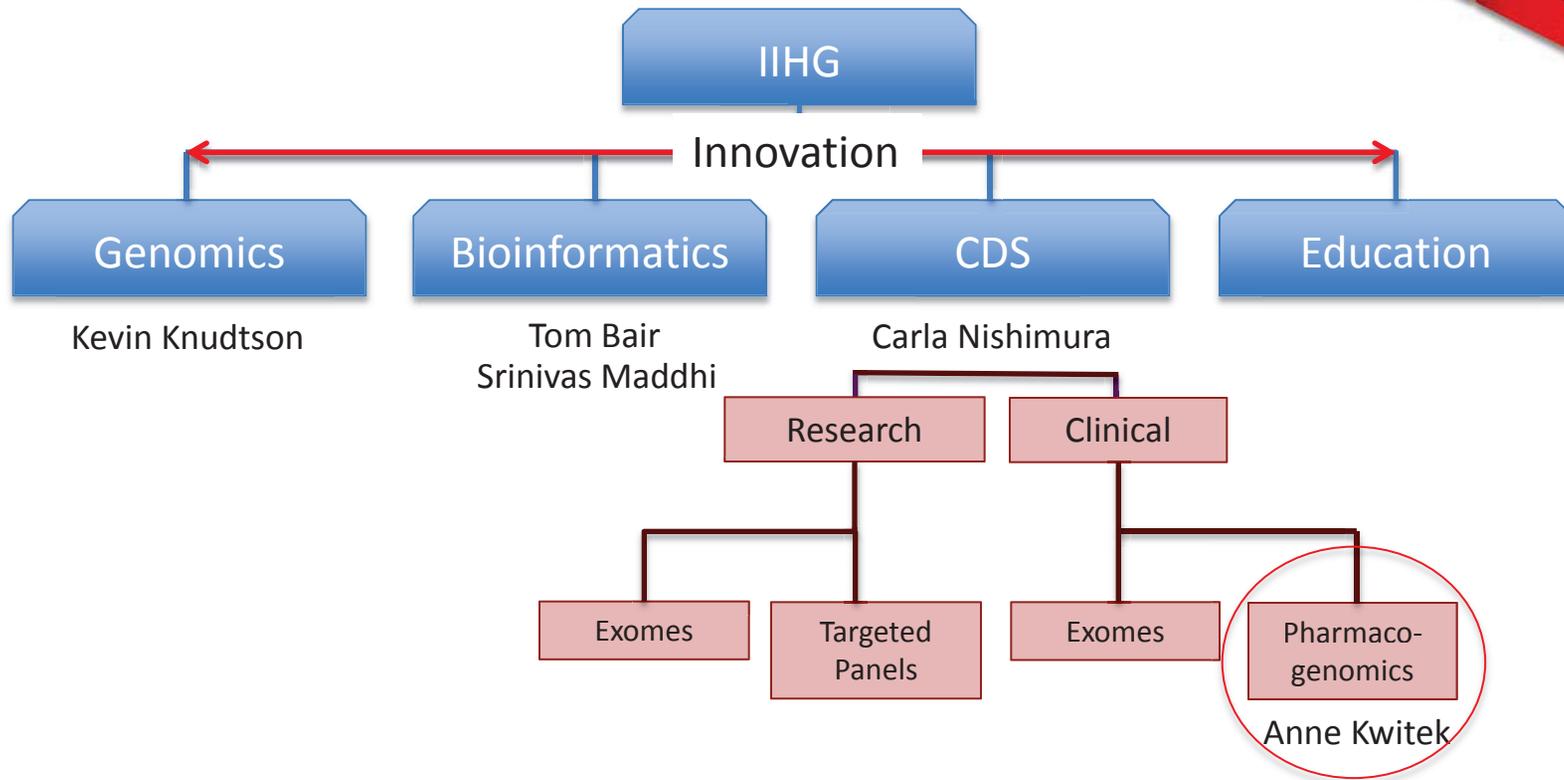
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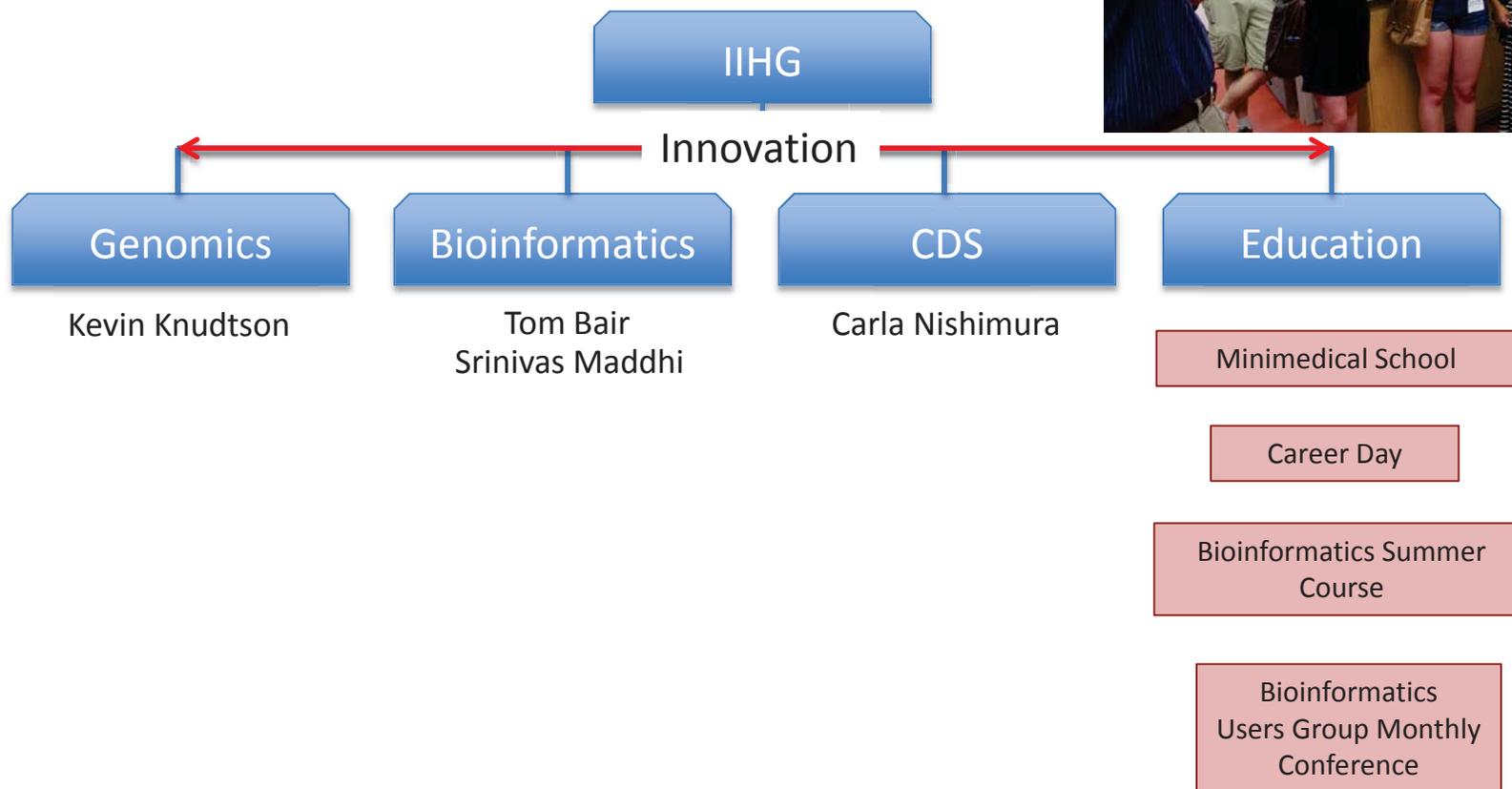


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Today's Goals



Pharmacogenomics (PGx)

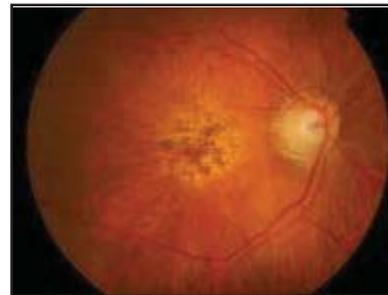
- a) Define personalized (precision) genomic medicine
- b) Demonstrate the need for PGx
- c) Review where we are at UIHC
- d) Why is it important to lowans?

What is Personalized Genomic Medicine?

