needs to be taught in small friendly doses tied to practical problems. Each analysis
note presented by Doug Gause has sketches drawn by artist Pat Gause.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Study Design

METHODS FOR IDENTIFYING CASE REPORTS OF SUSPECTED ADVERSE
DRUG REACTIONS: AN EVALUATION OF THE EFFICIENCY OF
ALTERNATIVE SEARCH STRATEGIES IN MEDLINE AND EMBASE

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To illustrate the precision and sensitivity of identifying case reports of adverse events
(AE) in MEDLINE and EMBASE, eight searching methods were created and applied
to two systematic reviews of case reports. Search methods included use of index-
text words for synonyms of AE and related terms, as well as drug, disease, and
study design. All eight methods combined the drug and combinations of other
search strings and ranked from broad to very specific. Searches were developed for MEDLINE
and EMBASE that were tested in each approach were checked and against a “gold standard” (GS) of case reports previously identified in two systematic
reviews (75 anti-TNF agent, 57 baclofen case reports). Sensitivity and precision of
each method were calculated. The broadest search, using drug terms alone, yielded
over 11,000 and over 3,600 references for each systematic review topic. Sensitivity
decreased as search methods became narrower; precision was consistently low (gener-
ally <6%). The search method for drug terms alone had 100% sensitivity for both
systematic review topics with very low precision (<1.6%). Precision was highest when
drug, disease, case report and AE were combined for baclofen (15%) with low sensi-
tivity (26%). Of the GS articles available from MEDLINE, 7% and 18% of anti-TNF
and baclofen case reports respectively were not indexed as case reports. Sensitive
search methods able to identify relevant case reports are important, but when a sensi-
tive search was constructed, this led to low precision. A sensitive search method must
be broad, and search both databases. Precision remains low with each combination
of approaches, making accurate identification of case reports rather labor intensive.
This illustration demonstrated the extent to which decisions made when developing
search methods impact the comprehensiveness of reviews. Further work is on-going
to confirm the generalizability of these findings to other drugs.

CANCER – Clinical Outcomes Studies

USE OF WHITE BLOOD CELL GROWTH FACTORS AND RISK OF
ACUTE MYELOID LEUKAEMIA OR MYELOPROLIFERATIVE SYNDROMES
AMONG ELDERLY NON-HODGKIN’S LYMPHOMA PATIENTS

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OBJECTIVES: Therapy-related myelodysplastic syndromes and acute myeloid leuke-
ia (t-MDS/t-AML) are devastating long-term complications of cancer therapy. Evi-
dence suggests that white blood cell growth factors (CSFs) may increase risk of t-MDS/t-
AML among patients (pts) receiving chemotherapy, possibly because they stimulate
the proliferation and differentiation of hematopoietic stem cells and also interfere with
apoptosis. The purpose of this retrospective study was to evaluate the association
between CSF use and t-MDS/t-AML among a large population-based cohort of elderly
non-Hodgkin lymphoma (NHL) pts treated with chemotherapy. METHODS: This prov-
ence was excluded. The remaining 1,023 pts (48% male) were identified from the Surveillance,
Epidemiology, and End Results-Medicare database diagnosed from 1992 to 2002 who received chemotherapy within 12 months of
diagnosis. Pts were followed from their initial chemotherapy until t-MDS/t-AML
development, death, or end of study period (December 31, 2006). Kaplan-Meier
and Cox proportional hazards analyses were used to evaluate the association between CSF
use and t-MDS/t-AML. RESULTS: A total of 13,203 pts were identified. Overall, 40%
(n = 5,266) received CSF. 272 (5.2%) pts receiving CSF developed t-MDS/t-AML vs.
230 (1.2%) who were not (p-value < 0.0001). In a multivariable Cox regression analysis adjusting for gender, histology, stage, comorbidities, chemotherapy
dates, and chemotherapy agent, CSF use was independently associated with a 33%
increased risk of t-MDS/t-AML (HR 1.33; 95% CI 1.26–1.4). A dose-response rela-
tionship was observed, with t-MDS/t-AML risk increasing by quartile of CSF claims.
In an evaluation of plausible biologic interactions, we found that 18% of anti-CSF
and antimitabolite chemotherapy (n = 1,567 pts) had a 2.5 fold increased risk of
t-MDS/t-AML (HR 2.49; 95% CI 1.91–3.26) vs. pts who received neither agent (p-inter-
action = 0.34). CONCLUSIONS: Our findings suggest that CSF use among elderly
NHL chemotherapy pts may increase risk of t-MDS/t-AML, even though absolu-
tate risk is low. Future studies are necessary to verify these results and to determine
the clinical implications of the observed interaction between CSF use and antimitabo-
late chemotherapy.

