Completed Research Submission Examples

Example 1:

Title: *Leflunomide for Cytomegalovirus Infections in Stem Cell Transplant Recipients*

Topic: *Clinical/Translational Research*

Background/Rationale:
Cytomegalovirus (CMV) disease plays a major role in contributing to morbidity and mortality following allogeneic stem cell transplant (allo-HSCT). Despite two major strategies of CMV prevention (prophylaxis or pre-emptive treatment), allo-HSCT recipients continue to develop refractory or recurrent CMV infection or disease, with or without evidence of genetic mutations. Due to the serious toxicities and intolerability of currently available therapies (valganciclovir/ganciclovir or foscarnet), refractory CMV infection and disease remain significant clinical challenges.

Leflunomide, commonly utilized for rheumatoid arthritis, also has anti-CMV activity, including activity against ganciclovir-resistant strains by uniquely inhibiting viral capsid assembly and not DNA replication. There are currently no prospective, randomized trials analyzing leflunomide use alone or in combination for CMV infection or disease in allo-HSCT recipients. In this study, we wanted to evaluate and describe the utility of leflunomide in allo-HSCT recipients for refractory CMV infections.

Objective:
The primary objective was to determine the clinical and virologic responses of leflunomide therapy for refractory CMV infections.
The secondary objectives were to describe the characteristics of allo-HSCT recipients receiving leflunomide for CMV reactivation and evaluate teriflunomide levels.

Methods:
We conducted a retrospective analysis of adult allo-HSCT recipients with refractory CMV infections receiving leflunomide therapy from January 1, 2005 to March 31, 2015 at the University of Texas MD Anderson Cancer Center. Patients were identified utilizing a pharmacy database query. Pertinent medical history and laboratory values were collected from electronic medical records utilizing a standardized collection form.

Results:

A total of 14 allo-HSCT recipients with CMV infection received leflunomide treatment. All patients received concurrent CMV therapy (monotherapy or combination with valganciclovir, ganciclovir, and/or foscarnet) at leflunomide initiation. Thirteen patients were tested for CMV genotype resistance, of which, 9 patients had documented UL97 and/or UL54 genotype(s). The most common leflunomide dosing schema utilized was a 100 mg daily for 3 day loading dose, followed by 20 mg daily maintenance. Nine patients achieved a virologic response with undetectable CMV titers via antigenemia. Of the 13 patients with teriflunomide levels, 8 patients were maintained at levels > 40 mcg/mL. The most common adverse effects were cytopenias (8 patients) and elevated liver function tests (4 patients).

Conclusions/Discussion:
CMV infection and disease remain a major clinical complication in allo-HCT recipients. The use of leflunomide for refractory cases appears to be efficacious and safe. Future prospective, randomized trials need to confirm these benefits, determine appropriate dosing schema, and target teriflunomide levels.

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Example 2:

Title: *Eculizumab For Treatment Of Thrombotic Microangiopathy In A Pediatric Hematopoietic Stem Cell Transplant Patient*

Topic: *Clinical/Translational Research*

Background/Rationale:
Thrombotic microangiopathy (TMA) is a severe complication of hematopoietic stem cell transplant (HSCT). TMA can cause microvascular injury leading to significant co-morbidities such as renal insufficiency, pulmonary hypertension and in the most severe cases multisystem organ failure and mortality. Treatment of this post-transplant complication is not well defined in pediatric patients. Eculizumab, a complement inhibitor may prevent tissue damage and has been used in the treatment of TMA in pediatric HSCT patients. Dosing for this off-label indication is typically modified from approved dosing for atypical hemolytic uremic syndrome (aHUS) regimens. The ability to characterize an effective dosing regimen to achieve complement blockade has not been fully established in pediatric HSCT patients with TMA.

Objective:
Our objective is to describe an effective dosing regimen, monitoring and clinical outcome of eculizumab used for treatment of TMA in a pediatric HSCT patient.

Methods:
A retrospective electronic medical record review was conducted to evaluate the clinical effect of eculizumab in a pediatric autologous HSCT patient treated at Children's Hospital Colorado. Clinical status, eculizumab dose and frequency, degree of complement blockade as measured by hemolytic complement level (CH50) and serum creatinine were collected. Complete complement blockade was considered achieved at CH50 levels of less than or equal to four complement enzyme activity units per milliliter.