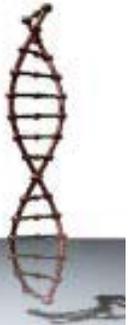


1. Personalized - risks are uniquely yours
2. Predictive - of the risks you have for specific disorders
3. Preventive – if you address exposures / behaviors with targeted intervention/screening to change outcomes
4. Participatory – requires your participation

- AMD affects one-third of adults over the age of 75
- Exercise, low fat diet, sun glasses, and eat plenty of fruits and nuts



Pharmacogenomics.....The Need



1. Over the past month, how many of us took 1 prescription drug?
...3 or more? ...5 or more?

FASTSTATS - Therapeutic Drug Use

http://www.cdc.gov/nchs/faststats/drugs.htm percent of drugs NOT effective

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FastStats

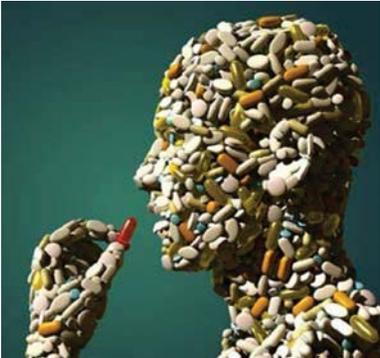
FastStats Homepage
State and Territorial Data

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Therapeutic Drug Use

(Data are for the U.S.)



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Hyattsville, MD
 1 (800) 232-4635
 cdcinfo@cdc.gov

- Percent of persons using at least one prescription drug in the past month: 47.9% (2005-2008)
- Percent of persons using three or more prescription drugs in the past month: 21.4% (2005-2008)
- Percent of persons using five or more prescription drugs in the past month: 10.5% (2005-2008)

Source: [Health, United States, 2011, table 99](#) [PDF - 9.8 MB]

Pharmacogenomics.....The Need



Search



Genetics and your health

Personalized medicine and you

Our research in action

Support the Laboratory

Personalized medicine and you

What is personalized medicine?

Benefits of personalized medicine

Current applications of personalized medicine

Societal impact

Related technology

The benefits of personalized medicine

Throughout history, the practice of medicine has largely been reactive. Even today, we have to wait until the onset of diseases and then try to treat or cure them. And because we don't fully understand the genetic and environmental factors that cause major diseases such as cancer, Alzheimer's and diabetes, our efforts to treat them are often imprecise, unpredictable and ineffective.

In addition, the drugs and treatments we devise are tested on broad populations and are prescribed using statistical averages. For example, on average, any given prescription drug now on the market only works for half of those who take it. Among cancer patients, the rate of ineffectiveness jumps to 75 percent. Anti-depressants are effective in only 62 percent of those who take them.

Personalized medicine is beginning to transform the practice of medicine. It is allowing health care providers to:

- Shift the emphasis in medicine from reaction to prevention



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Cancer research



Why?

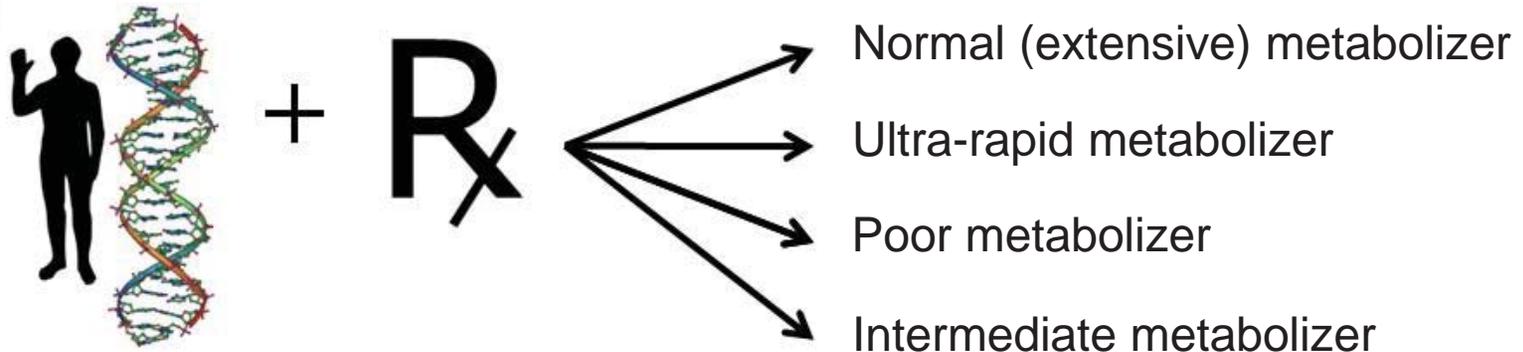
an ovarian cancer survivor. We're profiling people who personify the diverse and complex nature of cancer.

[Read Cheryl's story >](#)

Pharmacogenomics.....The Need

The facts

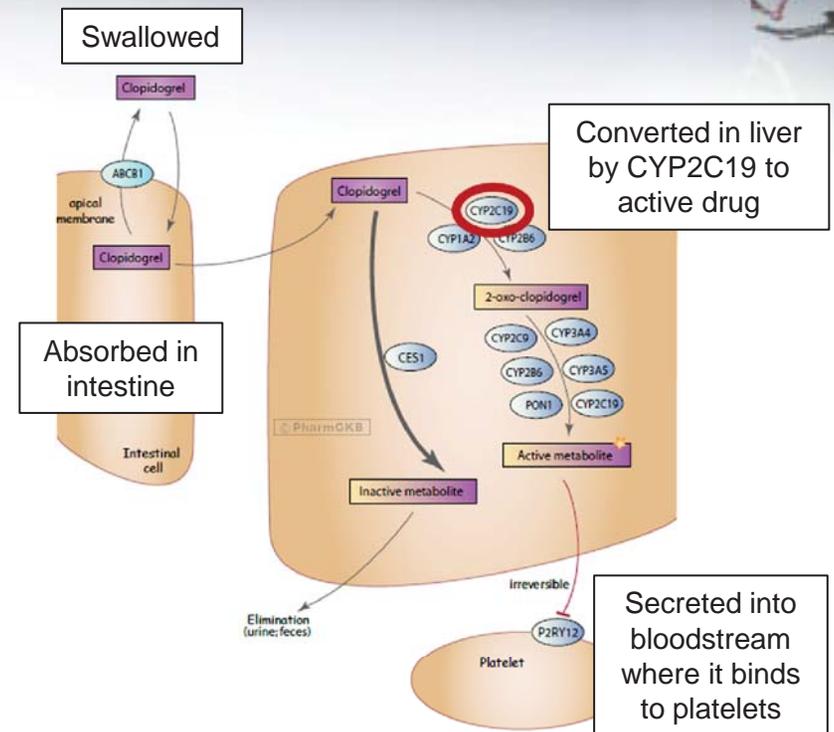
- Today, your medication dose is typically adjusted based only on your weight or body-surface area
- Your medication is NOT adjusted based on your genetics
 - Genetic variations can influence your response to a drug
 - PGx testing is used to link genetic variation to drug response



PGx – Where we are at UIHC...

