Strategies to Reduce Diagnostic Errors and Medical Malpractice Risks

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THE CSU DOCTOR OF NURSING PRACTICE

Objectives

1. Identify approximate annual death rates associated with medical errors
2. Identify medical malpractice rates among all medical providers
3. Identify the medical malpractice rates among Adult/Primary Care Nurse Practitioners (NPs)
4. Define the type of medical error known as 'failure to diagnose' (FTD)
5. Identify the percentage of failure to diagnose medical error among Adult/Primary Care NPs
6. Identify the most common diagnostic medical errors
7. Identify the five contributing factors to failure to diagnose medical errors
8. Verbalize the importance of reflective practice in diagnostic process
9. Identify the diagnostic tools in Diagnostic Tool Kit proven to increase the diagnostic accuracy
10. Understand the importance of adopting the Integrated Diagnostic Practice Guideline into your Practice

Lewis Blackman Story

- Healthy, gifted 15 year-old boy underwent elective surgery for pectus excavatum
- In most modern hospital, he bled to death over 30 hours
- Death due to medical error in 2000
  - Autopsy showed perforated duodenal ulcer, well-known risk of Toradol.
  - suffered from internal bleeding, lost 3-4th of his blood over course of 30 hours
- Case settlement $950,000
- His mom - Helen Haskell formed Mothers Against Medical Error
  - Strong Advocate for Patient Safety and Patient Empowerment

40 year-old male – presented to NP

- C/O – flare-up Gout. NP prescribe prednisone and gave him steroid injection
- NP – measured left calf as 42 CM, Right Calf as 40.5 CM. Documented doubted DVT, attributed to pain to gout, Baker's cyst, or radiculopathy.
  - If calf increase in swelling will order UTZ to R/O DVT
  - Later that day, pt. called office due to increase swelling and pain.
    - UTZ revealed DVT
      - Referred to ER
      - Shortly after arrival, patient arrested
      - Resuscitation unsuccessful, patient deceased.
      - Autopsy revealed Pulmonary Embolism

61 year-old obese male presented to NP

- C/o chest pain and pain radiating down both arms with heavy lifting. V/S WNL.
- NP diagnosed Costochondritis and muscle spasms
  - Prescribed: Toradol injection and prescribed Medrol and Celebrex.
  - Recommended: warm compress and advise to schedule appt. with cardiologist if symptoms did not improve, and go to ER if symptoms worsened.
- Four Days later - Condition worsen – ER – EKG showed Massive MI, taken to cath lab showed complete blockage left anterior descending artery, where he went into ventricular fibrillation, coded, intubated, arrested and deceased.

Significance of Problem

Institute of Medicine (IOM)– To Err Is Human (Kohn et al. 2000; Perez, 2016)
- 44,000-98,000 preventable deaths due to medical error (ME)

Recent studies approximately 400,000 deaths/year due to ME (James, 2013; Makary & Daniel, 2016)
- Four times more then what IOM originally reported
- MEs found 20-40% of cases during autopsy
- 1 in every 20 adults in the U.S affected by diagnostic errors (Singh et al. 2014)
- Medical errors 3rd most common cause of mortality in U.S. (Makary & Daniel, 2016)
- 17 – 29 billion annual estimated costs associated with MEs

Background

Diagnostic errors – unintentional act or omission, failure to accurately and timely diagnose medical conditions

Breakdown of lawsuits by type of diagnosis-related case (41%) with paid claims (Sweeney et al. 2017)

- Failure to diagnose (26.59%)
- Delay to diagnose (11.31%)
- Misdiagnoses (3.15%)

Failure to diagnose - Adverse practice outcomes (NSO, 2017)

- Average claim payout of $282,727
- Between 2012 to 2016 total of $16,680,875

Majority of claims against Adult/Family NPs occurred in outpatient setting (Tehrani et al., 2013)

Background – Recent study by Troxel et al. 2018

- Out of Diagnostic Error claims – 42% involved malignancy:
  - Most common: breast, colon, lung, ovary, and skin
- Common diagnoses associated with DE allegations:
  - Myocardial Infarction , pulmonary and arterial embolism, and venous thrombosis.
  - Acute Cerebral Vascular Accident, Spinal Epidural Abscess
  - Pneumonia

