UNIVERSITY OF CALGARY
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Manual for Chart Review

Comorbid Conditions and
Adverse Event Labels for
Electronic Medical Record
Algorithm Development

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Contents

GENERAL INFORMATION

Background

- Chart reviewers are not diagnosing patients, they are looking for diagnoses and information that is already recorded in the chart.
    - For example, we are not to diagnose sepsis based on the sepsis criteria, we are to look that a physician has diagnosed the patient with sepsis.
- The data collected by the chart reviewers will be compared to the data from a computer algorithm trained to pick up the same data.
    - Therefore, wording is important, such as specific language used to indicate a causal relationship (see causality section below)

REDCap

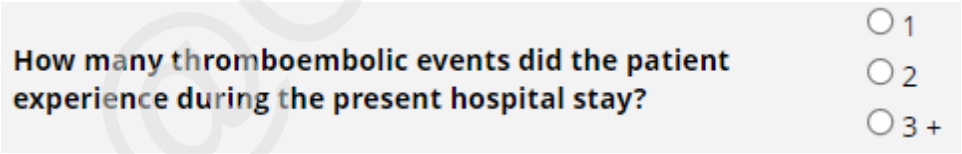
Three surveys in REDcap for each chart

1. Demographics
    - The first questions in the demographics section will be pre-populated
    - The second set of questions will require manual input
2. Comorbidities
3. Adverse Events
    - Medical adverse events
    - Surgical adverse events

Multiple Adverse Events

Some patients may have more than one adverse event of the same type. For example, two pressure ulcers in different locations are found in the chart. In these cases, please record the detailed information on the ***most severe*** of the two adverse events (see severity subsection below for further information).

Selected adverse events will have the option to input the number of adverse events of this type at the end of the subsection:



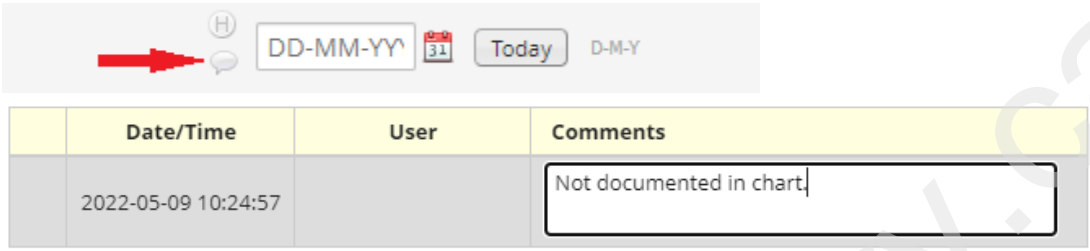
Missing Values

Dates

Ideally look for the date that an adverse event *occurred.* This documentation may not always be available. If it is not, use the date that the event was *discovered* (i.e., patient had a PE but the only date available is the CT-PE when the PE was discovered). If neither of these are available, use the

date of *documentation* (i.e., VAP was first charted in the discharge summary which was authored on a specific date).

- If the exact date is available then it is recorded as DD-MM-YYYY,
- If the date the event occurred/was discovered/was charted is **NOT** available, then it is left blank, and a comment is made stating "not documented in chart".



Textboxes

- If you looked for a value and it is missing from the chart, type "9999" in the textbox.

Dropdown and checkbox lists

- Will have an option "i.e., not documented in chart" to select if the information cannot be found, where appropriate.

Locations

Table 1: List of EMR locations indicated in RedCap. Select all that apply.

1. Discharge summary
2. Consultation notes
3. History & physical examination
4. Multidisciplinary progress records
5. Pharmacy care plan
6. Nursing transfer/admission notes
7. Operative/procedure reports
8. Emergency department records
9. Flowsheets (i.e., nursing assessment)
10. Diagnostic imaging reports
11. Laboratory results
12. Orders
13. Medications

Examples of inferring adverse events based on information in these locations:

- Nursing notes in the multidisciplinary progress records (MPR) can indicate the AE was being cared/treated, such as the daily pressure injury wound care.
- Diagnostic imaging results that indicate the presence of the AE, such as the compression U/S, CT, chest X-ray, or V/Q can indicate the presence of PE or DVT.

- A specific scoring system may be used to assess the severity of the AE. i.e., Waterlow scale, Braden scale, Jackson/Cubbin scale, and Norton scale indicate the presence of pressure injury.
- A specific treatment can indicate the presence of the AE, such as the direct oral anticoagulants (DOAC), subcutaneous or intravenous (IV) anticoagulants (e.g. rivaroxaban, apixaban, low-molecular-weight heparin (LMWH), warfarin) thrombolysis, inferior vena cava (IVC) filter, or surgical thrombectomy for VET treatment which is not for other reasons.

Causality

- The adverse event survey will ask "**was there a documented causal link between clinical care and the current adverse event?**"
- Nuances of language can indicate whether there is a causal link between a cause and an adverse event/harm [45]
- ***Only*** *if the following ICD-11 terminology suggesting a causal relationship is found in the chart can yes be answered to this question.*
- A causal relationship is **strongly** suggested by the following terms [45]
    - As a complication of, complicated by, complicating
    - As a cause of, caused, caused by, causing
    - As a result of, resulted in, resulting in, with resultant, with resulting
    - Because of
    - Due to
    - From
    - Induced, induced by
    - Leading to, led to
    - Related to
    - Precipitated by
    - Producing
    - Secondary to
    - Likely related to
    - May be the reason for
- The following terms hint at a causal relationship but do not explicitly indicate a causal link, therefore supplementary documentation is required.
    - Associated with
    - Accompanied by
    - Incidental to

Severity

- Severity is based on the available documentation in the charts.
- Within the chart was the severity of the adverse event indicated? If yes, complete these sub questions.
    - Was a particular scale used to indicate severity? If yes, indicate type of scale
    - What was the severity of the AE, as indicated in the chart?
    - Where was the severity indicated?

- What date was the severity indicated?

Query Items

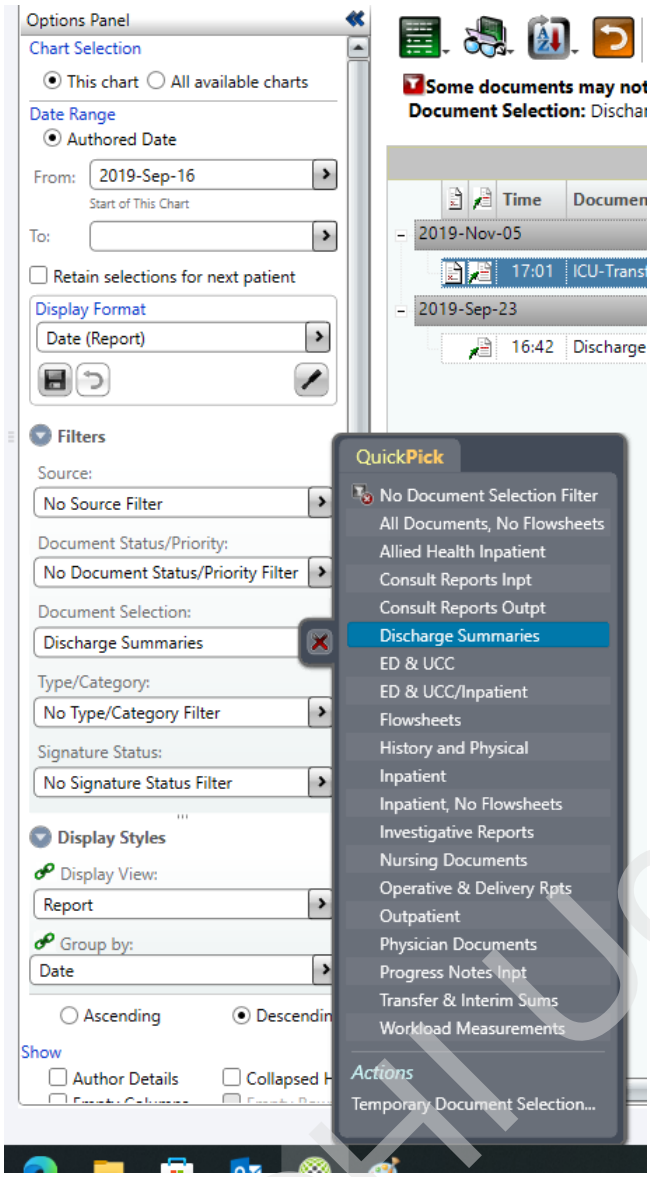
- Some charts may indicate a suspicion of a certain adverse event or comorbidity.
- Example: ?TIA, query sepsis, suspect infection.
- **We will not include unless it is a confirmed diagnosis.**

Finding Information in Sunrise Clinical Manager (SCM)

Filtering Documents

- "All documents, no flowsheets" - this will remove automatically generated documents from flowsheets such as nursing assessments and nursing care. This may make it easier to find MPRs and other relevant documents.
- "Discharge summary" - To show discharge summary. Often a good place to start to get an overview of the patient.
- "Physician documents" - Discharge summaries, history & physical, physician transfer reports, etc.

