Action on Patient Safety: High 5s

Standard Operating Protocol

Deutsche Version

Vermeidung von Eingriffsverwechslungen

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Action on Patient Safety: High 5s ist ein Kooperationsprojekt zum Thema Patientensicherheit, an dem sich ausgewählte Länder, die Weltgesundheitsorganisation (WHO) und das WHO Collaborating Centre for Patient Safety beteiligen.

Großzügige initiale Unterstützung für dieses Projekt gewährten die U.S. Agency for Healthcare Research and Quality, die WHO sowie der Commonwealth Fund. Als Projektsekretariat fungiert die Joint Commission International (JCI), die zusammen mit der Joint Commission das WHO Collaborating Centre for Patient Safety konstituiert.

Ziel des High 5s-Projekts ist die Förderung der Implementierung und Evaluation standardisierter Lösungskonzepte zur Patientensicherheit innerhalb einer globalen Lerngemeinschaft, um eine messbare, signifikante und nachhaltige Reduzierung von relevanten Patientensicherheitsproblemen zu erreichen. Zu den Teilnehmerstaaten gehören derzeit Australien, Deutschland, Frankreich, Großbritannien, Kanada, die Niederlande, Saudi-Arabien, Singapur sowie die USA. Im Rahmen dieser Kooperation hat Kanada die führende Rolle bei der Entwicklung der Handlungsempfehlung zur Sicherstellung der richtigen Medikation bei Übergängen im Behandlungsprozess übernommen; die Handlungsempfehlung zum Management von konzentrierten injizierbaren Medikamenten wurde unter Leitung von Großbritannien und die Handlungsempfehlung zur Vermeidung von Eingriffsverwechslungen unter Leitung der USA entwickelt. Alle teilnehmenden Länder haben ihre fachliche Expertise bei der Entwicklung der Konzepte zur Implementierung, den SOP-Indikatoren, der Zwischenfallanalyse und der Evaluation, allesamt integraler Bestandteil der Handlungsempfehlungen (SOP), eingebracht.

Inhaltsverzeichnis

Standard Operating Protocol
zur Vermeidung von Eingriffsverwechslungen
Action on Patient Safety: High 5s

Das vorliegende Standard Operating Protocol (SOP) wurde zur ausschließlichen Verwendung im Rahmen des Projekts Action on Patient Safety - High 5s entwickelt. Dabei handelt es sich um ein international koordiniertes Projekt mit einer begrenzten Teilnehmerzahl, in dem die Umsetzbarkeit von standardisierten Handlungsempfehlungen zur Patientensicherheit und die Auswirkungen einer Implementierung hinsichtlich bestimmter Patientensicherheitsoutcomes geprüft werden. Da eine Wirksamkeit dieser oder einer anderen High 5s-SOP noch nicht nachgewiesen werden kann, wird eine Implementierung außerhalb des High 5s-Projekts derzeit nicht empfohlen. Nach Abschluss des Projektes werden die Ergebnisse publiziert und die SOP nach einer Optimierung, falls erforderlich, für die Implementierung in einer breiten Öffentlichkeit zur Verfügung gestellt.

Beschreibung des Patientensicherheitsproblems

Ein Eingriff[1] an der falschen Körperstelle, die Durchführung eines falschen Eingriffs und die Durchführung einer Operation an der falschen Person (sog. Eingriffsverwechslungen) sind vermeidbar, und scheinen sehr viel häufiger vorzukommen als lange Zeit angenommen. In frühen Studien zu Eingriffsverwechslungen wurde als häufigste Ursache das Fehlen entscheidender Präventivmaßnahmen während der präoperativen Phase identifiziert. Neuere Ursachenanalysen haben ergeben, dass diese Präventivmaßnahmen zwar Eingang in die Verfahrensweisen gefunden haben, aber nicht einheitlich ausgeführt werden.