Medical Malpractice

Four Elements

- Duty - Must have provider-patient relationship
  - Obligation to act reasonably and appropriately when providing any type of care.
- Breach of Duty
  - Provider fails to uphold duty of care, fallen below acceptable standard of care. Failed to act competently
- Causation
  - Direct cause between injuries and provider's breach of duty
- Damages - Patient suffered actual harm. Economic/Non-economic (pain & suffering)

Medical Malpractice Claims Among Providers

National Practitioner Data Bank Compare Rates of Malpractice reports from 2005 thru 2014

- MDs (11.2 to 19.0 malpractice payment reports per 1,000 MDs)
- PAs (1.4 to 2.4 per 1,000 PAs)
- NPs (1.1 to 1.4 per 1,000 NPs)

NPs had higher diagnosis-related allegations compared to MDs, but lower then PAs

- MDs (31.9%)
- PAs (52.8%)
- NPs (40.6%)

Trend of NP Medical Malpractice Rates Increasing (Sweeney et al., 2017)

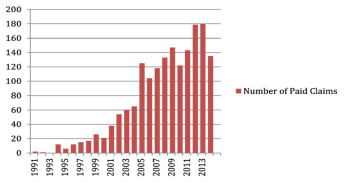


Fig. 1. NP paid malpractice claims by year (1990–2014). Number of paid nurse practitioner malpractice claims for years 1990–2014.

Medical Malpractice Claims by NP Specialty/Outpatient (NSO, 2017)

Closed claims between 1/1/2012 – 12/21/2016

- Adult/Primary Care/Family
  - 53.7% of all closed claims
  - Total paid indemnity $31,562,191
  - Average paid indemnity $267,476
- Behavior health (15.3%)
- Gerontology (11.9%)
- Women's health (gyn) (3.1%)
- Women's health (ob) (2.1%)
- Neonatal (1.0%)
- ER (5.7%)
- Hospitalist (1.0%); Spa/Medisap (1.7%)

Highest Closed Claims (2012-2016) increase since 2012 report

- Outpatient Settings (52.1%)
  - Physician office/NP Office Practice

Review of Literature

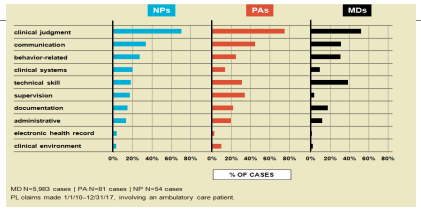
Contributing Factors to Failure to Diagnose (Kelly et al. 2012; Brock et al., 2017; Leigh & Flynn, 2015; Sweeney et al., 2017)

- Failure to practice:
  - Thorough medical history and physical examination
  - Order diagnostic studies
  - Formulate differential diagnosis
  - Recognize cognitive biases
  - Practice reflection

Evidence Based Guideline – Reflective Practice Model

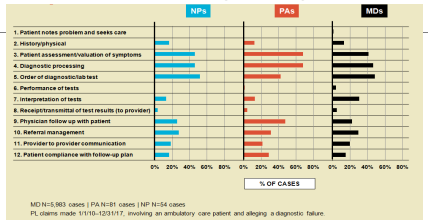
- Developed IDPG with Reflective Practice Algorithm and Diagnostic Tool Kit: Content experts critique/reviewed
- 1. Use Reflective Practice
- 2. Use Standardized Checklists to confirm: "red flags", "don't miss, "most commonly missed", and prioritize "worst case scenarios."
- 3. Intensive collaboration with Diagnostic Team (patient/family)

Contributing Factors to Diagnostic Errors/Medical Malpractice



Source: CRICO was founded 40 years ago, is insurance company that has provided medical malpractice insurance coverage to 26 hospitals, 13,500 MDs, and excess of 100,000 clinicians.