Note: Filters may not always capture the intended documents.

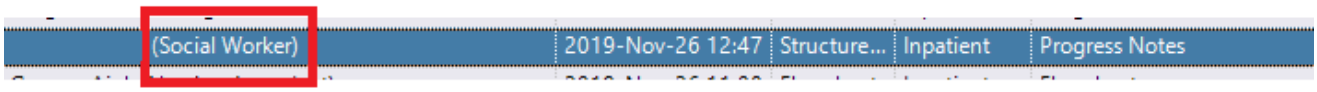


Document Authors

Looking for documents authored by different types of care providers to help find information.

Social workers - social determinants of health demographic questions such as homelessness & financial strain.

Occupational & physiotherapy – Employment & living situation questions.



DEMOGRAPHICS

Pre-populated

These fields will be automatically uploaded into RedCap for each chart.

1. Record ID
2. Institution (select from dropdown menu)
    - Foothills Medical Centre (80016)
    - Rockyview General Hospital (80020)
    - Peter Lougheed Center (80148)
    - South Health Campus (80576)
3. Sex at admission
    - M (male)
    - F (female)
4. Admission Date
5. Age at admission
6. Discharge Date
7. RHRN

Demographics / Social Determinants of Health

These fields will require the chart reviewer to manually input the data.

1. Date & time of review start (press Now button)
2. Was the patient transferred from another acute care hospital? **YES/NO**
3. Was the patient readmitted within 30 days of the last discharge from an acute care hospital? **YES/NO**
4. Did the patient die during this hospitalization? **YES/NO**
    - If **YES** – answer question 4, primary cause of death
    - If **NO** – move to question 5
    - *At the top of the chart, look for "Patient died on DATE" under the RHRN.*
5. Primary cause of death
    - It may be difficult to find the official cause of death as death certificate is a paper document.
    - Use Death Summary, Death Certificate, multidisciplinary progress notes. Write out the categories of death and stated condition(s)
6. Did the patient immigrate to Canada? (**YES/NO/Not documented**)
    - If **YES**
        - Answer question 7, what country did they immigrate from?
        - Answer question 8, were they a refugee?
    - **If NO** – move to question 9
7. What country did they immigrate from? (Select country of origin)

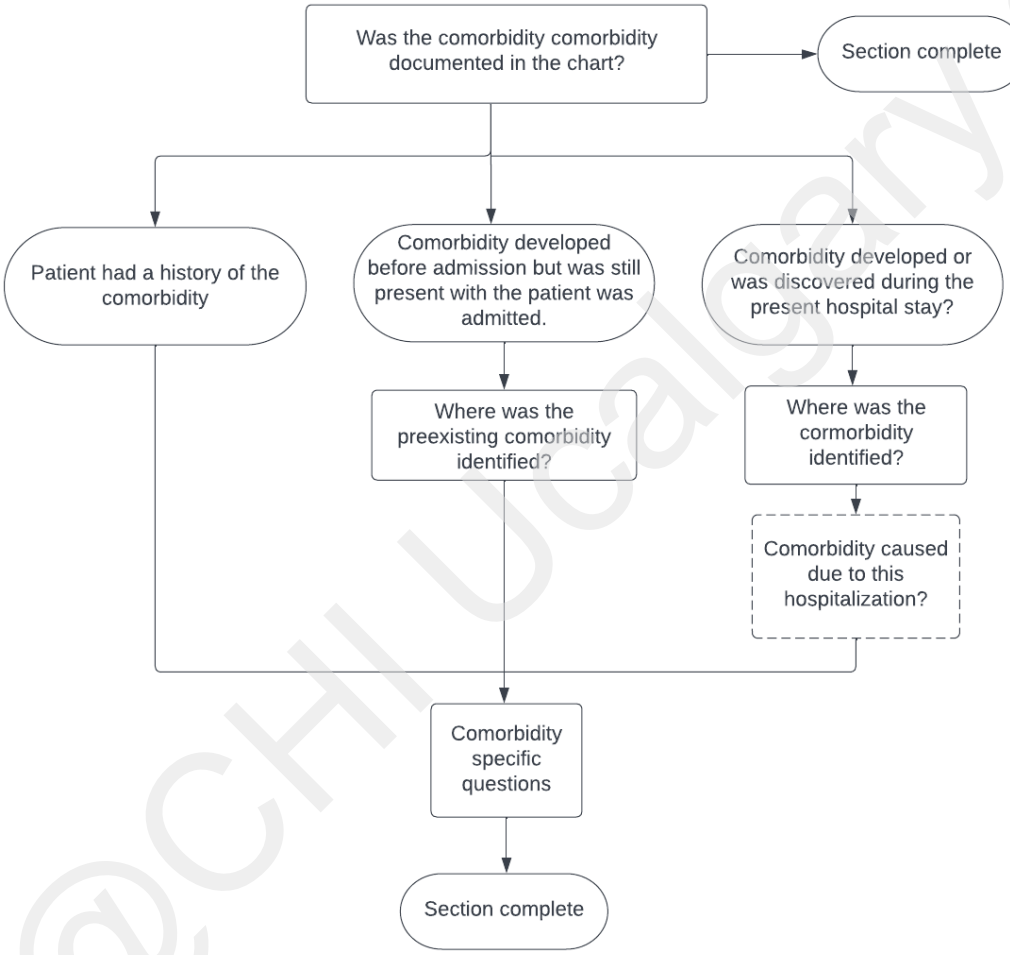
8. Were they a refugee? (**YES/NO/Not documented**)
9. Ethnicity
    - If patient is white South African or Japanese, select **other** & proceed to question 10.
    - Ethnicity may be found in the face sheet, history & physical and consult notes
10. Other ethnicity - if **other** selected for question 9, enter the patients' ethnicity here.
11. Marital status
    - If **other** is selected, answer question 15. Otherwise, move onto question 16.
    - Marital status may be found in the history & physical, nursing admission record, multidisciplinary progress record, discharge summary, social work, physiotherapy, and occupational therapy notes.
12. Other marital status – if **other** selected for question 14, enter the patient's marital status here.
13. Employment status
    - If the patient is **employed**, select **employed** from the dropdown menu and move to question 17.
    - Otherwise, select the correct option and move to question 18.
    - Employment status may be found in the history & physical, nursing admission record, multidisciplinary progress record, discharge summary, social work, physiotherapy, and occupational therapy notes.
14. Occupation
    - If **employed** selected for question 16, enter occupation here.
15. Was the patient living alone? (**YES/NO/Not documented**)
16. Is the patient homeless? (**Select the correct option**)
    - Homelessness describes the situation of an individual, family or community without stable, safe, permanent, appropriate housing, or the immediate prospect, means and ability of acquiring it.
    - May be found in the history & physical, nursing admission record, multidisciplinary progress record, discharge summary or **social work** notes.
17. Financial strain (**YES/NO/Not documented**)
    - If **YES** – answer question 18
    - If **NO** – move to question 19
    - May be found in the history & physical, nursing admission record, multidisciplinary progress record, discharge summary, or **social work** notes.
18. Describe the financial stain
    - If **YES** selected for question 20, describe the financial strain here.
19. Gender Identity (**textbox)**
    - e.g., male/female [specifically identified as gender, using gendered pronouns would be insufficient], genderqueer, genderfluid, non-binary, two-spirit, enby, agender etc.?
20. Transgender (**YES/NO/Not documented**)
    - YES – gender identity does not match sex assigned at birth
    - NO – gender identity matches sex assigned at birth
21. Date & time demographic review ends (press Now button)

COMORBIDITIES

Only data on the following comorbidities will be captured. The patient may have other comorbidities that aren't in this list, but data on those does not need to be collected.

1. Date and time comorbidity review starts
    - Before starting the comorbidity review, press Now button.

Figure 1. Flow of comorbidity survey



2. Date and time comorbidity review ends
    - After completing all the questions for each comorbidity, press Now button.