DIABETIC MEDICATIONS AND ITS ASSOCIATION WITH MORTALITY
IN HOSPITALIZED CANCER PATIENTS

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OBJECTIVES: The effect of diabetes and diabetic medications on the morbidity and
mortality in hospitalized cancer patients is a serious concern. We examined the asso-
ciation of diabetic medications with the transfer to ICU and inpatient mortality.
METHODS: Electronic patient records were prospectively collected in 5489 hospital-
izations to UT MD Anderson Cancer Center from May 1st, to July 31st, 2006. For the present demographic, laboratory and pharmacy data were used.
To determine the effect of diabetic medications, we selected only diabetic patients, which were
36.3% (1911) of the total hospitalization. Descriptive and logistic regression analyses were
performed. RESULTS: Out of 1911 hospitalizations for diabetic cancer patients,
forty-seven percent were male, sixty nine percent were White with median age of
sixty. These patients were on different diabetic medications and thirty one percent were
only on sliding scale insulin (SSI). After controlling for socio-demographic variables
and other medications like chemotherapy, we found cancer patients who were only on
SSI were more likely to be transferred to intensive care unit (ICU) (OR 2.27, CI:
1.7–3.2; P < 0.001) and die during hospitalization (OR 1.88, CI: 1.3–2.7; P < 0.001).
Glucocorticoids administration was also significantly associated with inpatient mor-
tality (OR 5.91, CI: 3.5–9.8; p < 0.001). CONCLUSIONS: We found strong associa-
tions between the method of administration of insulin (SSI) and transfer to ICU and
inpatient mortality in cancer patients with diabetes. Drug dosage and administration
in inpatient settings should be tailored to the need of the patients to optimize the
medication effect and minimize the side effects.

RELIABILITY OF CLINICIAN VS. CLINICIAN ADVERSE SYMPTOM
REPORTING

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OBJECTIVES: Adverse symptom reporting is essential in clinical trials and drug label-
ing to assess and ensure patient safety. The standard approach to collecting adverse
symptoms in cancer trials is clinician reporting using the Common Terminology
Criteria for Adverse Events (CTCAE), which rates symptoms based upon descriptive
clinical criteria. Despite the importance of this information, the reliability of these
ratings has not been verified. At Memorial Sloan Kettering Cancer Center (MSKCC),
symptoms are routinely evaluated via CTCAE items by a clinician in an office suite, and
again shortly thereafter by a second clinician in a chemotherapy suite, with no information
passed between clinicians. METHODS: To measure the reliability of these evaluations,
a retrospective analysis of medical charts was completed in a sample of 433 patients
aged 26–91 (M = 62.39; 41.8% male) receiving chemotherapy, who were enrolled in an
observational study conducted between March 2005 and August 2009. Cancer diagnoses
included lung (N = 153), prostate (N = 127), and gynecologic (N = 153). RESULTS:
For the first post-chemotherapy visit, intraclass correlation coefficients were
moderate for fatigue (0.52), dyspnea (0.75), nausea (0.55), vomiting (0.50),
diarrhea (0.63), constipation (0.48) and neuropathy (0.73). The average time between
evaluations was 70.42 minutes (range 67.97–72.88). These values were stable up to six
subsequent visits and did not differ based on age, gender, or elapsed time between
evaluations. CONCLUSIONS: Given the short period of time and lack of interventions
between reporting time points, the most likely cause of this lower than expected agreement
between different clinicians is limited reliability of clinician report-
ing of this information. This finding has implications to clinical trials, as it brings into
question the reliability or accuracy of symptom safety information. The investigators are
currently evaluating patient-reported outcomes as an alternative and potentially more
reliable method for collecting this information.

INSULINS AND RISK OF CANCER AMONG TYPE 2 DIABETICS: A
SYSTEMATIC REVIEW

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OBJECTIVES: There have been reports which suggest that insulin glargine use may
cause an increased cancer risk in some type 2 diabetic populations, in addition to
the fact that diabetes mellitus is also associated with certain types of cancer. There-
fore, the objective of the present study is to conduct a review of published studies on
insuls and the risk of cancer in patients with type 2 diabetes and summarize the
findings. METHODS: Several databases such as Medline and PubMed were used for
publication searching. Key words included insulin, tumor, cancer, type 2 diabetes, and
specific insulin names such as glargine, lantus, aspart, etc. Only English lan-
guage literature was considered for articles looking at the increased risk of cancer
among type 2 diabetic patients using insulins. RESULTS: About 30 articles were
selected, among those, 4 studies were conducted in humans using secondary database.
All were historic cohort studies, and the used Cox regression for analysis. Two
articles established a positive association between cancer incidence and insulin
function, while the other two found no association. Three studies also showed that
several insulins other than glargine are not associated with an increased risk of cancer.