Results:
Eculizumab was used for treatment of TMA post-HSCT in one pediatric patient, two months post-autologous HSCT. The patient presented with hypertension, renal insufficiency and respiratory compromise accompanied by pulmonary effusion. Eculizumab 600 mg administered intravenously was initiated at a frequency of twice weekly. CH50 levels became undetectable after only three doses. CH50 levels remained consistently undetectable at a frequency of eculizumab three times weekly. Serum creatinine levels trended down from 1.45 to 0.7 mg/dL. At three months post-

initiation of eculizumab, the patient is still receiving once weekly eculizumab infusions, has improved renal function just above baseline, achieved resolution of pulmonary compromise and effusion, has control of hypertension with three anti-hypertensive medications and was discharged from the hospital.

Conclusions/Discussion:
Treatment with eculizumab for post-HSCT TMA in a pediatric patient effectively achieved complete complement blockade and correlated with clinical improvement and avoidance of multi-organ failure. Eculizumab dosing frequency was escalated up to three times weekly and titrated based on CH50 levels. This suggests a requirement of increased dosing frequency from those approved for disease states such as aHUS.

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Example 3:

Title: *Incidence and Timing of Infusion and Hypersensitivity Reactions to Chemotherapy over Seven Years at a Community Cancer Center*

Topic: *Clinical/Translational Research*

Background/Rationale:
Infusion and hypersensitivity reactions to chemotherapy are a common cause of treatment interruption or discontinuation in outpatient Cancer Centers. There are no published reports of reaction incidences for all chemotherapy agents infused at a single site spanning more than one year.

Objective:
We aimed to understand infusion reaction and hypersensitivity incidences and characteristics at our Cancer Center since 2009, especially in regard to patient characteristics, timing, or medication-related factors that predominated.

Methods:
A retrospective review of every infusion reaction since 2009 was conducted. From the medical record we recorded the pre-medications, drug inciting the reaction, dose, number of previous exposures for that patient to the inciting agent, number of minutes to onset of reaction symptoms, description of the reaction per nursing dictation, outcome, reaction severity per National Cancer Institute (NCI) criteria, drugs and doses administered for reaction management, as well as patient age, gender, diagnosis, and number of documented allergies in the medical records. Summary statistics were utilized to report the demographics and characteristics of patients that experienced a reaction. To determine the incidence of infusion reactions, the total number of dispenses of each medication per year was obtained from the dispensing record.

Results:
A total of 268 reactions between 211 patients (60.6% female) occurred between September 2009 and December 2015, with 252 (94%) of the reactions being Grade 1/2 and 16 reactions (6%) being Grade 3/4 according to CTCAE v4.3. The vast majority of reactions (85%) occurred in response to one of five agents: rituximab, paclitaxel, docetaxel, carboplatin, and oxaliplatin. Our calculated incidences were lower than reported in package inserts. The majority (68%) of reactions to rituximab occurred with the first dose. Almost all taxane reactions occurred during Cycle 1 or 2 and within ten minutes of infusion; conversely, 70% of reactions to platinum agents occurred at Cycle 6 or greater.

Conclusions/Discussion:

Reactions to chemotherapy at our Cancer Center showed predictable timing for rituximab, taxanes, and platinum agents. As our reaction incidences are lower than data reported in package inserts, we propose no immediate changes to our current pre-medication practices. Further analysis with matched patients and multivariate regression analyses will determine which patient, chemotherapy, and pre-medication factors were positively associated with infusion reactions.

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Leflunomide for Cytomegalovirus Infection in Stem Cell Transplant Recipients

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BACKGROUND

- CMV disease contributes to morbidity and mortality after allo-HSCT.[1]
- Despite CMV prophylaxis or pre-emptive treatment, allo-HSCT recipients continue to develop refractory or recurrent CMV infection or disease.[2]
- Due to toxicities of current therapies, CMV infection remains a significant challenge.
- LEF has activity against ganciclovir-resistant strains by inhibiting viral capsid assembly.[3,4]
- There are no prospective, randomized trials analyzing LEF use alone or in combination for CMV infection.