Myocardial Infarct

- ***Includes*** patients with one or more definite or probable myocardial infarctions of this admission; these had electrocardiographic and/or enzyme changes and myocardial necrosis.
- Patients with electrocardiographic changes alone are ***not*** designated as having had an infarction.
- ST Elevation MI (STEMI) and Non-ST Elevation MI (NSTEMI) are both designated as MI.
- ***Excludes*** acute coronary syndrome - angina. (40)

Myocardial Infarct Specific Questions

1) Did the patient undergo any cardiac procedures: (**Surgical and/or non-surgical**)
    - Non-surgical procedures
        - Cardiac catheterization,
        - Percutaneous coronary intervention
        - Cardioversion therapy
        - Others – if others, specify which in the **textbox**
    - Surgical procedures
        - Ablation
        - Heart valve surgery
        - Pacemaker
        - Bypass surgery / coronary artery bypass surgery,
        - Heart transplant surgery
        - Others – if others, specify which in the **textbox**

Congestive Heart Failure

- ***Includes*** acute and chronic systolic or diastolic heart failure; includes left, right, and biventricular heart failure with reduced or preserved ejection fraction.
- ***Includes*** heart failure from congenital deformities, valvular disease, hypertension, or pregnancy.
- ***Includes*** pulmonary edema with heart failure.
- ***Includes*** cardiomyopathy (any kind); cardiomegaly if HF is also listed; if pulmonary hypertension, also look for right heart failure.
- Various forms of edema or anasarca can be due to HF; as can be portal hypertension and chronic or end-stage kidney disease.
- **Can include* post-procedural pulmonary edema or HF but then it must be designated as 'developed after admission'. (40)

Congestive Heart Failure Specific Questions

1. Was the EF/LVEF (left ventricle ejection fraction) recorded during the hospital stay? (**YES/NO**)
    - If **YES** – specify the EF value (textbox, e.g., 55%)
    - If **YES** – specify date of documentation
      Can be found in discharge summary or in the echocardiography report

2. Did the patient undergo any cardiac procedures: (**Surgical and/or non-surgical**)
    - Non-surgical procedures
        - Cardiac catheterization,
        - Percutaneous coronary intervention
        - Cardioversion therapy
        - Others – if others, specify which in the **textbox**
    - Surgical procedures
        - Ablation
        - Heart valve surgery
        - Pacemaker
        - Bypass surgery / coronary artery bypass surgery,
        - Heart transplant surgery
        - Others – if others, specify which in the **textbox**

Peripheral Vascular Disease

- ***Includes*** diseases of arteries and arterioles with intermittent claudication or those who had a bypass for arterial insufficiency, those with gangrene or acute arterial insufficiency, and those with treated or untreated thoracic or abdominal aneurysm, or grafts to femoral or other peripheral arteries.
- ***Includes*** venous insufficiency.
- Refers to obstruction of large arteries **not** within the coronary, aortic arch, or brain. (40)

Cerebrovascular Disease

- ***Includes*** a group of brain dysfunctions related to disease of the blood vessels supplying the brain, where hypertension is the most important cause. Hypertension should be mentioned. Includes a current or history of a cerebrovascular accident (stroke) with minor or no residual effects and transient ischemic attacks (TIA).
- ***Can include*** hemorrhagic stroke, ischemic stroke, or transient cerebral ischemia (intracranial and subarachnoid hemorrhages, cerebral infarctions).
- ***Includes*** aneurysm or dissection of the carotid artery; includes carotid stenosis; carotid atherosclerosis.
- ***EXCLUDES*** traumatic intracranial hemorrhage and vascular dementia. (40)

Dementia

- ***Includes*** patients with chronic cognitive deficit.
- ***Includes*** Alzheimer disease dementia, vascular dementia, Parkinson disease dementia, or dementias due to brain atrophy, infections, toxins, and metabolic abnormalities (40)

Chronic Pulmonary Disease

- ***Includes*** COPD, asthma, chronic bronchitis, chronic bronchiectasis, emphysema, lung diseases from toxic exposures, chronic respiratory conditions due to exposure to gases

and fumes, from radiation, drug-induced chronic lung disease, & cystic fibrosis (40).
- ***Excludes*** pulmonary heart disease.

Rheumatologic Disease

- ***Includes*** patients with moderate to severe rheumatoid arthritis or bursitis, diseases with positive rheumatoid factors. Includes rheumatoid lung disease and vasculitis. Extra-articular features include nodules, pericarditis, pulmonary fibrosis, peripheral neuropathy and amyloidosis.
- ***Can include*** heart involvement from rheumatic fever.
- ***Includes*** Fibromyalgia which is characterized by chronic diffuse pain, intense fatigue and sleep disturbances often associated with anxiety or depression and triggered by physical or psychological trauma. It was recognized as a rheumatic disease by the WHO in 1992. (40)

Peptic Ulcer Disease

- ***Includes*** patients who have required treatment for ulcer disease, including those who have bled from ulcers (in the past- CE). Includes GERD (gastric esophageal reflux disorder), gastric, duodenal, peptic, and gastrojejunal ulcers without hemorrhage or perforation.
- ***Includes*** patients with acid-reducing medications documented **AND** explicit diagnosis of peptic ulcer disease as listed above (group consensus).
- ***EXCLUDES*** GI bleeds, acute hemorrhagic erosive gastritis, malignant neoplasms of stomach or intestines. (40)

Drugs used to treat PUD:

Proton Pump Inhibitors	• Omeprazole (Prilosec, Prilosec OTC) & Omeprazole magnesium (Losec), • Lansoprazole (Prevacid, Prevacid FasTab) • Rabeprazole & Rabeprazole sodium (Pariet) • Pantoprazole (Pantoloc) • Esomeprazole (Nexium)
Antacids	• Aluminum hydroxide (Almagel, Maalox, Mylanta), • Calcium carbonate (Tums, Rolaids Antacid, Extra Strength Calcium Antacid Chewable, Antacid 2, Gastrocalm, Bismuth) • Magnesium carbonate (Magmix) • Magnesium hydroxide (Milk of Magnesia) • Magnesium oxide • Magnesium trisilicate (Gasulsol) • Magnesium citrate (Citro-mag) • Calmax • Maaloc • Sodium bicarbonate

	• Sodium citrate (Alka-Seltzer, Bromo Madelon, E-Z-Gas 2)
H2 Antagonists	• Cimetidine, • Ranitidine (Zantac) • Famotidine (Pepcid, Pepcid AC) • Nizatidine (Axid)

Liver Disease

- ***Includes*** patients with metabolic liver disease, infectious liver disease, alcoholic liver disease (cirrhosis), portal hypertension and a history of variceal bleeding, all hepatitis acute or chronic.
- ***Includes*** hepatic failure, non-alcoholic fatty liver disease, drug/ toxin induced liver disease, autoimmune liver disease, polycystic liver disease, vascular disorders of the liver. (40)
- ***Includes*** acute liver injury.

Disease Severity

- **Mild disease:** viral hepatitis B or C, autoimmune hepatitis, primary biliary cholangitis, primary sclerosing cholangitis, hemochromatosis, Wilson, NAFLD, alcohol related fatty liver diseases (***WITHOUT*** cirrhosis).
- **Moderate disease**: cirrhosis ***WITHOUT*** decompensated features which **includes** ascites, hepatic encephalopathy, variceal bleeding, jaundice, Hepatocellular carcinoma, hepatorenal disease.
- **Severe disease**: decompensated cirrhosis (any of the decompensated features).

Liver Disease Specific Questions

1. What is the severity of the liver disease? (**mild/mod/severe or not documented**)
2. Was the Child-Pugh (cirrhosis mortality) score documented? (**YES/NO**)
    - If **YES**, specify the score (**textbox**, e.g., 1-15)
3. Was the MELD (model for end-stage liver disease) score documented? (**YES/NO**)
    - If **YES**, specify the score (**textbox**, e.g., 0-40)
4. What is the etiology of the liver disease? (**Select correct answer or not documented**)
    - Viral infections (HBV, HCV, etc.),
    - Alcohol abuse,
    - Non-alcoholic fatty liver disease,
    - Autoimmune disorders
    - Etiology documented as unknown
    - Not documented in chart

Diabetes

- ***Includes*** uncomplicated (Type 1 or 2) (Also considered mild diabetes and includes all diabetes treated with insulin or oral hypoglycemics, but not diet alone; without end-organ damage or extreme blood glucose reactions).

- Complicated diabetes ***includes*** retinopathy, neuropathy nephropathy or circulatory disorders (if linked to diabetes). Includes patients who had previous hospitalizations for ketoacidosis, hyperosmolar coma, or control and those with juvenile onset or brittle diabetics. (40)
- ***EXCLUDES*** 'borderline diabetic'.