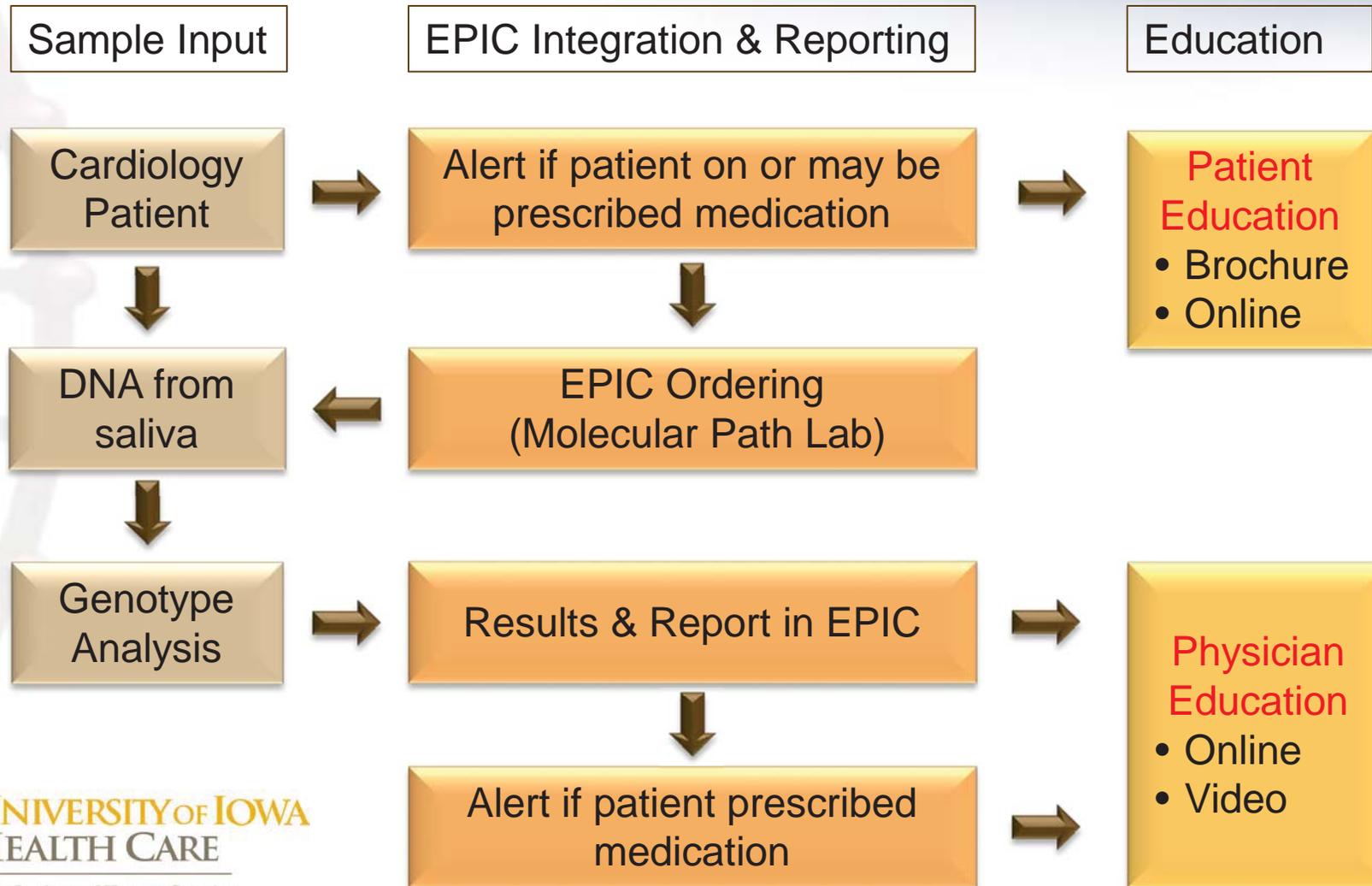


- Clopidogrel (Plavix®) at UIHC
 - Millions of Americans take Clopidogrel (Plavix®)
 - It is a blood thinner that helps to prevent stroke and heart attacks
 - It was the 3rd most commonly prescribed drug in 2010
- Up to 30% of people can be resistant to Clopidogrel
 - These persons are called ‘poor’ or ‘intermediate’ metabolizers
 - Variations in the *CYP2C19* gene affect how a person metabolizes and responds to Clopidogrel



CYP2C19 Genetic Types	Clopidogrel Metabolizer Status
*1/*1 (normal)	extensive metabolizer
*1/*17	ultrarapid metabolizer
*17/*17	ultrarapid metabolizer
*1/*2-8	intermediate metabolizer
*2-8/*2-8	poor metabolizer

PGx – Where we are at UIHC...



PGx – Where we are at UIHC...



Sample Input

Cardiology
Patient



DNA from
saliva



Genotype
Analysis

genetics_newsarticle.aspx?id=22468

Iow...



The Iowa Institute of Human Genetics (IIHG) offers pharmacogenomic testing for clopidogrel (Plavix®) response.

If you have ever taken prescription medications, you may have experienced some unintended effects – perhaps a medicine didn't work as expected or there were harmful side effects. You are not alone. Drugs do not work in up to half of people due to their genetic make-up.

Pharmacogenomics (PGx) testing is done to determine a person's genetic makeup affecting his or her response to a particular drug or class of drugs. This information makes precision medicine possible so that your healthcare provider can 'personalize' your optimal drug treatment.

Clopidogrel (Plavix®), for example, is commonly prescribed as a blood thinner to prevent heart attacks and stroke. Clopidogrel does not work properly in about 30% of patients, due to four common DNA changes in the gene *CYP2C19*.

The IIHG offers a simple test for these DNA variations so you can learn if clopidogrel will work for you or your patient. For more information on this test, please visit our websites for health care providers (<http://www.medicine.uiowa.edu/humangenetics/cyp2c19/>) and for patients (<http://www.medicine.uiowa.edu/humangenetics/CYP2C19/Patients/>).

Education

**Patient
Education**

- Brochure
- Online

**Physician
Education**

- Online
- Video

PGx - Why it is important to lowans?



- Provides lowans with better and more precise medical care
- Provides lowans with more economic medical care
- Reaching these goals is challenging
 - Must be responsive to the needs of health care providers
 - Must provide real-time education
 - Must justify changes in diagnostic and treatment paradigms
- CYP2C19 is a simple first step
 - Pre-emptive testing should be the goal
 - Offer to all patients at UIHC through EPIC
 - New PGx tests must be developed
 - Based on healthcare provider surveys
 - CYP2D6/codeine in progress

How Good is the IIHG?



An International Competition

Teams from the United States (including the NIH), Canada, China, India, Israel, Italy, Germany, the Netherlands, Singapore, Slovenia, Spain, Switzerland and Sweden

childrenshospital.org/gene-partnership-contest/about-the-clarity-challenge/ RSS ↻ 🔍 The Clarity Challenge

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- Challenge Design and History
- Team
- Why Boston Children's?
- CLARITY in the News

FAMILIES AND RESULTS

- MEET THE CONTESTANTS
- PRESS MATERIALS
- THE RESEARCH CONNECTION
- ADDITIONAL

About the CLARITY Challenge

The CLARITY Challenge (**C**hildren's **L**eadership **A**ward for the **R**eliable **I**nterpretation and appropriate **T**ransmission of **Y**our genomic information) is a contest initiated by Boston Children's Hospital. Its goal is to identify best methods and practices for the analysis, interpretation and reporting of individuals' DNA sequence data, to provide the most meaningful results to clinicians, patients and families.

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IHG – one of two runners-up



The competition—CLARITY stands for **Children's Leadership Award for the Reliable Interpretation and appropriate Transmission of Your genomic information**—was conceived by Isaac Kohane, David Margulies, and Alan Beggs at Boston Children's Hospital/Harvard Medical School. 30 teams from academia and industry initially entered the competition, although seven withdrew before the final phase.



Adam and Sarah Foye

The winning team—led by Shamil Sunyaev and assisted by investigators including Heidi Rehm (Harvard Partners), Daniel MacArthur (Mass General Hospital) and Mike Murray (Brigham)—receives the top prize of \$15,000. Two teams were named co-runners up and win \$5,000 apiece: the University of Iowa and a German team consisting of researchers from Genomatix, CeGaT (Tübingen) and the Institute of Pathology at University Hospital of Bonn.

The competition was launched in January 2012 and sponsored by Life Technologies and Complete Genomics, which also sequenced the genomes of the three patients and their parents. The results were announced at a press conference at the American Society of Human Genetics (ASHG) conference taking place in San Francisco this week.

Entries from the 23 registered teams were reviewed by a panel of judges chaired by Duke University geneticist Huntington Willard. The panel decided that the Brigham and Women's entry featured the best combination of bioinformatics analysis and utility of its clinical reports for the three families, as well as the correct identification of the genetic basis for the Foye family's disorder. The task of not only accurately interpreting the genetic basis of inherited diseases and cancer but also communicating those results in a medically meaningful and accessible way is considered a huge bottleneck towards the successful implementation of genomic medicine.

Of the two runners-up, the Genomatix team was considered to be the only group to correctly identify the putative mutation in all three families. The Iowa team drew credit for its approach to returning unexpected genetic results based on patient preferences and indicating regions of low confidence or coverage.

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live webinar:

Using CDISC
ODM to
streamline
study design
migration
between

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It takes a team



Ways to go

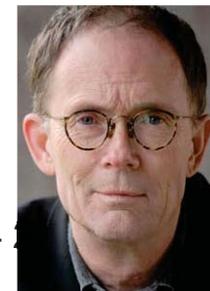


A Statewide Resource

Personalized Genomic Medicine = Precision in Medical Care

'The future is already here – it is just unevenly distributed.' *The Economist*, Dec 4

William Gibson



THANK YOU!