Poor Clinical Reasoning - Diagnostic Process



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Strategies to Enhance Clinical Reasoning

Urgent need to develop an evidence-based practice guideline to enhance the diagnostic process/clinical reasoning
- Family/Adult NPs the primary care outpatient settings

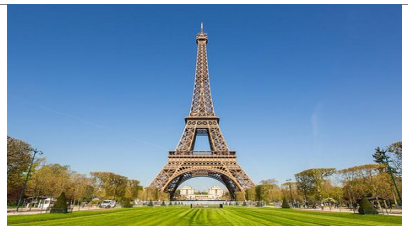
World Health Organization (WHO)
- Educations to enhance critical thinking and clinical reasoning is best way to decrease diagnostic errors

Cognitive Biases: Two Types of Clinical Reasoning

Cognitive Bias – over 100 biases
- Every provider has at least one cognitive bias
- Common biases: Anchoring, premature closure bias and availability bias
- Misdirect diagnostic reasoning & lead to medical errors

Two Types Clinical Reasoning:
- Intuitive reasoning (Type 1)
  - Usually associate with cognitive biases
  - Often 95% of decision occur during intuitive phase
- analytical reasoning (Type 2) – deliberate, slower, & usually involves self-reflection. Focused reflective clinical reasoning

Intuitive Reasoning (Type 1)



Analytical Reasoning (Type 2)

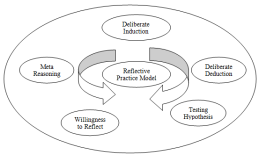
Strategies – Reflective Practice Model Utilize Type 2 Clinical Reasoning

Practice Reflection Model by:

- Dr. Silva Mamede, MD, PhD Psych – thesis on reflective practice in medicine
- Dr. Henk Schmidt, inspired by Dr. John Dewey

- Five Phases of Reflective Practice Model - lessen impact of cognitive biases:
  - Deliberate Induction
  - Deliberate Deduction
  - Testing Hypothesis
  - Willingness to Reflect
  - Meta Reasoning

Reflective Practice Model



Note. Reflective Practice Model by Mamede & Schmidt, inspired by Dr. Dewy. The structure of reflective practice in medicine. *Medical Education.* Copyright 2004 by Blackwell Publishing Ltd. Adapted with permission.

Benefits of Checklist in Healthcare

Checklists ensure compliance with procedures.
- Surgical Safety Checklist and other types of checklists
  - specific tasks or procedures

Quality Rounds Checklist
- Decrease in ventilator-associated pneumonia in the hospital from 8.74% to 1.66%

Care Management Checklist
- Helped patients with seizures follow guidelines
- One-year post implementation of the care management checklist
  - Reduction emergency room visits and unplanned hospitalizations 76% to 90%
  - Reduction hospital cost $188,130

Benefits of Diagnostic Checklists

- Diagnostic checklist is recognized as a multi-faceted tool to ensure that all aspects of the diagnostic process are thoroughly evaluated:
  - history taking & physical examination
  - diagnostic studies
  - formulating differential diagnosis

Use Diagnostic Checklists - diagnostic time out to assess for "red flags," prioritize differential diagnoses, and rule out the "worst case scenario"
- Assist providers in considering potential possibilities.
- Increase diagnostic accuracy for complex cases

Diagnostic Tool Kit: Specific Checklist, General Checklist, Cognitive Checklist, Differential checklist, and Safer Dx Instrument

Purpose Statement

- A practice gap exists for creation of an evidence based practice, Integrated Diagnostic Practice Guideline (IDPG) that provides a specific algorithm using reflective practice principles to reduce FTD ME by Adult and Family NPs in the primary care setting.
- DNP Project- Developed, educated, and evaluated IDPG; training NPs how to use an IDPG with the short term goal of increasing confidence and expressing intent to change practice by implementing IDPG.

Combined Conceptual Models

- Logic Model – Provided comprehensive plan to guide, implement, and evaluate project
- Reflective Practice Model – Served as intervention for project and embedded in the Integrated Diagnostic Practice Guideline.
  - Optimize diagnostic process
  - Engage NPs to critically evaluate their perceptions, attitudes, and feelings when evaluating patients through a deliberate and rational process

Integrated Diagnostic Practice Guideline

Goal: Evidence-Based Strategies with aim to Enhance Diagnostic Process

Reviewed/Critiqued by the content experts:

- Dr. Mark Graber – Founder and President of Society to Improve Diagnosis in Medicine
  - Nationally known for advocate for patient safety, has over 200 peer-review publications in all aspects of diagnostic errors and patient safety
- Dr. John Ely
  - well known field of the diagnostic errors and preventive measures to enhance diagnostic accuracy through implementation of checklists
  - Has written over 100 extensive publications all aspects of diagnostic errors and diagnostic checklists