Diabetes Specific Questions

1. Type of diabetes (**select correct answer or not documented**)
    - Type I
    - Type II
    - Other
    - Not documented in chart
2. Presence of *microvascular* complications (**select all that apply, or none documented**)
    - Retinopathy
    - Neuropathy
    - Nephropathy/dialysis/kidney transplant
    - None documented in chart
3. Presence of *macrovascular* complications (**select all that apply, or none documented)**
    - Coronary heart disease
    - Stroke
    - Peripheral vascular disease/amputations
    - None

Paralysis

- ***Includes*** patients with hemiplegia or paraplegia, whether it occurred because of a cerebrovascular accident or other condition.
- ***Includes*** quadriplegia, monoplegia, and diplegia (40).

Renal Disease

- ***Includes*** renal tubule-interstitial diseases, that is, any disease characterized by pathological changes to the renal tubules and interstitial tissues.
- ***Includes*** acute renal failure (acute kidney injury) including acute nephritis, pyelonephritis, acute tubular necrosis, acute renal infection (40)
- ***Includes*** chronic kidney disease with GFR <60 or presence of kidney damage that is present for more than 3 months. Evidence of kidney damage can include structural abnormalities (imaging or histology), albuminuria above normal limits, urinary sediment abnormalities or electrolyte disturbances due to tubular disorders.
- ***Includes*** chronic renal failure, chronic uremia, chronic renal insufficiency. Includes patients on or off all forms of long-term dialysis. (40)

Disease of Severity:

- **Mild renal**: includes those with serum creatinine of 2-3 mg%.
- **Moderate renal insufficiency**: includes patients with serum creatinine of >3 mg%. with uremia.
- **Severe renal disease**: includes patients on dialysis, those who had a transplant, and those with uremia.

Renal Disease Specific Questions

1. Type of disease
    - Acute renal failure
    - Chronic kidney disease
    - Other
    - Not documented in chart
2. Severity of disease (**mild/moderate/severe/not documented**)

Solid Tumor without Metastasis

- Tumor consists of patients with solid tumors ***without*** documented metastases, but initially treated in the last five years, including breast, colon, lung and a variety of other tumors.
- ***Includes*** malignant neoplasm, gastrointestinal stromal tumor, Merkel cell carcinoma of any location.
- ***Excludes*** tumor with metastasis.

Solid Tumor Specific Questions

1. Specify the type/location of cancer (**textbox**)
2. Cancer <u>pathological</u> TNM stage
    - *Cancer <u>pathological</u> TNM stage is a preferable measurement to cancer <u>clinical</u> TNM stage.*
    - If the cancer <u>pathological</u> TNM stage is documented, **select the stage here.**
    - If **not documented**, select **not documented** and move to clinical TMN question.
3. Cancer <u>clinical</u> TNM stage
    - If the cancer <u>pathological</u> TNM stage has already been documented, select "pathological TNM stage documented"
    - Otherwise, **select** the appropriate cancer clinical TMN stage or **not documented**.
4. Was this a recurrent tumor? (**YES/NO**)

Metastatic Cancer

- Metastatic cancer includes patients with metastatic solid tumors, including breast, lung, colon and other tumors.

Metastatic Cancer Specific Questions

1. Specify the location of metastasis (**textbox**)

2. Specify the location of the original cancer (**textbox**)

Leukemia

- ***Includes*** patients with acute and chronic myelogenous leukemia, acute and chronic lymphocytic leukemia, and polycythemia vera.

Lymphoma

- ***Includes*** patients with Hodgins, lymphosarcoma, Waldenstrom's macroglobulinemia, myeloma, and other lymphomas.

HIV/AIDs

- Human immunodeficiency virus disease / Acquired immune deficiency syndrome (HIV/AIDS).
- A case of HIV infection is defined as an individual with HIV infection irrespective of clinical stage including severe or stage 4 clinical disease, (also known as AIDS) confirmed by laboratory criteria. Includes patients with definite or probable AIDS, i.e., AIDS related complex. (42)

Hypertension

- ***Includes*** patients with any form of hypertension diagnosis, including controlled hypertensives; essential hypertension (e.g., from renal artery stenosis; aging), secondary hypertension, or hypertensive crisis. (40).
- Look at BPs only if diagnosis is contradictory. Systolic pressures must consistently be > 140 mmHg or diastolic pressures above 90 > Hg. (Use antihypertensive meds as a cue to look for hypertension which must be stated).

Psychosis

- Schizophrenia and other primary psychotic disorders are characterized by significant impairments in reality testing and alterations in behavior manifest in positive symptoms such as persistent delusions, persistent hallucinations, disorganized thinking (typically manifest as disorganized speech), grossly disorganized behavior, and experiences of passivity and control, negative symptoms such as blunted or flat affect and avolition, and psychomotor disturbances.
- Primary psychotic disorders include schizophrenia, acute and transient psychotic disorder, schizoaffective disorder, delusional disorder, and "other primary psychotic disorder". [50].
- Brief/transient psychotic disorder: "cannot be better accounted for by schizophrenia, schizoaffective disorder, mood disorder with psychotic features, or be a direct result of a drug, medication, or medical condition like thyrotoxicosis, sarcoidosis, or syphilis." [51]
- The symptoms occur with sufficient frequency and intensity to deviate from expected cultural or subcultural norms. These symptoms are the primary features of these disorders; they do not arise as a feature of another mental and behavioral disorder (e.g., a

mood disorder, delirium, or a disorder due to substance use). (Use antipsychotic meds as a cue to look for psychosis which must be stated, or the clusters of the stated symptoms must be present). (42)

Depression

- Depressive disorders are characterized by depressive mood (e.g., sad, irritable, empty) or loss of pleasure accompanied by other cognitive, behavioural, or neuro-vegetative symptoms that significantly affect the individual's ability to function.
- Depressive disorder should not be diagnosed in individuals who have ever experienced a manic, mixed or hypomanic episode, which would indicate the presence of a bipolar disorder. (40)
- Include if prescribed antidepressant drugs at admission **AND** discharge with a diagnosis of depression **OR** have a clear diagnosis of depression.
    - *Some of the drugs below are used in other conditions than depression, such as, anxiety problems, chronic pain, attention-deficit/hyperactivity disorder and as a smoking cessation aid. Look for depression or description of depression specifically.*

Drugs used to treat depression:

Selective serotonin reuptake inhibitors (SSRIs) **Also used to treat anxiety & chronic pain*	• fluoxetine (Prozac) • fluvoxamine (Luvox) • sertraline (Zoloft) • paroxetine (Paxil, Seroxat) • escitalopram oxalate (Lexapro, Cipralex) • citalopram (Celexa)
Serotonin and norepinephrine reuptake inhibitors (SNRIs) **Also used to treat anxiety & chronic pain*	• venlafaxine (Effexor) • duloxetine (Cymbalta) • desvenlafaxine (Pristiq).
Norepinephrine and dopamine reuptake inhibitors (NDRIs) **Also used to treat attention-deficit/hyperactivity disorder & as a smoking cessation aid*	• bupropion (Wellbutrin, Zyban) • Noradrenergic and specific serotonergic antidepressants • Mirtazapine (Remeron)
Cyclics	• amitriptyline (Elavil) • maprotiline (Ludiomil) • imipramine (Tofranil) • desipramine (Norpramin) • nortriptyline (Novo-Nortriptyline) • clomipramine (Anafranil)

Monoamine oxidase inhibitors (MAOIs)	• phenelzine (Nardil) • tranylcypromine (Parnate) • moclobemide (Manerix)

Remember!

After completing all the questions for each comorbidity, fill out the date and time that the comorbidity review ended, or press Now button.

ADVERSE EVENTS OVERVIEW

1. Date and time adverse event review starts
    - Before starting the adverse events review, press Now button.
2. Reason for current hospitalization as stated as the first problem on history and physical (**textbox**).
3. Did the patient undergo surgery during the present hospital stay?
    - If **YES** conduct review for **both** medical and surgical AEs.
    - If **NO**, only conduct review for medical AEs.

Medical Adverse Events

Please answer the following questions and review the patient chart, as appropriate, for the following Adverse Events. **Please reference the definition section of this document** to guide your identification.

1. Did the patient undergo a transfusion during the current hospital stay or have a history of transfusion mentioned in their chart? If yes, please review the patient's chart for **transfusion reaction**
2. Did the patient receive an **intravenous/central line or a catheter or mechanical ventilation** during their present hospital stay, or do they have a history of receiving one of these interventions mentioned in their chart? If yes, please review the patient's chart for **hospital acquired infection**.
3. Did the patient undergo **IV contrast CT or MRI or experience hospital-acquired dehydration** during the present hospital stay, or have a history of such mentioned in their chart? If yes, please review the patient's chart for **acute kidney injury**.
4. Did the patient **utilize a ventilator** during their present hospital stay or have a history of such mentioned in their chart? If so, please review the patient's chart for **ventilator related injury**
5. Please review the patient chart for the following:
    a. **Thromboembolic event**

b. **Pressure injury/decubitus ulcer**
c. **Falls and consequent harms (e.g., hip fracture or intracranial hemorrhage) during hospitalization**
d. **Adverse drug event**

Was a medical adverse event identified during the chart review?