Explanation of Proposed Amendments to the Bylaws of the UIHC and Its Clinical Staff

In early 2013, the CEO and the Chief of Staff charged a task force to review the Subcommittees of the University Hospital Advisory Committee (UHAC) and make recommendations concerning the subcommittees and their charges. These amendments incorporate the recommendations of that task force, as approved by the UHAC.

The task force recommended the elimination of one subcommittee (Subcommittee on Scientific and Moral Aspects Concerning Death) because its responsibilities had previously been reassigned to the Department of Neurology. It also recommended the creation of a new Compliance Subcommittee to raise the awareness of the increasing importance of compliance activities in healthcare. The charges of several other subcommittees were modified to reflect current terminology and responsibilities.

The task force also made recommendations concerning the structure of all subcommittees designed to promote a stronger subcommittee structure and more active participation by subcommittee members.

This amendment also includes modifications of the process for assuring the technical and professional competence of new members of the Clinical Staff, primarily by increasing the responsibility of the existing clinical staff members assigned as proctors for new staff.

Finally, statutory references were updated to reflect changes that have been made to the Code of Iowa since the last revision of the Bylaws.

1. Article I, first paragraph, is amended to read as follows:

The UIHC is a major teaching hospital whose existence is predicated upon the provisions contained in Chapters 225, ~~255~~ ~~and 262,~~ and 263 of the Code of Iowa (See ~~Appendix I~~Appendices II-V). The UIHC, in compliance with the Code of Iowa, serves as the teaching hospital and comprehensive health care center for the State of Iowa, thereby promoting the health of the citizens of Iowa, regardless of their ability to pay. The UIHC, in concert with the University of Iowa health science colleges, functions in support of health care professionals and organizations in Iowa and other states by: 1) offering a broad spectrum of clinical services to all patients cared for within the UIHC and through its outreach programs; 2) serving as the primary teaching hospital for the University; and, 3) providing a base for innovative research to improve health care.

2. Article III, Section 5, is amended to read as follows:

Section 5: Subcommittees

A. Structure

Subcommittees shall be either standing or ad hoc. All subcommittee chairpersons and members, except Credentials Subcommittee members and the Chair of the Professional Practice Subcommittee, shall be appointed by the Chairperson of the Hospital Advisory Committee, in conjunction with the Vice-Chairperson, subject to approval by the Hospital Advisory Committee membership. Membership of a subcommittee may consist of Clinical Staff members, hospital administrative staff members, and other professional staff of the hospital as designated by the Chairperson, in conjunction with the Vice-Chairperson, except that the Credentials Subcommittee shall have the composition specified in the second paragraph of this subsection. Appointments to standing committees shall

be ~~for an indefinite period subject to the discretion of the staff member and~~ made by the Chairperson of the Hospital Advisory Committee, in conjunction with the Vice-Chairperson, with the concurrence of the Hospital Advisory Committee membership.

Subcommittee chairs shall be appointed to five year renewable terms unless their appointment is associated with a specific administrative office or leadership position they hold within the UIHC.

Subcommittee members shall be appointed to three year renewable terms if the positions they occupy are not assigned by the Head of the Clinical Service, associated with a specific administrative, management or supervisory position or other UIHC sponsored positions.

The Credentials Subcommittee shall be composed of one Active Clinical Staff member for each Clinical Service, designated by the Head of the Clinical Service. Clinical Service Heads and members of the Hospital Advisory Committee shall not be members. The members of the Credentials Subcommittee shall be divided into Medical and Surgical Credentials Panels as follows: Medical -- Dermatology, Emergency Medicine, Family Medicine, Internal Medicine, Neurology, Pathology, Pediatrics, Psychiatry, Radiation Oncology, and Radiology; and Surgical - - Anesthesia, Dentistry, Neurosurgery, Obstetrics-Gynecology, Ophthalmology and Visual Sciences, Orthopaedics and Rehabilitation, Otolaryngology—Head and Neck Surgery, Surgery and Urology. The Chairpersons of each Panel shall be selected from among the voting membership of the Panel by the Chairperson of the Hospital Advisory Committee, in conjunction with the Vice-Chairperson. Each Panel shall also include a member of the hospital administrative staff ex officio, without vote.

Two subpanels, the physician assistant/advanced registered nurse practitioner (PA/ARNP) subpanel and the health care professional subpanel, shall report jointly to the Medical and Surgical Credentials Panels. The PA/ARNP

subpanel shall be composed of two physician assistants, two advanced registered nurse practitioners, one physician supervising the practice of a PA, one physician with a collaborative agreement with an ARNP, and a Chairperson selected by the Chairperson of the Professional Practice Subcommittee. Members of the PA/ARNP subpanel shall be appointed by the Chairperson of the Professional Practice Subcommittee, upon recommendations from the Clinical Services Heads in which physician assistants and advanced nurse practitioners practice. The PA/ARNP subpanel will be representative of the Clinical Services in which physician assistants and advanced registered nurse practitioners practice.

The health care professional subpanel shall be composed of four health care professionals, representative of the Clinical Services in which health care professionals practice, two physicians, and a Chairperson selected by the Chairperson of the Professional Practice Subcommittee. Members of the health care professional subpanel will be selected by the Chairperson of the Professional Practice Subcommittee, upon recommendations from the Clinical Service Heads in which health care professionals practice. Subpanel membership will be representative of these Clinical Services.

Each subpanel shall also include a member of the hospital administrative staff ex officio, without vote.

The Vice-Chairperson of the Hospital Advisory Committee shall be the Chair of the Professional Practice Subcommittee.

Standing subcommittees shall meet at least annually. Minutes shall be kept of such meetings that shall include a listing of the members in attendance. Any member who misses two consecutive meetings without an excuse approved by the Chairperson of the subcommittee shall be notified that a third consecutive unexcused absence shall be deemed a resignation from the subcommittee. Upon a third consecutive unexcused absence, the

Chairperson shall notify the member and the Chairperson of the University Hospital Advisory Committee that the member's position is vacant and a new member shall be appointed by the Chairperson of the Hospital Advisory Committee subject to approval by the Hospital Advisory Committee membership.

B. Standing Subcommittee Charges

Standing subcommittees and their respective charges are as follows:

1. Professional Practice Subcommittee

To ensure that patient care delivered by the clinical staff of the UIHC is at a quality assured level and consistent with professionally recognized standards of care. In carrying out this charge, the Professional Practice Subcommittee will transmit its reports and recommendations to the University Hospital Advisory Committee for review and action. On infrequent occasion, the very nature of a matter under consideration may dictate the direct involvement of the Dean of the College of Medicine, Dean of the College of Dentistry and/or the Director of UIHC. Responsibilities of the Professional Practice Subcommittee shall be to:

- a. Coordinate the quality ~~assurance-related~~and performance improvement activities of the subcommittees of the University Hospital Advisory Committee and the ~~medical and dental patient care evaluation~~quality and performance improvement committees of the Clinical Services and hospital departments.

~~b. Assure optimal compliance with applicable accreditation standards and governmental regulatory controls relating to the Clinical Staff.~~

e.b. Review, analyze and evaluate on a continuing basis the performance of the Clinical Service ~~patient care evaluation~~ quality and performance improvement committees in formulating standards of care; measuring outcomes of care; and taking constructive intradepartmental action on the evaluation results, as specified in the UIHC Quality Assurance Performance Improvement Program.

~~d. Serve as a liaison between the UIHC and the Iowa Peer Review Organization (PRO).~~

e.c. Submit recommendations to the University Hospital Advisory Committee on the establishment of and adherence to standards of care for the purpose of improving the quality of patient care delivered in the hospital.

~~f.d.~~ Hear and adjudicate problems of a professional and ethical nature involving the clinical practice of either house staff or clinical staff members.

~~g. Recommend objectives to the University Hospital Advisory Committee for the inclusion in the clinical Staff's continuing medical education programs aimed at enhancing clinical practice patterns for given diagnoses or Clinical Services.~~

~~h.e.~~ Review interdisciplinary or inter-clinical department conflicts with the corollary responsibility for recommending to the University Hospital Advisory Committee policy statements or protocols to remedy such occurrences and otherwise foster harmonious interdepartmental relationships aimed at ensuring quality patient care.