OBJECTIVES

Primary objective

- Describe the characteristics of allo-HSCT recipients who received LEF therapy for CMV infection.

Secondary objectives

- Discuss the clinical and virologic responses of using LEF as therapy for CMV infections in allo-HSCT recipients.
- Identify the most common side effects associated with LEF therapy.

METHODS

- This is a retrospective analysis of adult allo-HSCT recipients with refractory CMV infections receiving LEF therapy from January 1, 2005 to March 31, 2015 at the University of Texas MD Anderson Cancer Center.
- Patients were identified utilizing a pharmacy database query.
- Pertinent medical history and laboratory values were collected from electronic medical records utilizing a standardized collection form.

RESULTS

Table 1. Patient Demographics

Patient	Age	Gender	Disease	Transplant Type	Conditioning Regimen	Intensity	GVHD Prophylaxis
1	48	M	MDS	Haplo	Flu/Mel	RIC	Tacro/MMF/Cy
2	62	F	AML/MDS	MRD	Flu/Mel	RIC	Tacro/MTX
3	40	M	T-cell NHL	Haplo	Flu/Mel/Thio	RIC	Tacro/MMF/Cy
4	59	F	AML	MUD	Flu/Mel/ATG	RIC	Tacro/MTX
5	52	F	AML	Cord	Flu/Mel/ATG	RIC	Tacro/MMF
6	65	F	AML	MUD	Flu/Mel/Thio	RIC	Tacro/MMF/Cy
7	56	M	AML	MUD	Flu/Mel/ATG	RIC	Tacro/MTX
8	69	F	AML	Haplo	Flu/Mel/TBI	RIC	Tacro/MMF/Cy
9	22	M	MDS	Cord	Flu/Mel/Thio/Ritux	RIC	Tacro/MMF
10	70	F	AML	Haplo	Flu/Mel/TBI	RIC	Tacro/MMF/Cy
11	59	M	AML/MDS	MUD	Bu/Flu/Clo/ATG	MA	Tacro/MTX
12	59	F	AML	MUD	Flu/Mel/Alem	RIC	Tacro/MTX
13	55	M	AML	MUD	Flu/Mel/ATG	RIC	Tacro/MTX
14	26	F	T-cell ALL	Cord	Bu/Flu/Clo/ATG/TBI	MA	Tacro/MMF

Alem = alemtuzumab, AML = acute myeloid leukemia, ATG = antithymocyte globulin, Bu = busulfan, Clo = clofarabine, Cord = double cord blood, Cy = cyclophosphamide, Flu = fludarabine, GVHD = graft versus host disease, Haplo = haploidentical, MA = myeloablative, Mel = Melphalan, MDS = myelodysplastic syndrome, MMF = mycophenolate mofetil, MRD = matched related donor, MTX = methotrexate, MUD = matched unrelated donor, RIC = reduced intensity conditioning, Ritux = rituximab, Tacro = tacrolimus, TBI = total body irradiation, T-cell ALL = T-cell acute lymphoblastic leukemia, T-cell NHL = T-cell non-Hodgkin lymphoma, Thio = thiotepa

Table 2. CMV Characteristics at Time of Leflunomide Initiation

Patient	Prior CMV Treatment	CMV Genotype Mutations	Transplant Day of CMV Reactivation (Day+)	Transplant Day of LEF Initiation (Day+)	Concurrent CMV Therapy	Concurrent IVIG Use	Use of CMV CTLs
1	VGCV, FCN	UL97	41	98	VGCV, FCN	Yes	No
2	GCV, FCN	N/A	134	142	VGCV, FCN	Yes	No
3	FCN	Negative	45	72	FCN	Yes	No
4	GCV, VGCV, FCN	UL97	106	231	GCV	Yes	No
5	GCV, FCN	Negative	107	169	FCN	Yes	No
6	GCV, VGCV, FCN	UL97, UL54	117	175	GCV	Yes	No
7	GCV, VGCV, FCN, CDF	UL97, UL54	389	434	FCN	Yes	Yes
8	GCV, FCN	UL54	124	124	GCV	Yes	Yes
9	GCV, FCN, CDF	Negative	539	558	GCV	Yes	No
10	GCV, FCN, CDF	UL54	70	89	FCN	Yes	Yes
11	GCV, FCN	Negative	110	113	FCN	Yes	No
12	GCV, FCN	UL97	249	253	FCN, BCDF	Yes	Yes
13	GCV, FCN	UL97, UL54	139	172	GCV, FCN	Yes	Yes
14	GCV, VGCV, FCN	UL97, UL54	202	203	CDF	Yes	Yes