- If **YES**, answer questions related to the medical adverse event identified.
- If **NO**, review surgical adverse events if applicable (i.e., had a surgery in the current hospital stay).

Surgical Adverse Events

Please answer the following questions and review the patient chart, as appropriate, for the following Adverse Events. **Please reference the definition section of this document** to guide your identification:

1. Did the patient undergo a procedure such as **subclavian jugular catheter insertion, or thoracentesis**, or have a history of this procedure mentioned in their chart? If so, please review the chart for **iatrogenic pneumothorax.**
2. Please review the patient chart for the following:
    a. **Surgical site infection**
    b. **Retained surgical item or unretrieved device fragment**
    c. **Wrong site surgery**
    d. **Post operative respiratory failure**
    e. **Post operative wound dehiscence**
    f. **Accidental puncture and laceration (APL)**

Was a surgical adverse event identified during the chart review?

- If **YES**, answer questions related to the surgical adverse event identified.

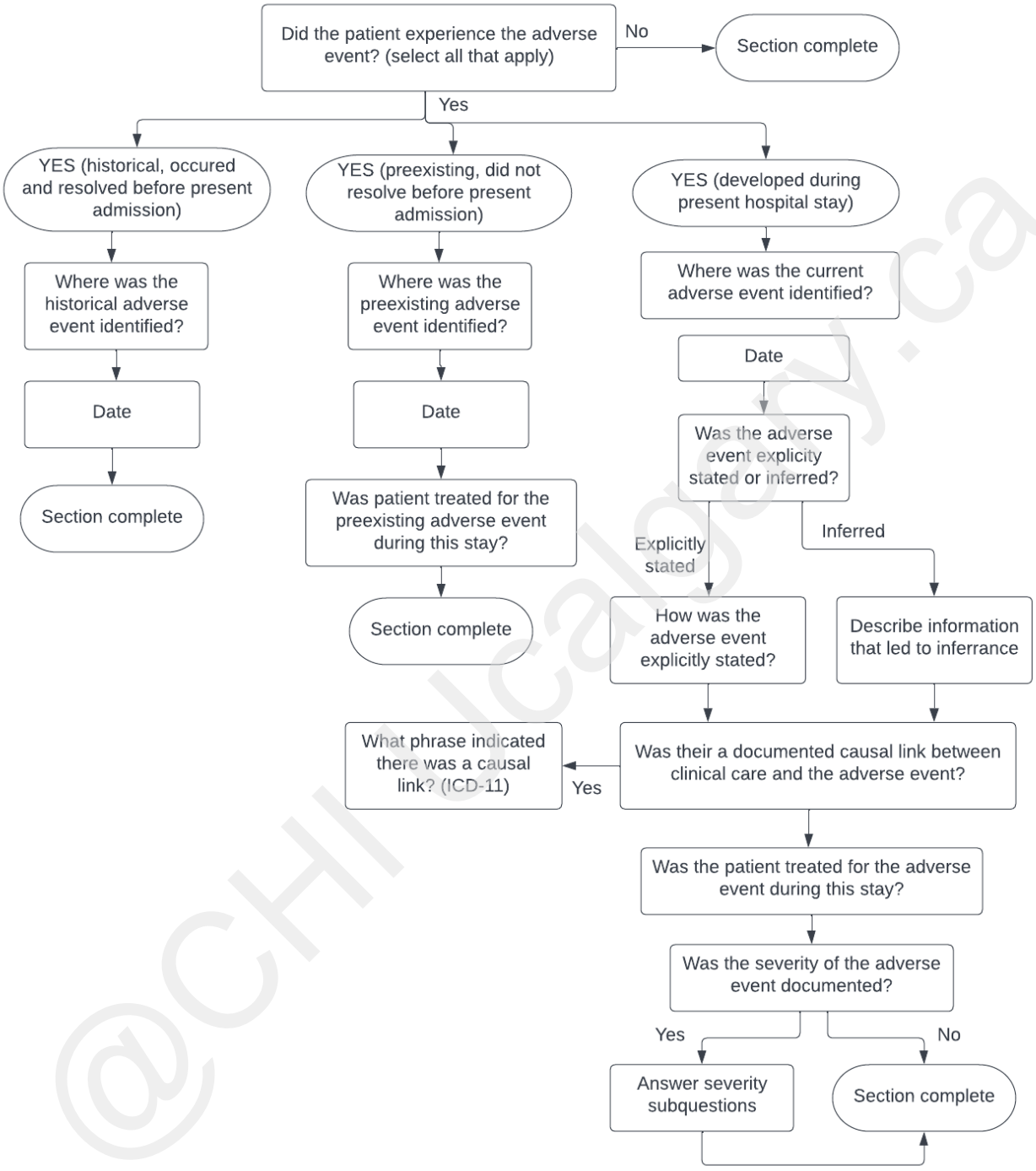
Notes

- Please see Figure 1 (flow of adverse events survey) for the general flow of questions related to each adverse event.
- Some adverse events may have questions specific to those adverse events that are not included in the flow diagram. These will be indicated in the adverse events definition section.
- There can be an overlap of Adverse Events (AEs) listed below, such as sepsis and medical care caused infection

Remember!

After completing all the questions for each adverse event identified, fill out the date and time that the adverse event review ended, or press Now button.

Figure 2. Flow of adverse events survey



ADVERSE EVENT DEFINITIONS

MEDICAL RELATED ADVERSE EVENTS

Transfusion Reactions

Definition:
A transfusion reaction is an adverse event caused by receiving whole blood, blood cells, or plasma through a transfusion. It can present as a minor allergic reaction, febrile non-haemolytic transfusion reactions (FNHTRs), transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), hypotensive reactions, anaphylactic reactions, venous thromboembolism (VTE), transfusion-transmitted bacteraemia or viral infection, transfusion-related sepsis, hyperfibrinolysis, and haemolysis [28].

Indicators:

- Transfusion reactions can occur during a transfusion (acute transfusion reaction) or days to weeks later (delayed transfusion reactions) [39]
- A transfusion order or documentation should be available in the chart.
- Completion of a type and screen may also indicate a patient had a transfusion.
- Signs and symptoms:
    - Common: fever, chills, urticaria, and itching [39].
    - Serious reactions: anaphylaxis, respiratory distress, high fever, hypotension, and hemoglobinuria [39].
- Look for MPR documentation of a reaction and how it was treated.
    - May be treated with fluids, epinephrine, or antihistamines (i.e., benadryl)

Notes:

- Similar wording or **synonyms** for transfusion may include transfuse, blood exchange, transfer, transmission, exchange, blood-transfusion, or transference.
- **Transfusion reaction specific questions**: If it occurred, find out the **type** of transfusion reaction (e.g., FNHTRs, TRALI, TACO, VTE, or transfusion-transmitted bacteria or viral infection). There might be multiple different types of transfusion reactions documented due to the same or different transfusions.
    - Febrile non-hemolytic transfusion reaction (FNHTR) - most common
    - Transfusion related acute lung injury (TRALI)
    - Transfusion-associated circulatory overload (TACO)
    - Venothromboembolism (VTE)
    - Transfusion-transmitted bacterial or viral infection
- Record any transfusion reactions present at the time of admission or historically (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Selected Hospital Acquired Infections

- ***Intravenous / Central Line Infections***
- ***Catheter Related Urinary Tract Infections***
- ***Ventilator Associated Pneumonia***

Definition:
As opposed to the community acquired infection, hospital acquired infections are infections occurring in hospital settings regarded as adverse events caused by medical care such as intravenous (IV) or central line insertion, catheter-related urinary tract infection (UTI) & ventilator associated pneumonia (VAP).

Ventilator associated pneumonia (VAP) is defined as "pneumonia occurring more than 48 hours after patients have been intubated and received mechanical ventilation" [46].

Indicators:
- A **cause** (IV/central line/urinary tract catheterization/mechanical ventilation) for the infection should be established.
- Common IV or central line insertions include:
    - Peripherally Inserted Central Catheter (PICC),
    - Subclavian jugular catheter insertion,
    - Peripheral IV (IV catheter placed in the hand or arm)
    - Femoral or internal jugular (IJ) line,
    - Dialysis line
    - Tunneled central line.
- Bacterial cultures are usually ordered when infection is suspected
    - Blood cultures in line infections
    - Urine cultures in UTIs
    - The tip of the line may also be sent for analysis
- Patients in the ICU are especially at risk of ventilator associated pneumonia [46]
    - Ventilator associated/acquired pneumonia (VAP) is often explicitly stated in the patient's chart.
    - Be careful of distinguishing between VAP & community acquired pneumonia that leads to intubation/ventilation. Community acquired pneumonia does not count as a healthcare associated infection.