2. Compliance Subcommittee

To provide oversight and guidance for the regulatory audit and compliance activities of UIHC. Ensuring the organization has adopted and implemented policies and procedures that will meet the intent and comply with all applicable laws, rules, regulations and policies. The Subcommittee will:

a. Review and address the activities of the Joint Office for Compliance as it relates to the seven elements of the Federal Compliance Program Guidance (1998 and 2005) including: Designation of a Compliance Officer; Development of Compliance Policies and Procedures; Developing Open Lines of Communication; Provision of Appropriate Training and Education; Internal Regulatory Monitoring and Auditing; Response to Detected Deficiencies; and Enforcement of Disciplinary Standards.

b. Annually review the "Code of Ethical Behavior, a Guide for Staff" to assure it addresses all applicable

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federal, state and local laws, regulations and other compliance requirements.

2-3. Credentials Subcommittee

To review the credentials of all applicants for initial or increased clinical privileges and of members, or other practitioners as described in Article IV, Section 4, Part F, for whom there is a request for decreased privileges; to make a recommendation to the Hospital Advisory Committee on each application or request; and to report problems related to clinical practice or professional policy through the Professional Practice Subcommittee to the Hospital Advisory Committee.

3-4. Critical Care Subcommittee

To formulate cross-departmental policies, procedures and programs, identify and seek solutions to current challenges, develop plans for future operations and to enhance the overall utilization and operating efficiency of all UIHC intensive care units so that standards of patient care may be maintained at the highest level. The Subcommittee will also oversee the hospital-wide system for management of acute cardiopulmonary resuscitation emergencies and advise the Director of the Respiratory Care Department on policy formulation, establishment of patient care and didactic instruction programs, and on the provision of effective and efficient respiratory care services.

4-5. Diagnostic Services Advisory Subcommittee

To provide the clinical staff and the Hospital's administration with information and advice concerning the quality, availability, and proper use of clinical laboratory and imaging services.

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- a. To assist in formulating operational policies designed to assure the most expeditious performance of diagnostic services for patients in all clinical departments in accord with available resources.
- b. To advise and make recommendations regarding optimal provision and utilization of clinical laboratory and imaging services for patients coordinate with cost considerations and market forces extant within the health care industry and in accord with the patient care, educational and research missions of UIHC.
- c. In accord with these recommendations and other pertinent factors including regulatory provisions and accreditation standards, review and provide recommendations on additions to and deletions from UIHC publications and documents on diagnostic services such as the Pathology Department, Laboratory Services Handbook.

5-6. Emergency Management Subcommittee

The Emergency Management Subcommittee organizes, conducts and updates an all hazards emergency management program to assure that the UIHC is prepared to deal effectively with all disaster situations and the treatment of mass casualties which may result therefrom. In addition, the Subcommittee:

- a. Conducts a Hazard Vulnerability Analysis (HVA) on an annual basis.
- b. Maintains a written Emergency Operations Plan which features a Hospital Incident Command System (HICS) for organizing the UIHC's response to all hazards and standard operating procedures to address the hazards identified.

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- c. Arranges at least twice yearly exercises of the Emergency Operations Plan.
- d. Provides continuity of operations plans to guide the UIHC's maintenance and restoration of essential services.
- e. Ensures that all staff with HICS assignments and other staff designated for responding to disasters and major emergencies receive training in accord with UIHC requirements and regulatory guidelines and understand their role(s) and responsibilities for responding to various disasters and emergencies.
- f. Maintains relationships and participates in County, State and Federal programs related to emergency management.
- g. Assures that UIHC meets the Emergency Management Standards of the Joint Commission and CMS Conditions of Participation in Medicare and Medicaid programs and follows the National Incident Management System (NIMS) and HICS as standardized organizational and operational structures for meeting the demands of major emergencies and disasters.

6-7. Environment of Care Subcommittee

To establish, implement and maintain the UIHC Environment of Care Program, in accordance with the requirements of the Joint Commission on Accreditation of Healthcare Organizations and applicable state and federal laws. The Subcommittee develops and/or approves recommendations and interventions to protect the well-being of patients, visitors and staff in the areas of fire protection, safety, hazardous materials and waste, medical equipment, utilities and security.

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7-8. Ethical Issues Ethics Subcommittee

To formulate operational and educational policies, procedures and programs regarding the ethical aspects of patient care. In fulfilling this charge, the Subcommittee shall:

- a. Develop and carry out educational programs that will enhance awareness and understanding of biomedical ethical issues for clinical and hospital staff, undergraduate and graduate trainees, patients and their families.
- b. Propose policies and guidelines regarding the ethical aspects of medical, surgical and dental practice for approval by the Professional Practice Subcommittee and the University Hospital Advisory Committee.
- c. Provide consultation on ethical issues to other members of the UIHC Clinical Staff, House Staff and Professional Staff.

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8. 9 Graduate Medical Education Committee

In general, to advise on all matters pertaining to the house staff training programs at UIHC, including, but not limited to the following:

- a. To assist in the recruitment, orientation, and scheduling of house staff physicians and dentists;
- b. to conduct periodic reviews of all UIHC residency programs in accordance with Accreditation Council for Graduate Medical Education guidelines;

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- c. to provide a forum for house staff problems as expressed by the house staff representatives on the Subcommittee or by other house staff;
- d. to help develop policies in response to external mandates to alter the number or make-up of house staff physicians and dentists at UIHC; and
- e. to recommend candidates for Patient Care Enrichment Fund support.

9-10. Health Information Management Subcommittee

To review, analyze and evaluate the medical records system to assure that the form and written content thereof satisfy prevailing accreditation standards, legal precedents, hospital policy, and reimbursement protocols. In collaboration with the Hospital Information Systems Advisory Subcommittee, provide advice on the development of policy pertaining to clinical information systems and propose innovations with which to enhance their efficiency and effectiveness. The responsibilities of the Health Information Management Subcommittee shall be to:

- a. Review, analyze and evaluate the quality of medical records in the hospital.
- b. Submit recommendations to assure the maintenance of complete, accurate medical records for compliance with applicable policies and regulations of the Professional Practice Subcommittee, governmental agencies, accrediting bodies, and purchasers of care.
- c. Review all medical record forms and make appropriate recommendations for their improvement.

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- d. Review existing policies, rules and regulations for the completion of medical records, and make appropriate recommendations for their improvement.
- e. Review procedures for safeguarding medical records against loss, defacement, tampering, or use by unauthorized persons, and make appropriate recommendations for their improvement.

10.11. Hospital Information Systems Advisory Subcommittee

The Hospital Information System Advisory Subcommittee is charged with broad responsibility for the ongoing development of the Hospital Information System at the University of Iowa Hospitals and Clinics (UIHC). Specific functions include:

- a. Review strategic planning for application system development.
- b. Evaluate the appropriateness of security and backup procedures for hospital data in all settings, including the exchange of data with other computers.
- c. Review for consistency the strategic plans of UIHC projects which have incremental computing equipment implications and/or an impact on patient and management data maintained on the Hospital Information System.
- d. Authorize the use of computer generated electronic signature facilities for patient reports or other administrative functions within UIHC on an application by application basis.
- e. Review the use of computers in UIHC administrative and patient care settings with particular regard to appropriateness of application, security of patient information, and system maintenance.

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- f. Monitor system processes to ensure compliance with regulatory guidelines for safeguarding patient data security.

Following review of project and equipment requests, the Subcommittee will forward recommendations to the Director of the University of Iowa Hospitals and Clinics.

41. 12 Infection Control Subcommittee

~~To define, survey, correlate, review, evaluate, revise and institute any recommendations necessary for the prevention, containment, and investigation of environmental and infectious disease problems in the UIHC. review infection data, policies, procedures and processes. To revise policies and procedures, and recommend changes in procedures and practices. To recommend interventions to prevent infections in the UIHC and its associated clinics.~~

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42. 13 Pharmacy and Therapeutics Subcommittee

Promote evidence-based, best practice standards in the formulary decision-making process to assure clinical efficacy, patient safety and cost-effective prescribing within UI Health Care. Review policies and procedures related to proper medication administration to assure medications are administered safely and appropriately. Facilitate education of healthcare providers and students regarding medication-related issues. Assure that medications are prescribed appropriately, safely and effectively through medication use evaluation processes. Assure compliance with JCAHO, FDA and other regulatory guidelines related to medication use. Review and support investigational medication studies to ensure patient safety and adherence to UI Health Care policies. Evaluate and assess point-of-care and other technology systems and

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processes to effectuate safe, prompt and efficient prescribing in both the inpatient and ambulatory care settings.