BCDF = brincidofovir, CDF = cidofovir, CMV = cytomegalovirus, CTLs = cytotoxic T lymphocytes, FCN = foscarnet, GCV = ganciclovir, IVIG = intravenous immunoglobulin, N/A = not available, LEF = leflunomide, VGCV = valganciclovir

RESULTS

Table 3. Leflunomide Characteristics and Virologic Response

Patient	LEF Loading Dose*	Initial LEF Maintenance dose*	Final LEF dose*	Initial TEF Serum Level (mcg/dL)	Final TEF Serum Level (mcg/dL)	Initial CMV Ag**	Peak CMV Ag**	End of Treatment CMV Ag**	LEF Treatment Days
1	100 x 3 days	20	100	23.9	65.7	45	577	0	513
2	100 x 3 days	20	N/A‡	N/A‡	N/A‡	8	21	0	24
3	100 x 3 days	20	20	22.1	16.2	9	84	0	51
4	60 x 5 days	30	40	30.5	47.6	4	1441	0	137
5	100 x 3 days	20	30	20	20	13	194	0	34
6	100 x 3 days	20	120	15.8	80	5	628	0	505
7	None	20	30	11.6	27.1	9	8561	215	586
8	100 x 3 days	20	40	28	26.7	6	791	N/A‡	N/A‡
9	100 x 3 days	20	20	21.4	21.5	10	69	0	255
10	100 x 3 days	20	40	29.6	44.1	80	96	0	82
11	100 x 1 day	20	40	13.5	42.3	14	30	0	56
12	100 x 3 days	20	50	35.8	83.3	11	954	83	85
13	100 x 3 days	40	60	28.2	43.8	3	958	85	93
14	100 x 3 days	40	20	50.7	96.4	1054†	41477†	2130†	199

*mg/day, **CMV Ag = cells/million white blood cells, ‡Data unavailable, †CMV viremia measured as quantitative PCR
Ag = antigenemia, CMV = cytomegalovirus, LEF = leflunomide, N/A = not available, TEF = teriflunomide

DISCUSSION AND CONCLUSION

- The use of leflunomide with concurrent antiviral therapy for refractory CMV cases appears to be efficacious and safe.
- The most common adverse effects were cytopenias (n=8) and elevated liver function tests (n=4).
- CMV infection and disease remain a major clinical complication in allo-HSCT recipients.
- Future prospective, randomized trials are needed to confirm these benefits, determine appropriate dosing schema, and define target teriflunomide levels.

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Eculizumab for treatment of thrombotic microangiopathy in a pediatric hematopoietic stem cell transplant patient

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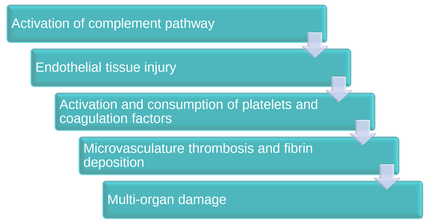
Introduction

Rationale for Research

- Treatment of hematopoietic stem cell transplant (HSCT) –associated thrombotic microangiopathy (TMA) is not well defined in pediatrics
- Eculizumab treatment regimens for HSCT-associated TMA are off-label and are extrapolated from regimens that are approved for atypical hemolytic uremic syndrome (aHUS)

Thrombotic Microangiopathy

- Pathophysiology: disease of microvasculature coagulopathy



- Diagnostic criteria:

Diagnostic Criteria	Parameters
Elevated lactate dehydrogenase (LDH)	LDH > upper limit of normal
Thrombocytopenia	Platelet count (Plt) < 50 x 10^9/L or > 50% decrease
Anemia	Hemoglobin (Hg) < lower limit of normal or requirement of transfusion support
Intravascular hemolysis	Haptoglobin < lower limit of normal
Microangiopathic changes	Presence of schistocytes in peripheral blood or histologic evidence of microangiopathy on a tissue specimen
Absence of coagulopathy	-
Absence of hemolytic anemia	Negative Coombs test
Absence of TTP	Normal ADAMTS13 activity
Proteinuria	Presence of protein in urine
Hypertension	Blood pressure elevated above upper limit of normal for age or new need for antihypertensive medications

- Complications: hypertension, pulmonary hypertension, polyserositis, cardiac tamponade, central nervous system injury, renal impairment

Eculizumab

- Mechanism: antibody that blocks complement activation by inhibiting formation of the membrane attack complex
- Adverse effects: infection risk (black boxed warning for risk of meningococcal infection), infusion reactions
- Monitoring: eculizumab serum trough concentrations (goal > 99 µg/mL), degree of complement blockade as measured by total serum hemolytic complement activity (CH50)
- Pediatric literature support: complete clinical response achieved in 4 of 6 pediatric HSCT patients at Cincinnati Children's Hospital Medical Center

Objective

Describe an effective dosing regimen, monitoring and clinical outcome of eculizumab used for treatment of TMA in a pediatric HSCT patient at Children's Hospital Colorado

Methods

Retrospective Patient Case Report

- Retrospective electronic medical record review using Epic® software

Data Collection

- Patient demographics, eculizumab treatment regimen, hemolytic complement activity (CH50), basic metabolic panel, complete blood count with differential and trend in patient's clinical course

Results

Past Medical History

- 9 year old, 28.7 kg, female with stage IV malignant rhabdoid tumor, status-post induction chemotherapy, radiation, abdominal tumor de-bulking surgery, myeloablative chemotherapy (carboplatin, etoposide, melphalan) and autologous peripheral blood stem cell transplant

Clinical Presentation

- Progressive hypertension, renal insufficiency as evidenced by rising serum creatinine and pulmonary effusions leading to respiratory distress
- Progressive pleural and pericardial effusions
- Increased oxygen requirements requiring pediatric intensive care unit monitoring

Laboratory Parameter	Laboratory Value	Reference Range
Blood Pressure	136/88 mmHg	(< 123/80)
Creatinine, Serum	1.24 mg/dL	(0.23 – 0.61)
LDH, Total (Serum)	2345 U/L	(420 – 750)
Platelet Count	10 x10^3/µL	(150 – 500)
Hemoglobin	10.7 g/dL	(11.1 – 14.5)
Haptoglobin	< 14 mg/dL	(30 – 200)
Protein, Urine	≥ 300 mg/dL	Negative
ADAMTS13 Activity	67%	(≥ 70%)

Hospital Interventions

- Interventional radiology bilateral chest tube placement and drainage of pleural effusions
- Increased blood pressure control with aggressive antihypertensive medication regimen
- Forced diuresis with furosemide
- Initiation treatment with eculizumab 600 mg IV weekly

Clinical Outcome

- Complete complement blockade achieved after 3 doses of eculizumab
- Eculizumab administered weekly based on monitoring of CH50 and stable blockade (< 4 units/mL)
- Control of blood pressure on 3 anti-hypertensives
- Normalization of renal function to near baseline

Date	Eculizumab Dose Given	Serum Creatinine (mg/dL)	CH50 (Units/mL)
7/13/16			63
7/15/16	X	1.45	-
7/20/16			13
7/22/16	X	1.55	20
7/25/16			6
7/27/16	X	1.17	4
7/29/16			< 3
8/1/16	X	1.12	< 3
8/3/16			< 3
8/8/16	X	1.07	3
8/10/16			< 3
8/22/16	X	0.77	11
8/29/16	X	0.74	10
9/6/16	X	0.67	11
9/14/16	X	0.68	-
9/20/16	X	0.71	11
9/26/16	X		-
10/6/16	X	0.6	< 3

Discussion

Treatment with eculizumab for HSCT-associated TMA in a pediatric patient effectively achieved complete complement blockade and correlated with clinical improvement and avoidance of multi-organ failure. Eculizumab dosing frequency was retained at once weekly based on monitoring of CH50. When spaced to twice weekly as indicated in pediatric aHUS, the patient experienced an increase in complement activity above the desired goal range of < 4 units/mL. These findings suggest a requirement of increased eculizumab dosing frequency from that approved for pediatric aHUS in pediatric HSCT patients.