Integrated Diagnostic Practice Guideline

General considerations:

- Involve patient/family/diagnostic team
- Utilize Five Phases of Reflective Practice Model to Assist with:
  - Perform history and physical, order diagnostic studies, formulate differential diagnosis, & aware of cognitive biases
- Utilize the Diagnostic Tool Kit (DTK) Resources:
  - General checklist/Specific checklist
  - Differential diagnosis checklist
  - Cognitive biases checklist
  - Safer Dx Instrument

Phase One: Deliberate Induction

- Identify problems & consider all possibilities
- Ignore or confront issues of uncertainty
- Involve diagnostic team – frontline staffs
  - Involve patients/family
    - Listen to patients' stories
    - Ask open-ended questions
  - Providers personally
    - obtain medical history
    - perform thorough examinations
- Use DTK=General, Specific, Cognitive & Differential Dx Checklists

Phase Two: Deliberate Deduction

Deliberate Deduction – explore alternative explanations or possibilities
- Explores other alternative signs/symptoms
- Perform focused, purposeful exam
- Perform diagnostic tests
- Explore alternative differential diagnosis – including atypical medical conditions
- Thorough H/P with diagnostic study increase diagnostic accuracy 90%

Use DTK Resources
- Consider "worst case scenario", "Red Flags", the "Don't Miss", and the "Commonly Missed" diagnoses
- Formulate differential diagnosis
  - Prioritize diagnoses – life-threatening conditions on top

Phase Three: Testing Diagnostic Hypothesis

Diagnostic process - intentional connection
- Thorough/detailed medical history/physical exam, diagnostic testing
- Order appropriate diagnostic studies – review and consider if results suggestive of alternative medical conditions
  - Confirm or rule out
- Review Diff. Dx/Validate diagnosis
  - Establish Most Likely Dx, Red Flags, Life-threatening Conditions
  - Use Diff. Checklist to increase breath/deep of knowledge of Differential Dx
- Use all the resources in the DTK

Phase Four: Meta-Reasoning

Critically analyze diagnosis - Pause and step back and look at "big picture"
- Was patient involve in diagnostic process
- Was medical history/physical examination obtained and completed
- Diagnostic testing ordered and results reviewed
- Were diagnostic decisions made based on cognitive bases
- Were resources in the DTK utilized
- Were differential diagnosis formed and prioritized with life-threatening conditions
- Any steps missing or inaccurate, restart back in Phase one briefly to back track. Reflective Practice Model is dynamic, fluent, and opened to correction with reassessment

Confirm Diagnosis with Safer Dx Instrument

Phase Five: Willingness to Reflect

Comprehensive reasoning allows the provider to reasonably assess, evaluate, diagnose, treat and reassess again, if necessary

Consider, rule out, and prioritize life-threatening conditions
- Engaging in reflective practice?
- Was Cognitive Bias considered?
- Consider all "red flags", "don't miss" diagnoses, "commonly missed" diagnoses

Were the resources in DTK utilized?
- General Checklist/Specific Checklist
- Differential Checklist/Cognitive Bias Checklist/Safer Dx Instrument

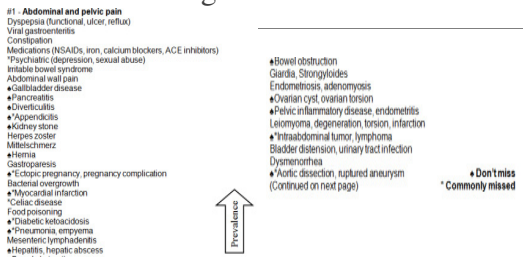
General Checklist

- ❑Involve patient/family members/diagnostic team
- ❑Obtain own comprehensive medical history
- ❑Perform complete physical exam
- ❑Formulate differential diagnosis list
- ❑Practice reflection during diagnostic process
- ❑Take diagnostic time out
- ❑Educate patient on working diagnosis, warning signs, when to go to ER, & schedule return F/U appointments
- ❑Validate diagnosis with Safer Dx Instrument

Specific Checklist

- ❑Did I perform a comprehensive exam
- ❑Did I consider all potential possibilities including atypical presentations?
- ❑Did I consider all the danger signs
- ❑Did I consider all the "don't miss" diagnosis"
- ❑Did I consider "worst-case-scenarios?"
- ❑Did I prioritize diagnosis with life-threatening conditions first?
- ❑Did I order and follow up on all diagnostic studies
- ❑Did I formulate differential diagnosis
- ❑Did I base the diagnosis on any biases
- ❑Was the diagnosis given to me correct?
- ❑Were there any inconsistencies that did not fit the big picture?
- ❑Did I diagnose under time-pressure environment?