13.14. Product Line Oversight and Analysis Subcommittee

Review and resolve product selection/purchasing issues referred from UHAC Subcommittees, committees addressing standardization and supply chain issues and the Value Analysis Program. In carrying out this charge, the Subcommittee will:

- Make ultimate decisions on all product selections, standardizations and purchases which increase expenses without an off-setting reduction in other expenses and/or in which decisions were not reached by subcommittees/committees.
- Include liaison members in its membership so that decisions on matters originally addressed by subcommittees/committees will be made by the Ad Hoc Product Line Oversight and Analysis Subcommittee members and two liaison members – the Head of Department seeking approval and Chair of subcommittee/committee that originally considered the request.
- Assure that faculty/staff seeking product approval, will have ample opportunity to present their proposal and address questions.
- Accord each member/liaison member one vote and make decisions based on a simple majority of all member votes.

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- Serve as the forum for the Value Analysis Facilitator and UHC consultants to present benchmark data for identifying potential savings opportunities and proposed goals and tactics.
- Meet/communicate with leaders of subcommittees/committees on potential savings opportunities and proposed goals and tactics.

14.15. Subcommittee on Protection of Persons

To assure compliance with provisions in the Code of Iowa, accrediting and regulatory bodies to protect abused or neglected or potentially abused or neglected children and dependent adults and victims of domestic violence, the Subcommittee will recommend and monitor consistent application of policies and procedures to identify, treat and as permitted or required by law report cases of suspected child or dependent adult abuse or domestic violence.

~~15. Subcommittee on Scientific and Moral Aspects Concerning Death~~

~~To review the criteria and procedure for declaring the state of cerebral death and to recommend necessary changes in the determination of the diagnosis of cerebral death.~~

16. Surgical Services Subcommittee

To review, deliberate, resolve, and, where indicated, formulate recommendations relative to all appropriate operational elements of the several surgical services with special emphasis upon the operating room suite.

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17. Transfusion Subcommittee

To review the records of transfusions of blood and blood components so as to assess transfusion reactions, to evaluate blood utilization, and to make recommendations regarding specific improvements in the transfusion service program.

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18. Utilization Management Subcommittee

To promote the ~~most~~ efficient use of hospital facilities and services ~~by inpatients and outpatients~~, including coordination ~~of the ongoing conduct~~ of admission and continued stay reviews. ~~To and to~~ formulate, ~~recommend~~, maintain and ~~periodically~~ review a ~~written~~ utilization review plan appropriate for the hospital and consistent with applicable federal requirements. ~~With the assistance of the program of Clinical Outcomes and Resource Management (CORM), to conduct and monitor special utilization studies, on its own initiative or as requested by the Professional Practice Subcommittee or the University Hospital Advisory Committee.~~ ~~To report and make recommendations to the Professional Practice Subcommittee concerning changes in clinical practice patterns in order to comply with applicable regulations or hospital policy or to improve the utilization of the hospital facilities and services.~~ ~~To advise the program of Clinical Outcomes and Resource Management on its activities related to clinical resource utilization, including coordination and implementation of UIHC participation in clinical consortia activities such as clinical benchmarking studies.~~ ~~The Transfusion, Diagnostic Services, and Pharmacy and Therapeutics Subcommittees will have ex officio representation.~~ This plan will:

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- 1) Describe hospital activities to ensure that services provided to patients are medically necessary and at the appropriate level of care;

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2) Monitor utilization activities and outcomes;

3) Minimize reimbursement penalties and physician sanctions through screening and appropriate documentation; and,

4) Centralize communication with external review agencies (ERA's), including the Quality Improvement Organization (QIO).

The Transfusion, Diagnostic Services, and Pharmacy and Therapeutics Subcommittees will have ex officio representation.

C. Ad Hoc Subcommittees

Ad hoc subcommittees shall be appointed by the Chairperson to study particular problems in response to the recommendations of the University Hospital Advisory Committee. Subcommittee membership shall be constituted in relationship to the particular problem to be addressed.

3. Article IV, Section 5(B), is amended to read as follows:

B. Provisional Status

All initial clinical privileges shall be provisional for the first ~~three~~ six months. The Head of the Clinical Service in which clinical privileges are granted shall designate one or more members of the active clinical staff to ~~observe~~ proctor the individual's clinical competence and professional ethical conduct for that time period. ~~The clinical privileges shall automatically cease to be provisional at the end of the three months, unless the designated staff member submits a written report to the Head and the individual recommending otherwise.~~ The clinical privileges

shall cease to be provisional at the end of the six months, following a written report from the proctor to the Clinical Service Head verifying the individual's clinical competence and professional/ethical behavior. The Clinical Service Head shall forward the report to the Chairperson of the appropriate Credentials Panel recommending termination of the provisional status. If necessary, the proctor shall submit a written report to the Clinical Service Head recommending additional reviews. If such a report is submitted, the Head, after consultation with the individual and the Chairperson of the appropriate Credentials Panel, shall take appropriate action. ~~_, which may include~~ This includes (1) extending the provisional status or (2) recommending modification in the individual's clinical privileges. The total period of provisional status may not exceed one year. If modification, including termination, of clinical privileges is recommended, the recommendation shall be handled as provided in Section 6.

4. Article IV, Section 5(C), first paragraph, is amended to read as follows:

C. Biennial Review of Clinical Privileges

Biennially, the Head of each Clinical Service shall review the clinical privileges and the physical and mental condition of all members and practitioners who hold clinical privileges in that Clinical Service and forward a recommendation to the applicable Credentials Panel, along with the supporting documentation which should include the results of Ongoing Professional Practice Evaluations and, if applicable, Focused Professional Practice Evaluations. The review of clinical privileges and the physical and mental condition of the Clinical Service Heads shall be conducted by an ad hoc review committee composed of three members of the Active Clinical Staff who have the rank of professor and who are selected by the Chairperson of the applicable Credentials Panel. The review shall be documented and the recommendation forwarded to the applicable Credentials Panel, along with the supporting documentation.

5. Article V, Sections 1 and 2, are amended to read as follows:

Section 1: ~~Quality Assurance~~Performance Improvement Program

The University Hospital Advisory Committee shall adopt, annually review, and, as necessary, revise a Quality Performance Improvement Program to evaluate the quality of professional services and to take appropriate actions based on those evaluations. The ~~Quality Assurance~~Performance Improvement Program shall include the Clinical Service ~~patient care evaluation~~quality and performance improvement committees, the Professional Practice Subcommittee, the University Hospital Advisory Committee, and other committees designated by the University Hospital Advisory Committee.

Section 2: Medical and Dental Audit

Each Clinical Service shall have a Medical or Dental ~~Patient Care Evaluation~~Quality and Performance Improvement Committee which shall be appointed by the Clinical Service Head and be a subcommittee of the Professional Practice Subcommittee. The Committee shall measure the extent to which patient care delivered in the Clinical Service satisfies standards of care formulated pursuant to the ~~Quality Assurance~~Performance Improvement Program and take constructive intradepartmental action on the evaluation results.

How does genetic testing work?

Iowa Institute of Human Genetics



UNIVERSITY OF IOWA
HEALTH CARE

Iowa Institute of Human Genetics

What is a genetic test?

A genetic test looks at your DNA to find changes (variants) that cause disease or put you at greater risk to develop disease. DNA is the code our bodies use to make genes, and genes are the instructions for our bodies.

In the past, it was possible to screen, or test, only one gene at a time to try to find the cause of a disease. This method is still used for many diseases, but it can be costly and time consuming. It is now possible to screen thousands of genes at once.

Why would I have a genetic test?

A genetic test can help you and your doctor:

- Find the cause of your disease or symptoms
- See if you are at risk to develop a disease in the future
- Tell you if you could pass a disease on to your children
- Choose the best treatment for you
- Provide better counseling for you

It is always your choice if you want to have genetic testing or screening.

What are different types of genetic tests?

- **Clinical genetic tests:** These are tests ordered by your doctor and done in a certified lab. Results of a clinical genetic test become part of your medical record.
 - **Diagnostic test:** to find the cause of a disease or symptoms you already have
 - **Presymptomatic test:** before you have symptoms, to find if you are at risk to get a disease in the future
 - **Carrier test:** to find DNA variants that can cause disease if both parents pass these variants on to their children; carriers usually do not have symptoms of the disease
 - **Prenatal test:** a test during pregnancy to see if the baby will have a disease
 - **Newborn screen:** a test performed one to two days after a baby is born to see if the baby has certain diseases
 - **Pharmacogenomic test:** to find the best medicine and dose for you based on your DNA variants
- **Research genetic test:** You volunteer to participate in a research study, and the results are not put in your medical record.