Conclusions

1. Eculizumab may safely and effectively be used for the treatment of HSCT-associated TMA in pediatric patients
2. Pediatric patients being treated for HSCT-associated TMA may require more frequent dosing of eculizumab than that indicated for aHUS
3. Dose and dosing frequency of eculizumab for treatment of HSCT-associated TMA should be adjusted based on degree of complement blockade as measured by hemolytic complement activity (CH50)

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Jens Goebel, MD – Children's Hospital Colorado

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Incidence and Timing of Infusion and Hypersensitivity Reactions to Chemotherapy Over Seven Years at a Community Cancer Center

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INTRODUCTION

- Infusion and hypersensitivity reactions to chemotherapy are a common cause of treatment interruption or discontinuation
- There are no published reports of reaction incidences for all chemotherapy agents infused at a single site spanning greater than one year

OBJECTIVE

Describe the incidence and characteristics of infusion-related reactions occurring over a span of seven years at a single outpatient institution

METHODS

- Continuous documentation since September, 2009
- Retrospective chart review
- Total number of dispenses of each medication obtained for incidences
- Data collected:

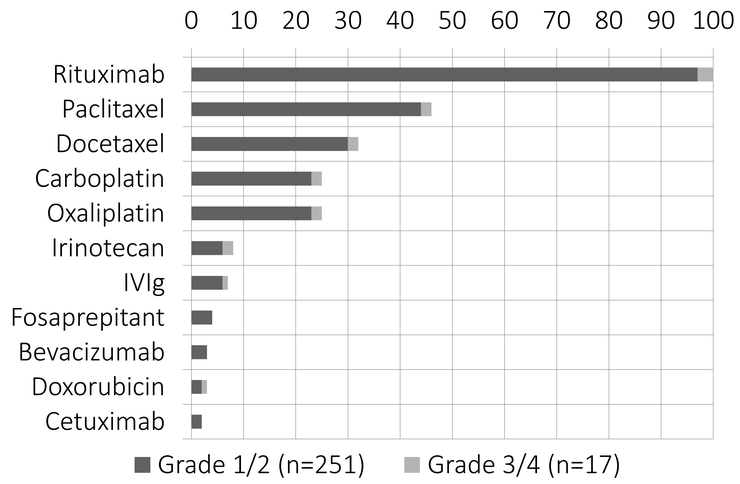
Inciting Agent	Patient Information	Result
Drug	Gender	CTCAE Grade
Dose	Age	Outcome
Cycle	Diagnosis	Rechallenge
Time to Reaction	Recorded Allergies	Description
Pre-Medications	Previous Exposures	Medications Administered

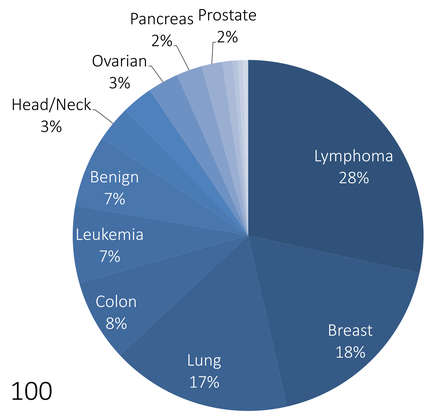
RESULTS

Patient Demographics

	All Patients	Female	Male	p-value
N (%)	211	128 (60.6%)	83 (39.3%)	--
Age (SD) in years	61.7 (14.5)	60.2 (14.8)	64.1 (13.9)	0.05 (t-test)
Experienced >1 Code (%)	41 (19.4%)	24 (18.8% of F)	17 (20.5% of M)	0.76 (z-test)
Number of Drug Allergies (SD)	1.22 (1.70)	1.54 (1.90)	0.72 (1.18)	0.0002 (t-test)