Notes:
- **Synonyms/inclusions for hospital acquired infection**: nosocomial infection, iatrogenic infection, and medical care induced infection.
- There might be multiple infections that occur during the same hospital stay such as UTI + IV/central line infections.
- Identify and record infections present at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations findings at the time of admission).

Acute Kidney Injury due to Medical Care

Definition:
Acute kidney injury (AKI) is a sudden decline of renal function or kidney damage/failure that happens within a few hours or days [32, 33]. The acute decline of renal function is usually caused by functional or structural changes in kidneys [34]. AKI is common among hospitalized patients, especially in older patients and intensive care unit patients [35]. Due to a build-up of waste products in blood, AKI can affect other organs such as the brain, heart, and lungs, thus causing a wide range of symptoms [36]. AKI due to medical care is AKI that has an identified medical care cause.

Indicators:

- The determination of **causal** relationship (such as temporality) between AKI and medical care is key.
- IV contrast CT or MRI
- Severe dehydration
- Elevated creatinine, decreased estimated glomerular filtration rate (eGFR)
- Secondary to other adverse events/comorbidities
    - Hospital acquired sepsis
    - Conditions affecting the flow of blood to the kidneys such as heart failure, shock, certain surgeries.
- The presence of AKI increases the odds of developing chronic renal damage or failure, so if patient was diagnosed with chronic renal failure, then look for potential AKI prior to chronic renal failure.

Notes:

- Record all instances of AKI present at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission)
- **Possible synonyms/inclusions for AKI:** acute kidney failure (AKF) or acute renal failure (ARF).
- Severity of AKI [43]
    - **Stage 1**: Serum creatinine 1.5-1.9 times baseline and/or urine output <0.5 ml/kg/h for 6–12 hours
        - OR increase in serum creatinine ≥0.3 mg/dl (>26.5 µmol/l) increase
    - **Stage 2**: Serum creatinine 2.0-2.9 times baseline and/or urine output <0.5 ml/kg/h for ≥12 hours
    - **Stage 3**: Serum creatinine 3.0 times baseline and/or urine output <0.3 ml/kg/h for ≥24 hour Or Anuria for ≥12 hours
        - OR increase in serum creatinine to ≥4.0 mg/dl (353.6 µmol/l)
        - OR initiation of renal replacement therapy

Ventilator Related Injury

Definition:

Ventilator related injury is the injury **caused by mechanical ventilation**, which may include oxygen toxicity and lung injury. Ventilator related lung injury resembles the symptoms of acute respiratory distress syndrome (ARDS) and can be classified as volutrauma (due to large tidal volumes), atelectrauma (repeated alveolar collapse and expansion), biotrauma (due to mediators and activated leukocytes), and barotrauma (caused by high alveolar pressure) [37, 38]. Oxygen toxicity includes absorption atelectasis (high concentrations of oxygen causing circulating nitrogen reduction and then decreased surface tension), and hypoventilation/hypercapnia (supplemental oxygen administration results in decreased respiratory drive) [38].

Indicators:

- Although ventilator related injury could be caused by non-invasive mechanical ventilation, most of the time it is a result of **invasive ventilation**.
- Look for patients who have had a **history of ICU admission or underwent surgery** during this admission or previous as those patients are more likely to have undergone mechanical ventilation.
- Recurrent use of mechanical ventilation or a history of mechanical ventilation use should be identified in the chart.

Notes:

- Flag all instances of ventilator related injury presented at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).
- **Exclude** ventilator acquired pneumonia (VAP) as it is captured in the healthcare acquired infection category.
- **Possible synonyms/ inclusions for ventilator related injury**: ventilator-induced lung injury, ventilator-associated lung injury, ventilator-dependent lung injury.

Thromboembolic Event

Definition:

Thromboembolic events (TE) or venous thromboembolisms (VTEs) include deep vein thrombosis (DVT) and pulmonary embolism (PE).

- **Deep Vein Thrombosis (DVT):** a blood clot (thrombus) forms in one or more of the deep veins – usually in the lower extremities (e.g., leg, thigh) or pelvis, but can also occur in the arms. The risk of DVT is increased by various factors such as surgery, cancer, smoking, overweight/obesity, increased estrogen (e.g., oral contraceptives), or prolonged bed rest.
- **Pulmonary Embolism (PE):** a blockage of the lung's main artery or one of its branches by a substance that has traveled from elsewhere in the body through the bloodstream (embolism). PE usually results from a DVT. A small proportion of cases are caused by embolization of air, fat, or talc in intravenous drugs, or amniotic fluid.

Indicators:

- **Radiologic examination**
    - compression U/S, CT, chest X-ray, or V/Q scan
    - A positive radiological report of **PE** includes those where a filling defect was identified in the central, segmental, or subsegmental pulmonary arteries.
    - A positive radiological report of **DVT** is where a thrombus identified in the proximal deep veins of the lower extremities (e.g., external iliac, common femoral, deep femoral, or popliteal), in the deep distal veins of the lower extremities (e.g., peroneal and posterior tibia), or in the deep veins of the upper extremities (e.g., brachial, radial, ulnar, axillary or subclavian).
- Patients may have a positive d-dimer; however, this alone is not a definitive indicator of PE.
- **Treatments**
    - Medications (may also be prophylactic, e.g., atrial fibrillation, immobile patients)
        - Direct oral anticoagulants (rivaroxaban, apixaban, dabigatran, etc.)
        - Warfarin
        - Subcutaneous or intravenous (IV) anticoagulants
            - IV Heparin, Subcutaneous heparin
            - Enoxaparin, Fondaparinux
    - Thrombolysis
    - Inferior vena cava (IVC) filter
    - Surgical thrombectomy

Notes:

- ***Exclude*** thrombus identified in a superficial vein of the lower extremity (e.g., saphenous) in a superficial vein of the upper extremity (e.g., cephalic), or in a perforating vein of the lower extremity but not extending into a deep vein.
- ***Exclude*** line thrombosis.
- **Possible synonyms/inclusions for DVT:** Venous thrombus, venous thrombosis, venous thromboembolism, proximal-vein thrombosis, calf-vein thrombosis, distal vein thrombosis.
- **Exclusion for DVT:** superficial thrombophlebitis.

Pressure Injury / Decubitus Ulcer

Definition:

Pressure injuries are localized injury to the skin and/or underlying tissue, commonly over a bony prominence, resulting from pressure alone or in combination with shear and/or friction [1]. Although it is preventable, the prevalence is still high. Varying by healthcare facility and patient group, the prevalence of PI can be as high as 38% [2]. They commonly occur in patients with limited mobility, such as those in hospital or long-term care settings. In patients using wheelchairs, the common sites of PI include the tailbone/buttocks, shoulder blades and spine, backs of arms and legs. For patients staying in bed, the common sites of PI include the back or sides of the head, shoulder blades, hip, lower back or tailbone, heels, ankles and skin behind the knees. A PI can lead to further comorbidities such as osteomyelitis, tunneling, fissure, or event sepsis.

Indicators:

- Wound dressing change documentation, which may be found in the MPR.
- Frequent repositioning to reduce pressure, which may be noted in the MPR, nursing & care assessments.
- Wound care consult in orders and MPR.
- **Pressure injury risk scoring systems**:
    - PI risk scoring systems include Waterlow scale, Braden scale, Jackson/Cubbin scale, and Norton scale**.**
    - **High** score (>=1) on the Waterlow (for general patients) scale indicates a **high risk** of PI.
    - **Low** score on the Braden (for general patients), Jackson/Cubbin (for ICU patients), and Norton scales (for general patients**) indicates high risk** of PI.
    - Use these scores (if present) to look further for pressure ulcers if the risk is high.

Notes:

- Stages of pressure injuries:
    - **Stage 1**: The skin does not present with an open wound. The skin may be painful, but it has no breaks or tears. The area can feel either firmer or softer than the area around it.
    - **Stage 2**: The skin breaks open, wears away, or forms an ulcer, which is usually tender and painful. The sore expands into deeper layers of the skin. It can look like a scrape (abrasion), blister, or a shallow crater in the skin. Sometimes this stage looks like a blister filled with clear fluid.
    - **Stage 3**: The sore gets worse and extends into the tissue beneath the skin, forming a small crater. Fat may show in the sore, but not muscle, tendon, or bone.
    - **Stage 4**: The pressure injury is very deep, reaching into muscle and bone and causing extensive damage. Damage to deeper tissues, tendons, and joints may occur.
- **Possible synonyms/inclusions for PI:** pressure ulcers, decubitus ulcers, bedsore, skin breakdown, skin ulceration
- If the patient presented with stage 1 or 2 PI initially but **progressed** to stage 3 or 4 during hospitalization, then a PI adverse event should be considered during hospitalization.