What is the genetic testing process?



1
Your visit to
the doctor's
office



2
Prepare
your DNA



3
Sequencing
your DNA



4
Analyzing
your DNA



5
Interpreting
your DNA



6
Receiving
your results

How is a genetic test performed?

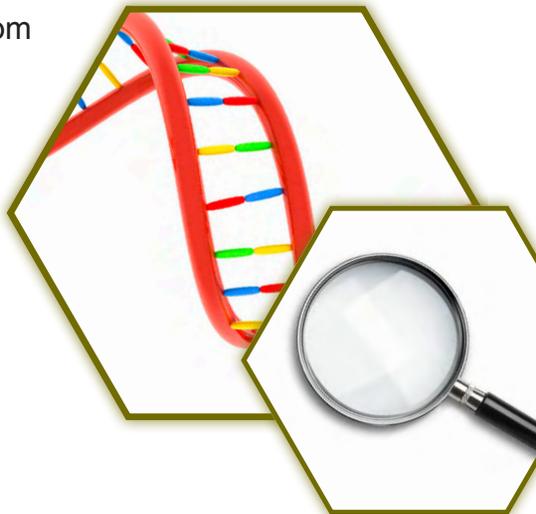
Step 1 – In the doctor's office:

- Your doctor or genetic counselor will talk to you about the test, what it may or may not tell you, insurance coverage, and risks of insurance discrimination.
- You may have to sign a consent form depending on the lab performing the test.
- Your doctor or nurse will get a sample from you. Samples are usually blood samples, but sometimes can be saliva, skin, fluid around the baby during pregnancy, or tumor.
- You may be asked to give another sample if the first sample does not work.
- The sample is sent to the lab.



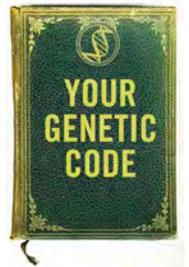
Step 2 – Prepare your DNA

- The lab will get your DNA from the sample to test.
- To find the cause of a disease, the lab can use different ways to look at all or part of your DNA. The way the lab looks at your DNA will depend on the type of genetic test your doctor ordered.



Step 3 – Sequencing your DNA

- Sequencing tests read your DNA and look for variants (changes) in the DNA.
- Sequencing tests can give detailed information about:
 - Specific genes and DNA variants (targeted sequence capture)
 - All of the genes that make proteins in a person (whole exome sequencing)
 - All of the DNA in your genome (whole genome sequencing). The human genome is made of DNA and contains all of a person's genetic information (like a set of books).
- The lab may put all or part of your DNA on a machine called a DNA sequencer.
- The DNA sequencer reads your DNA and collects data known as short "reads." Each "read" represents a very tiny part of your total DNA sequence (each read is like a page in a book).



Step 4 – Analyzing your DNA

- Computers are used to put all of the pieces (reads) of your DNA together (like putting the pages of the book in the right order).
- Computers are used to compare your DNA to all of the DNA in the human body (the human reference genome).



Step 4 – Analyzing your DNA (continued)

- The lab gets a report from the computers, which lists any variants in your DNA.
 - We all have DNA changes (variants)
 - Some DNA variants cause disease (like a word spelled wrong); other variants do not cause disease (like a word with different spellings: grey and gray).
 - We do not know what every DNA variant means at this time.

Step 5 – Interpreting your DNA

- A team of experts talks about and analyzes your results. Doctors, scientists, genetic counselors, and computer experts are all on the team (like a group of people sitting down to read and talk about a book).
- To decide which variant causes the disease you are interested in, the team looks at your results (your list of variants), your symptoms, and your family history.
- The team may or may not be able to find the cause of the disease you are interested in.
- If the team finds the cause of the disease, they confirm the result with a different test.
- Some reasons why the team may not be able to find the cause of the disease can be:
 - Some parts of the DNA cannot be sequenced.
 - Not enough is known about the disease at this time.
 - The test that was performed did not look at the part of your DNA that is causing the disease, and a different test needs to be ordered.
 - The team was not given enough information about your symptoms or family history to interpret the results.



Step 6 – Receiving your results

- The lab will give the written results back to your doctor or genetic counselor. Results of clinical tests will go in your medical record. Research study results do not go in your medical record.
- Your doctor and/or genetic counselor will tell you the results and answer your questions.
- Your doctor may need to perform more medical or genetic testing based on the results of your test.
- The amount of time to get your test results can vary.



Did you know?

Every person has
3 to 4 million
DNA variants.

Helpful Websites

Iowa Institute of Human Genetics (IIHG)

Information for patients, health care providers, researchers, and students on human genetics and personalized genomic medicine

>> www.medicine.uiowa.edu/humangenetics/

National Human Genome Research Institute (NHGRI)

Information on human genetic disease and human genetic disease research, and an explanation of your rights concerning genetic discrimination

>> www.genome.gov

Genetics Home Reference

Information about how genes affect your health: what genes are, how they work, and how they can cause illnesses

>> www.ghr.nlm.nih.gov

Helpful Websites (continued)

Genes in Life

Information about genetics and how it affects you and your family, why you should talk to your health care providers about genetics, how to get involved in genetics research, and more

>> genesinlife.org

Ask for our other booklets about personalized genomic medicine, genetic counseling, exome sequencing, and pharmacogenomics.



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HEALTH CARE

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Goals of the IIHG

- Operate a world-renowned institute of excellence that integrates statewide activities in human genetics
- Provide a high-profile focal point for the vast array of talent in the state of Iowa
- Integrate with the wider university and lay community

The IIHG Vision

- To develop and foster a culture of innovation in human genetics
- To support scientists and health care providers with shared interests in human genetics
- To improve the health of Iowans through personalized genomic medicine
- To provide cutting-edge facilities to support our nationally and internationally recognized human genetics research
- To capture the interest and imagination of the next generation
- To incorporate the four supporting pillars of clinical, education, research and innovation in all initiatives



What is Personalized Genomic Medicine?

Personalized genomic medicine is the tailoring of medical treatment and health decisions based on an individual's genetic makeup. Genes are passed down to us from our parents and are responsible for things such as our height and hair color. They can also cause or predispose us to disease. Personalized Genomic Medicine can be used to:

- Identify the cause of disease
- Identify potential treatment or preventative options
- Predict drug response

Partner with us!

How can we work with you? If you are interested in partnering with the Iowa Institute of Human Genetics, please contact us at iihg@uiowa.edu.

Contact Information

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285 Newton Road | 5296 CBRB
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Web: medicine.uiowa.edu/humangenetics



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The Iowa Institute of Human Genetics



Bringing personalized genomic medicine to Iowans



The Iowa Institute of Human Genetics

Growth in human genetics research is driving the increasing use of genetics in medical practice. The environment of the Iowa Institute of Human Genetics (IIHG) provides unique opportunities to make progress in both the discovery and translational phases of human genetics.

The IIHG is a statewide resource that promotes clinical care, research, and education in human genetics and is focused on bringing personalized genomic medicine to the state of Iowa. The IIHG provides an interface with, and support for, university and statewide activities related to human genetics. The institute was approved by the Iowa Board of Regents in August 2012.

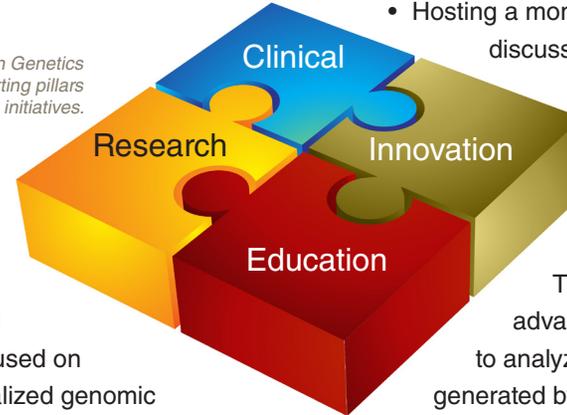


Clinical Diagnostic Division

A major mission of the IIHG is to bring personalized genomic medicine to patients across Iowa and beyond. The Clinical Diagnostic Division:

- Develops genetic tests that target specific diseases or patient groups
- Performs diagnostic genetic testing in a CLIA-certified laboratory
- Collaborates with professionals with broad clinical expertise to interpret test results
- Current initiatives include: pharmacogenomics (the study of how genetics impact an individual's response to medication) and genetic testing for rare diseases

The Iowa Institute of Human Genetics incorporates all four supporting pillars in all of its initiatives.