Differential Diagnosis Checklist



Cognitive Bias Checklist

- ❑Affective Bias – Is the patient I like or dislike too much.
  - ❑Consideration– providers need to be cognizance about their feelings about the patients they are providing care to because it may affect their clinical reasoning during the diagnostic process.
- ❑Anchoring Bias - Did I base my diagnosis on early impression or interpretation, ignoring subsequent evidence?
  - ❑Consideration – provider needs to consider all differential diagnoses, not just the initial diagnosis.
- ❑Premature Closure Bias - Did I formulate the diagnosis before listening to patient's complete story?
  - ❑Consideration– Need to listen to patient's complete story and consider all alternative diagnoses and possibilities, including the atypical. Did I base the diagnosis based on my feelings about the patients because either like or dislike patients? Affective Bias
- ❑Confirmation Bias - Did I only ask questions only just to confirm the diagnosis and failed to consider other evidence that are more persuasive or convincing? Anchoring bias, premature closure bias are very similar as such these three biases usually occurs concurrently.
  - ❑Consideration– ascertain medical evidence to refute the diagnosis, not just to confirm the diagnoses.
- ❑Availability Bias - Am I working with limited available diagnosis and ask patients about symptoms/signs pertaining only to the limited list of available diagnosis?
  - ❑Consideration – needs to utilize the differential diagnosis checklist to broaden the differential diagnosis list

Safer Dx Instrument

Rate the following items for the episode of care under review

1= Strongly Agree 1 2 3 4 5 6 6 = Strongly Disagree

1. The history that was documented at the patient-provider encounter was suggestive of an alternative diagnosis, which was not considered in the assessment.
2. The physical exam documented at the patient-provider encounter was suggestive of an alternative diagnosis, which was not considered in the assessment.
3. Diagnostic testing data (laboratory, radiology, pathology or other results) associated with patient-provider encounter were suggestive of an alternative diagnosis, which was not considered in the initial assessment.
4. Alarm symptoms or "Red Flags" were not acted upon at an earlier assessment

Note: Rating of 1 most likely represent diagnostic error and rating of 6 indicate no error was identified.

Methods – Descriptive Non-Experimental design

Target Population - Sample
- Inclusion- Adult/Family NPs outpatient settings
- Exclusion - NPs not working in Adult/Family practice and working in inpatient settings

Setting and Procedure
- Conference Meeting Room

Instruments
- Pre-Test: Demographic Survey, Practice Setting Survey, C-Scale
- Post-Test: C-Scale Survey and ORIC Survey

Methods – Data Analysis

Statistical Package for Social Sciences (SPSS) version 25 used for following:

Descriptive statistics
- Analyze frequency, means, standard deviation of demographic, practice setting data, and intent to change practice (ORIC survey)

Paired Sample T-Test
- Compare confidence level (C-Scale) pre-training and post-training of IDPG

Pearson Correlation
- Compare relationship of confidence level and intent to change level post-training of IDPG

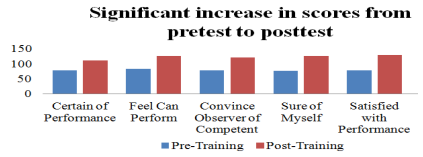
Results – Practice Setting Data

Demographic Data

34 Participants (85% Female & 15% Male)
- Age 45-64 (29.4%)
- Asian (41.2%), Caucasian (29.4%)
- Years in Practice as NP (1-20 years)
- Full time (73.5%)
- MSN Highest Degree (82.4%)
- Family NP Certification (79.4%)