Falls and Consequent Harms during Hospitalization
(e.g., Hip Fracture or Intracranial Hemorrhage)

Definition:

A fall is an unplanned descent event that results in a person coming to rest inadvertently on the ground or floor or other lower level [13, 14]. Around one third of falls cause physical injury [15]. Some falls in hospitalization may only result in mild injury such as bruise, pain, laceration, while some falls may lead to devastating consequences such as hip fracture or intracranial hemorrhage. Falls in hospital are common adverse events with incidence around 6 per 1,000 occupied bed days [16, 17].

Indicators:

- Use of a bed alarm may indicate the patient is at a high risk of falls. Documentation of "bed alarm on" may be found in the nursing assessment.
- In the patient chart, falls may be indicated by "fall", "patient found on floor", "side rails up X4", or similar notation, often in the MPR.
- The patient may require imaging such as a head CT post-fall.
- More frequent monitoring of patient and vital signs post-fall.
- Surgery, closed reduction for fractures.

Notes:

- Flag all falls, and related injuries present at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Sepsis due to Medical Care

Definition:

- Sepsis is a dysfunctional syndromic response to infection causing damage to tissue or organs, which is frequently a final common pathway to death from many infectious diseases [21].
- Clinically, sepsis is determined by presence of infection **plus** two systemic inflammatory response syndrome criteria [22].
    - **SIRS criteria**: Temperature >38.0°C (or <36.0°C), heart rate >90/minute, respiratory rate >20 /minute, white blood cells >12*109/L (or <4*109/L) [23,25]
- **Severe sepsis** is sepsis with at least one consequent organ failure (organ failure present 48 hours prior to onset of sepsis is excluded) [21].
- **Sepsis due to medical care** is defined as sepsis that occurs because of medical care such as surgery, catheterization, hospital acquired infection [23]. The key is to identify the causal relationship between medical care and sepsis.
- ***Include*** sepsis related to an infection of a remotely inserted device (I.e., artificial bladder the patient has had x 5 years).
- Patients with severe underlying chronic disease or undergoing complex procedures are predisposed to sepsis. The common preceding conditions of sepsis include healthcare-acquired infection (HAI) (infection that is contracted in a healthcare facility). Technically, sepsis is the systemic inflammatory response syndrome (SIRS) following documented or presumed infection.

Indicators:

- Infections need to be identified before the occurrence of sepsis due to medical care.
- Patient may have been flagged as having a hospital acquired infection or surgical site infection as an adverse event which would indicate to look for sepsis.
- Technically, any type of infection caught in a healthcare facility is a HAI, however some types of bacteria are more common in these types of places than others. These include:
    - Methicillin-resistant Staphylococcus aureus (MRSA),

  - Clostridium difficile (C. difficile or C. diff)
  - Vancomycin-resistant Enterococcus
  - Norovirus
- There may be the presence of a sepsis protocol order set.
- Sepsis has a high rate of occurrence in the ICU [27]; an ICU stay can indicate to look for sepsis.
- SOFA (Sequential Organ Failure Assessment) score [26] may appear in the chart indicating the organ failure. Basically, SOFA score >=2 indicates >10% in-hospital mortality.

Notes:

- It is crucial to establish the **causal relationship** between sepsis and health care causes. For example, a non-septic patient developed sepsis after a non-emergent procedure should be highly suspected for sepsis due to medical care
- Some wording or terms may indicate sepsis: infection and organ dysfunction/failure, septic shock, persisting hypotension requiring vasopressors to maintain; infection and SIRS, acute respiratory distress syndrome (ARDS) (a type of respiratory failure).
- Other diagnostic confirmation of sepsis: laparotomy or surgical findings of infection, surgical debridement, chest X-ray consistent with ARDS/ALI. Any X-ray/CT consistent with ischemia, any X-ray/CT consistent with infection, any X-ray/CT consistent with abscess, abdominal X-ray/CT consistent with free air [27].
- Record infections diagnosed at admission or before (i.e., community-acquired infections) such as pneumonia, kidney, bladder and other parts of the urinary system, digestive system, bloodstream (bacteremia), catheter sites, wounds or burns, need to be captured and scrutinized when determining medical care caused sepsis. Sepsis presented at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations findings at the time of admission).

Adverse Drug Event

Definition:

- Adverse drug events include **all harm caused by a medication** whether it is
  a. a known pharmacological property of the medication
  b. the result of the medication being given in error (wrong dose, wrong route, wrong patient)
- Adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product' [48].
- Harm caused by medication can include any abnormal sign, symptom, laboratory test, syndromic combination of such abnormalities, untoward or unplanned occurrence (e.g., an accident or unplanned pregnancy), or any unexpected deterioration in a concurrent illness during or after administration of a medication [47].
- May be preventable (i.e., wrong dose given) or non-preventable (i.e., Lasix increasing creatinine – a known side effect).

Indicators:

- **Symptoms:**
  - Skin reactions (urticaria, pruritis)
  - GI symptoms: constipation, diarrhea, nausea +/- vomiting, mucositis
  - Fatigue, drowsiness, myelosuppression, alopecia, anorexia
  - Anaphylaxis in severe drug allergies
  - Medication specific reactions (i.e., extra beta blocker dose = bradycardia)
- A report about the ADE may be available in the chart if an ADE occurred, likely found in MPR.
- The drug classes mainly involved include:
  - Antithrombotic
  - Antibiotics
  - Renin-angiotensin system (RAS)-inhibitors,
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Diuretics.
- Any drug class can be involved in a medication error.

Notes:

- The common ADEs range from cutaneous, gastrointestinal, hematological, vascular, metabolic, neurological, cardiac, and general disorders.
- There might be multiple ADEs that occurred during the same hospitalization. Some patients may be admitted to hospital due to ADE or may have had a historical ADE. Ensure to record all ADEs presenting historically or those diagnosed at time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).
- **Possible synonyms/inclusions for ADE**: medication errors, adverse drug reactions, allergic reactions, overdoses and missed doses

OPERATION / PROCEDURE RELATED ADVERSE EVENTS

Iatrogenic Pneumothorax

Definition:
Iatrogenic pneumothorax is a traumatic pneumothorax that results from injury to the pleura, with air introduced into the pleural space secondary to diagnostic or therapeutic medical intervention. While the most common causes of iatrogenic pneumothorax include pulmonary needle biopsy (transthoracic and transbronchial), placement of a central venous line, or positive pressure ventilation, it may be a result of many other procedures involving the thorax and abdomen [20].

Indicators:

- Within the current admission, a **specific procedure** needs to be identified prior to iatrogenic pneumothorax.
- Procedures:
    - Pulmonary needle biopsy (transthoracic and transbronchial)
    - Placement of central venous line (e.g., subclavian jugular catheter insertion)
    - Thoracentesis
    - Pacemaker insertion
    - Positive pressure ventilation
    - Other procedures involving the thorax and abdomen

Notes:

- After this is identified then look for the description of the iatrogenic pneumothorax including site, severity, and repairing treatment for the iatrogenic pneumothorax, etc.
- To determine the severity (tension or open pneumothorax) of iatrogenic pneumothorax utilize information available in the chart such as the progress notes, nursing notes, discharge summary, or imaging reports.
- There could be multiple iatrogenic pneumothoraces occurring at the same time or different times. Some patients may experience or present at admission with pneumothorax (such as primary spontaneous, secondary to existing lung disease, or traumatic pneumothorax. These types of pneumothoraces need to be distinguished from iatrogenic pneumothorax.
- If a patient is diagnosed with chest injury or trauma or pleural effusion, or a procedure (e.g. diaphragmatic surgery or repair, thoracic surgery, cardiac surgery, Lung or pleural biopsy, operation on esophagus, anterior thoracic spinal fusion or thoracic duct surgery) done before the admission, then exercise caution when determining if iatrogenic pneumothorax occurred.
- To be cautious record Iatrogenic pneumothorax presenting at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Surgical Site Infection

Definition:
Surgical site infection (SSI) is an infection that occurs after surgery in the part of the body where the surgery took place, **usually within 30 days of surgery** [3]. SSI can be superficial, involving the skin alone, or more serious involving tissues under the skin, organs, or implanted material. Risk factors of SSI include the type of wound (dirty or contaminated wound), long surgery time (>2 hours), overweight, old age, cancer, smoking, compromised immunity, diabetes, emergency surgery, and abdominal surgery.