Education Division

A major mission of the IIHG is to provide to all Iowans informational and educational opportunities focused on the power and promise of personalized genomic medicine. The Education Division:

- Sponsors lectures for the general public, students and professionals
- Speaks about human genetics at schools
- Provides summer internships for college students
 - Develops and provides a variety of resources for researchers, health care providers, students, patients and families



Genomics Division

The IIHG Genomics Division (DNA Facility) provides resources necessary for researchers to carry out state-of-the-art genetics experiments. This broad spectrum of services includes:

- Experiment Consultation
- Massively parallel sequencing
- DNA sequencing and genotyping
- Microarrays
- Real-time PCR amplification
 - Hosting a monthly user interest group to discuss the latest techniques in human genetics research



Bioinformatics Division

The Bioinformatics Division uses advanced computer techniques to analyze and manage data generated by human genetics and diagnostic tests. The division:

- Provides expertise and infrastructure to carry out analysis of complex data sets
- Utilizes a high-performance computing cluster to support rapid data analysis
- Develops and maintains custom analysis pipelines
- Hosts a monthly user interest group
- Hosts a summer course and provides training and resources to interested students and investigators to help them participate in or complete their own analyses



Will my insurance company be able to access this information?

Yes, any information in your medical record can be seen by your insurance company. But, if your test was performed as part of a research study, those research results will not be in your medical record and will not be seen by your insurance company. Your genetic counselor can answer any questions you have regarding insurance companies and genetic information.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects people from genetic discrimination in health insurance and employment. It says you cannot be denied a job or denied health insurance because of your genetic condition. Your genetic counselor will talk to you about exceptions to this law.

Helpful Websites

Iowa Institute of Human Genetics (IIHG)

Information for clinicians, researchers, patients, and students, including research, clinical and educational initiatives, and resources supported by the IIHG

>> www.medicine.uiowa.edu/humangenetics

National Human Genome Research Institute

Information on the Human Genome project, including the latest research, educational materials (for students, teachers, and patients), and an explanation of the Genetic Information Nondiscrimination Act (GINA) and your rights concerning genetic discrimination

>> www.genome.gov

Genetics Home Reference

Information about how genes affect your health: what genes are, how they work, and how they cause disease

>> www.ghr.nlm.nih.gov

Contact

Iowa Institute of Human Genetics, University of Iowa
285 Newton Road, 5296 CBRB, Iowa City, IA 52242
Phone: (319) 335-3688 | Email: iihg@uiowa.edu



Exome Sequencing:

Information for Families



This booklet is for you and your family to read before meeting with a genetic counselor. Your genetic counselor will explain this information to you and answer questions you may have.

What is your exome?

The exome is the part of the genome (all your DNA) that includes all of your exons. Exons are the parts of genes that contain code to build the proteins found in your body. Exons make up about 1 percent of your DNA. Most known disease-causing variants, or DNA changes, are found in the exome.

What is exome sequencing?

In the past it was only possible to screen one gene at a time to find the cause of a disease. This method is still used for many diseases, but it can be costly and time consuming. It is now possible to screen a person's entire exome at once.

Why is my doctor suggesting this test?

Genes are passed down to us from our parents before we are born. Genes have changes (DNA variants) that determine things like our height or hair color. They can also cause disease or increase our risk for disease. By sequencing your DNA, doctors may be able to find a genetic cause for your disease or health condition.

Finding a genetic cause of a disease **may or may not**:

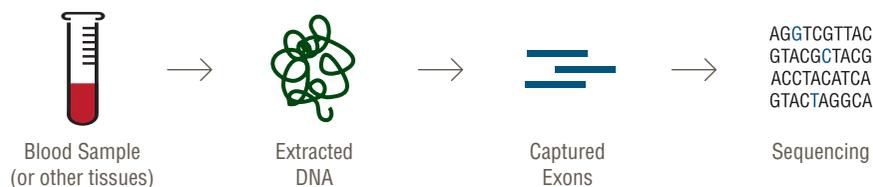
- Tell you the cause for your disease or symptoms
- Help you and your health care provider choose the best treatment for you
- Determine recurrence risks, or the chances that you or your family members will develop a disease

A genetic counselor will talk about the test, possible results, and the meaning of the results with you during the informed consent process.

What will happen to my sample?

We will need a blood sample so we can get your DNA to sequence, or screen.

You may be asked to give another sample of blood if the first sample does not provide enough DNA for the test.



Genetic Testing Possible Results

Types of Findings

1. **Primary Findings:** Changes in your DNA that cause the condition or predispose you to the condition for which you were tested (putting you at higher risk than the general population)
2. **Secondary Findings:** Changes in your DNA that are unrelated to the reason you received this test. These secondary findings could influence your future medical care. To understand more about secondary findings, please talk to your health care provider or genetic counselor.

Types of Results

1. **Positive:** A change in your DNA that is known to cause disease has been found.
2. **Negative:** No changes in the genes that were screened
3. **Variant of uncertain (clinical) significance (VUS):** A change in a gene known to cause disease was found, but the effect of this change is unknown. It could also mean a change in a gene that is not yet known to cause disease has been found. Therefore, the significance of the change is unknown.

How will the results be given to me?

A doctor and/or a genetic counselor will contact you with your results to explain them and answer questions you may have. Your doctor will get recommendations that may or may not include more genetic testing based on the results of your test.

Test Limitations

Your genetic counselor will explain the limitations of exome sequencing to you during your counseling appointment. Sometimes more testing is needed.



Helpful Websites

Iowa Institute of Human Genetics

Information for patients, health care providers, researchers, and students

>> www.medicine.uiowa.edu/humangenetics

Genetics Home Reference

Information about how genes affect your health: what genes are, how they work, and how they can cause illnesses

>> www.ghr.nlm.nih.gov

The Pharmacogenomics Knowledgebase

Information about how genes interact with medicines

>> www.pharmgkb.org



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CYP2C19

Genetic Screen

for People Taking
Clopidogrel (Plavix®)

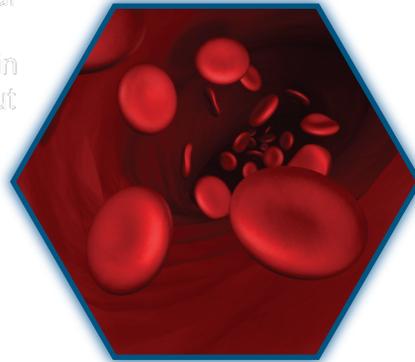


What is clopidogrel (Plavix®)?

- Clopidogrel (Plavix®) is a medicine used to thin your blood to prevent blood clots
- People with heart disease take clopidogrel to prevent heart attack and stroke

What are genes?

- Genes are short pieces of DNA that contain information about our bodies
- Genes are passed down to us from our parents before we are born
- Genes have DNA changes (variants) in them that determine a great deal about us, including what we look like and how our bodies react to medicine



What is a genetic screen?

- It is a test used to show the gene changes in a person

Why would I have a genetic screen for clopidogrel (Plavix®)?

- Your body may process clopidogrel normally, very fast, or poorly
- The *CYP2C19* gene controls how your body will process (metabolize) clopidogrel
- The type of *CYP2C19* gene you have will help your doctor decide if clopidogrel will work for you
- Learning about your *CYP2C19* gene can help your doctor choose the right medicine and the right dose for you

How do variants in this gene affect me?

- If your *CYP2C19* gene is the type that processes clopidogrel poorly, the drug will not work well for you
- If your *CYP2C19* gene is the type that processes clopidogrel too fast, you may get too much clopidogrel in your blood stream

What do I need to do for a genetic screen?

- You will be given a small sponge to wipe across the inside of your cheek to collect a sample of your DNA (genes)
- The sample will be used to study your *CYP2C19* gene
- You also may be asked for a sample of saliva or blood in case the sponge does not work

How will I learn about my results?

- Your doctor or nurse can tell you the results at your next appointment
- The results also will be in your MyChart account (mychart.uihealthcare.org)

Are there any limitations to this screen?

- This screen only looks at the four most common variants of *CYP2C19*
- Other variants in *CYP2C19* will not be found, but they can affect how your body will process clopidogrel
- Please let your doctor or nurse know if you are taking other medicines

Can my insurance get my genetic screen results?

- Yes, your insurance company can get the results of this screen from your medical records
- We have a genetic counselor who can answer your questions about insurance companies and genetic information