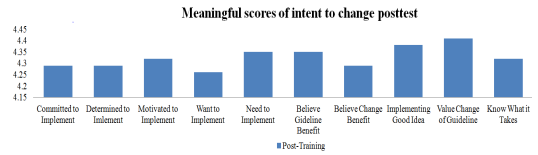
Practice Setting Data
- Felt rushed (70.6%)
- Practice reflection (76.5%)
- Strategies to reduce MEs (79.4%)
- Do not utilize diagnostic checklists (79.4%)
- Do not utilize Safer Dx Instrument (91.2%)
- Open Implement EBP guideline (94.1%)

Results – Confidence Level



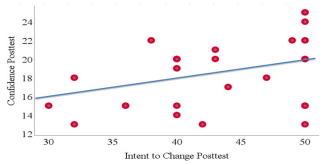
Note: Pre-training and post-training C-Scale of Paired Sample t-tests revealed statistically significant differences across all five questions. *(n = 34)*

Results – Intent to Change Data



Note: ORIC Survey post-training revealed the mean scores between 4.29 to 4.41 with a standard variation range of .109 to .132 across the ten questions of the ORIC post-training, which indicated "highly likely to change." (*n*=34)

Results – Correlation



Note: Significant correlation between confidence level and intent to change posttests. High confidence levels of IDPG are associated with higher levels of intent to change practice. (n = 34)

Discussion

- Training for use of IDPG was effective in increasing NPs' confidence in IDPG and intent to change practice post-training.
- Higher scores on confidence level of IDPG associated with higher scores on intent to change, demonstrating positive potential of NPs willingness to adopt IDPG into practice.
- Most NPs felt rushed – experts believe using focused diagnostic checklists enable NPs to effectively and succinctly review pertinent clinical information.
- High patient load, increase in complex patients, feeling rushed, and lack of administrative support were reasons for switching from primary care specialty. Further studies needed to explore if these were contributing factors to FTD MEs.

Implications for Practice

- Diagnostic errors are complex and multifaceted medical practice problem.
  - No single organization, person, or one strategy alone could solve problem.
  - Utilizing Integrated Diagnostic Practice Guideline based on evidence is one step in right direction
- NPs are advocating for Full Practice Authority (FPA).
  - With FPA, NPs need tools and knowledge to reduce MEs such as FTD.
- Adopting an evidence based practice, IDPG, could reduce Adult/Primary Care NPs FTD MEs

Legal Implications

- Utilization of diagnostic team: patients/family members, supervisory physicians, specialties outside of scope
- Establish/Aware of Scope of Practices and Clearly Identified/Discussed with Supervisory Physicians
- Consult/Refer when outside Scope of Practice, not done until F/U
- Education – Involve patients/families, with consent
  - Disease process, alternative diagnoses, treatment plans, risks/seriousness of, including if failed to F/U
- Documentations
- Have established routine/Adopt Integrative Diagnostic Practice Guideline
  - Routine reflective practice /checklists
  - Cognitively able to walk through your diagnostic process
  - Consider differential diagnoses, rule out worst case scenarios, red flags, don't miss, and commonly missed diagnosis.
  - Prioritize care – rule out the worst case scenarios first!

Limitations

- Three training sessions at two different locations
  - 34 NPs participated
  - Limited number of NPs participation created a small sample size which restrict generalization of findings to other populations.
  - Reflective Practice was not clearly defined – Type 1 or Type 2
  - Strategies were not defined

Conclusion

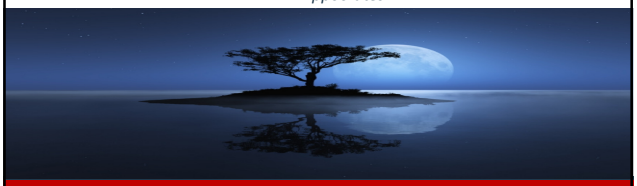
Urgent need for educational reforms to include FTD ME prevention strategies due to:

- Increased numbers of NP providers
  - by 2025 estimated shortage of PCP from 30,000 to 80,000
  - Primary care/Adult NPs are expected to fill the gap
- High ME rates/malpractice claims – IOM and WHO indicated urgent need for educational reforms in nursing curriculum to include subjects on strategies and preventions of diagnostic error
- Especially when NPs are advocating for Advancement of FPA for NPs to practice without a doctor's supervision

Pursue Diagnostic Excellence

"Whenever a doctor cannot do good, he must be kept from doing harm"

Hippocrates



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