Indicators:

- An incident recorded on the post–operation complications severity, i.e., Clavien-Dindo Classification 'surgical wound classification' can be indicative of possible SSI.
- Phrasing such as 'clean-contaminated, contaminated, and dirty/infected' can suggest a possible SSI despite this not being explicitly noted in the patient's chart [4]
- An incision with pain, tenderness, localized swelling, redness, heat/fever, abscess or other evidence of infection involving an organ or organ space (related to a surgery/procedure) that is found on physical exam, during an invasive procedure, pathology report, or imaging test (e.g., ultrasound, MRI, CT).
- Organisms isolated from a(n) [aseptically obtained] culture of fluid or tissue from an incision and/or subcutaneous tissue around operative site, an incision was opened or drained with positive culture.

Notes:

- A laparoscopic trocar site is considered a surgical incision (not a stab wound).
- A **tracheostomy** site infection will be considered a surgical site infection.
- According to ASEPSIS scoring system, potential indicators of severity include additional treatment, serous discharge, erythema, purulent exudate, Separation of deep tissues, isolation of bacteria and stay as inpatient prolonged over fourteen days [5,6].
- The below scenarios, by themselves, are **not** considered as an SSI:
  1. Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet criterion for superficial incisional SSI.
  2. A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration), does not meet criterion for superficial incisional SSI.
  3. A localized stab wound, or pin site infection is **not** considered an SSI. Depending on the depth, these infections might be considered either a skin or soft tissue infection.
- **Other possible synonyms indicating SSI:** surgical wound infection, wound infection, surgical incision infection.

Retained Surgical Item or Unretrieved Device Fragment

Definition:

- A **retained surgical item** is any surgical sponge, instrument, tool, or device that is unintentionally left in the patient at or after the completion (e.g., after skin closure) of a

surgery or other procedure [7].
    - For instance, even if the patient is still in the operating room under anesthesia, a vaginal sponge remaining after a vaginal procedure or delivery is considered a retained surgical item.
- An **unretrieved device fragment** is a broken or fractured portion of a medical device that was never intended to remain in a person's body for an extended time, either because no attempt was made to retrieve it, or the attempt was unsuccessful [8].
    - For instance, catheter and guidewire fractures that result in unretrieved device fragments can be caused by inappropriate techniques, flaws in its manufacture, design, or damaged materials in shipment or storage. Although both incidents are rare, the consequences are significant.

Indicators:
- The specific surgery/procedure should be present in the chart (surgery report). Common surgical types include vascular, colectomy, pancreatectomy, proctectomy, hepatectomy, thyroidectomy, esophagectomy, appendectomy, gynecology, hysterectomy, hip fracture, cystectomy, nephrectomy and prostatectomy
- Retained items or unretrieved device fragments may include:
    - Medical needle, gauze, sponge, medical/surgical supply, including disposable products (e.g., catheter, surgical stapler).
    - **Most commonly retained surgical items**: Woven cotton surgical sponge (including laparotomy pads and smaller sponges) [7].

Notes:
- The retained surgical item might not be explicitly described in the notes. Therefore, to be cautious, flag cases with principal diagnosis of **retained surgical item** or **unretrieved device fragment** at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Wrong-Site Surgery

Definition:
Wrong-site surgery refers to surgery on the wrong site / side, the wrong procedure, the wrong implant, or the wrong patient. The estimated rate of wrong-site surgery is about 1 in 100,000 procedures based on one systematic review [9].

Indicators:
- The specific surgery/procedure should be present in the chart (surgery report). Common surgical types include vascular, colectomy, pancreatectomy, proctectomy, hepatectomy, thyroidectomy, esophagectomy, appendectomy, gynecology, hysterectomy, hip fracture, cystectomy, nephrectomy and prostatectomy
- More common wrong-site surgery sites

- Symmetrical structures involved in surgery (eyes, lungs, kidneys, legs)
- Body parts with similar components involved in surgery (digits, spinal levels)
- The location of surgery consists of multiple structures (medial vs. lateral, anterior vs. posterior, proximal vs. distal, etc.)

Notes:

- Wrong site surgery might not be explicitly noted in the patient chart.
- To be cautious, flag cases with wrong-site surgery diagnosis or history at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Post-Operative Respiratory Failure

Definition:
Postoperative respiratory failure (PRF) is ventilator dependency for more than 48 hours or unplanned reintubation within 30 days of procedure or surgery, which could be failure to wean from the ventilator immediately following the procedure or prolonged intubation any time within 30 days of procedure or surgery [9]. Although the incidence is low (1%–3%) [10], it results in significantly worse mortality and morbidity, and financial burdens for the health system. Risk factors for PORF include emergent procedures, higher American Society of Anesthesiologists classification, emergency operations, more complex operation, preoperative sepsis, and elevated creatinine, older age, male sex, smoking, and history of congestive heart failure and/or chronic obstructive pulmonary disease, among others.

Indicators:

- The specific surgery/procedure should be present in the chart (surgery report).
  - Common surgical types include vascular, colectomy, pancreatectomy, proctectomy, hepatectomy, thyroidectomy, esophagectomy, appendectomy, gynecology, hysterectomy, hip fracture, cystectomy, nephrectomy and prostatectomy.
- **Indirect indicators** (PRF might not be explicitly documented in the patient chart)
  - Frequent blood gas testing/monitoring after surgery indicating low PO2 or high PCO2
  - ICU transfer
  - Failed extubation following surgery.
- **Treatment**
  - Oxygen supplementation
  - Postoperative reintubation & mechanical ventilation
  - Use of non-invasive mechanical ventilation
    - e.g., continuous positive airway pressure (CPAP)
- Comorbidities may increase patient risk of PRF
  - Congestive heart failure
  - Chronic obstructive pulmonary disease (COPD)
- Respiratory therapist documentation in the MPR or other locations may help identify PRF and

treatments.

Notes:

- To be cautious, flag cases with principal diagnosis of respiratory failure at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Post-Operative Wound Dehiscence

Definition:

Post-operative wound dehiscence is a partial or total separation of previously approximated wound edges, due to a failure of proper wound healing, which usually occurs about 5-8 days after surgery [11]. The risk factors of dehiscence include ischemia, infection, increased tissue tension / pressure around the wound, diabetes, malnutrition, smoking, and obesity [12].

Indicators:

- The specific surgery/procedure should be present in the charts (surgery report).
    - Common surgical types include vascular, colectomy, pancreatectomy, proctectomy, hepatectomy, thyroidectomy, esophagectomy, appendectomy, gynecology, hysterectomy, hip fracture, cystectomy, nephrectomy and prostatectomy.
- **Indirect**
    - Wound infection
    - Prolonged wound healing/care (most wounds heal within 2 weeks of surgery)
    - Surgical repair of the wound
- The MPR may have documentation on the wound and dressing changes.
- Look for a wound care consult in the orders and MPR.

Notes

- To be cautious flag cases with principal diagnosis of post-operative wound dehiscence at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

Accidental Puncture and Laceration (APL)

Definition:

- Accidental puncture or laceration (APL) is an accidental perforation during a procedure on a blood vessel, nerve, or organ.
- ***Excludes*** iatrogenic pneumothorax, laceration due to implanted device, dural laceration during spine surgery, and any injury sustained during pregnancy, childbirth, and puerperium [18].
- ***Excludes*** fractures that are a known complication of surgery (i.e., rib fractures due to retractors, femur fractures during hip replacement surgery).

- APLs range from small serosal tears to internal organ injuries. Accidental puncture and lacerations are not uncommon with the risk-adjusted rate of APL being around 3 per 1,000 eligible patients [19].

Indicators:

- A specific procedure needs to be identified as the cause for the APL.
    - Surgery, endoscopy, infusion, dialysis or other perfusion procedures, heart catheterization, or other **non-excluded** procedures [18]
- Documentation of the APL may be found in the procedure record
- The MPR may have documentation about care of the APL post procedure.
- Enterotomy (surgical incision into intestine) may cue for APL.

Notes:

- Once identified, describe the specific APL including site, type, severity etc.
- To determine the **severity** of ALP, look for documentation regarding how the ALP affected the patient and the entire care plan including a description of the consequences of the APL, documentation of increased operating time and changes to the intended procedure(s) due to the APL, documentation of potential increased length of stay due to the APL.
- There could be **multiple** APLs occurring at the same time or different times. To be cautious record APL presenting at the time of admission (e.g., evidence in medical history, admission diagnosis, or physician examinations finding at the time of admission).

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