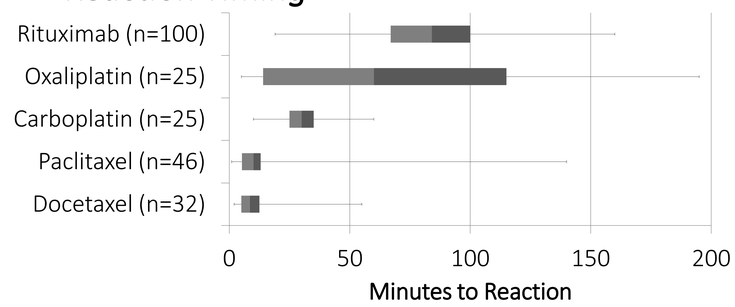
Number of Reactions

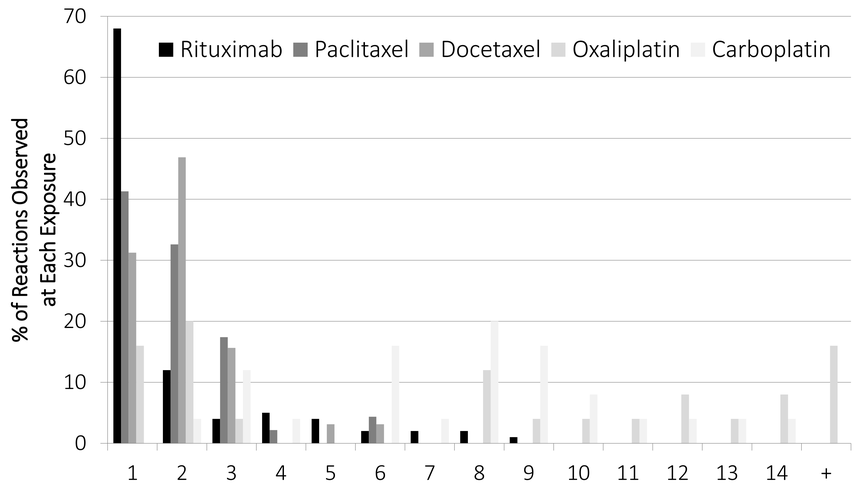


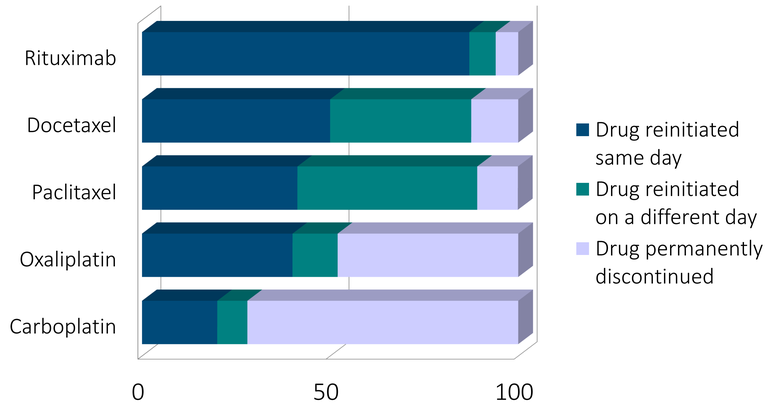


Drug	Reaction Incidence, 2009-2015
Rituximab	4.7%
Docetaxel	2.1%
Paclitaxel	1.23%
Oxaliplatin	0.99%
Carboplatin	0.73%
Irinotecan	0.53%

Reaction Timing







DISCUSSION

- Our observed infusion reaction rates were lower than in package inserts
- Most infusion reactions were manageable with interventional medications and did not progress to Grade 3/4 reactions
- Reactions to rituximab were common, especially with the first exposure, but mild and rarely resulted in discontinuation
- Taxane reactions occurred shortly after initiation of infusion, and were mostly rechallenged successfully
- The majority of platinum reactions occurred after the 6th exposure and were permanently discontinued after the reaction

North Memorial Health Care

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Dr. Whalen: Non-CE Presentations (Merck and Genentech), Advisory Boards (Merck and AstraZeneca)