Beschreibung des präoperativen Vorbereitungsprozesses

Grundlagen und Hintergründe

Eine ordnungsgemäß durchgeführte Operation erfordert die korrekte Identifizierung des Patienten, die korrekte Diagnosestellung, die Auswahl des richtigen Verfahrens, die Festlegung des korrekten Operationssitus, die richtige Lagerung des Patienten sowie die Verfügbarkeit aller erforderlichen Apparate und Instrumente. Diese SOP basiert auf folgenden Prinzipien:

- Eine Operation an der falschen Körperstelle, die Durchführung eines falschen Eingriffs und die Operation an der falschen Person können und müssen verhindert werden.
- Es bedarf einer stabilen Vorgehensweise (unter Anwendung mehrerer einander ergänzender Strategien), um eine Operation an der falschen Körperstelle, einen falschen Eingriff sowie den Eingriff an der falschen Person zu vermeiden.
- Wichtig für den Erfolg ist die aktive Beteiligung und effektive Kommunikation aller Mitglieder des perioperativen Teams.
- Der Patient (bzw. sein gesetzlicher Vertreter) sollte in dem Maße, in dem dies möglich ist, in diesen Prozess eingebunden werden.
- Die größte Wirksamkeit lässt sich durch die einheitliche Implementierung eines Standard Operating Protocol erzielen.

[1] Diese SOP bezieht sich auf alle Patienten, die in einem stationären OP-Bereich einem Eingriff unterzogen werden (auch ambulante Eingriffe). Ausgenommen sind Eingriffe und Prozeduren, die in der Endoskopie, in Katheterlaboren, geburtshilflichen und ambulanten Einrichtungen durchgeführt werden.

Drei Bestandteile der effektiven Implementierung

Die Vermeidung von Eingriffsverwechslungen verlangt nach der einheitlichen, effektiven Implementierung der drei folgenden Komponenten:

1. **Präoperativer Verifikationsprozess**
   - **Ziel**: Verringerung des Risikos einer Verwechslung von Patient und operativem Eingriff, indem sichergestellt wird, dass alle relevanten Dokumente und diagnostischen Untersuchungsergebnisse vor Operationsbeginn vorliegen, dass diese Unterlagen korrekt identifiziert und gekennzeichnet sind und sich auf den richtigen Patienten beziehen; dass sie überprüft wurden und mit den Erwartungen des Patienten sowie den Informationen des Operationsteams über den zu operierenden Patienten, den Eingriff, den Eingriffsort und gegebenenfalls etwaige Implantate übereinstimmen. Vor Operationsbeginn müssen fehlende Informationen beschafft oder Diskrepanzen ausgeräumt werden.
   - **Prozess***:* Fortlaufender Prozess der Beschaffung und Verifizierung von Informationen, der mit der Entscheidung über die Durchführung des Eingriffs anfängt, sich über sämtliche Bereiche und Interventionen erstreckt, die in die präoperative Vorbereitung des Patienten eingebunden sind, und schließlich mit einem „Team-Time-Out" kurz vor Operationsbeginn endet.
2. **Markierung des Eingriffsortes**
   - **Ziel**: Zweifelsfreie Identifizierung des richtigen Eingriffsortes zur korrekten Bestimmung der Inzisions- oder Insertionsstelle.
   - **Prozess**: Bei allen Eingriffen, bei denen die Körperseite oder mehrere Strukturen, Körperflächen oder -ebenen eine Rolle spielen, muss der vorgesehene Eingriffsort so markiert werden, dass die Markierung nach Hautdesinfektion und steriler Abdeckung des Patienten noch sichtbar ist (gilt nicht für routinemäßige Venenpunktionen oder das Legen eines peripheren Venenkatheters).
3. **Ein „Team-Time-Out" unmittelbar vor Beginn des Eingriffs**
   - **Ziel**: Durchführung der abschließenden Verifikation des richtigen Patienten, des richtigen Eingriffs, des richtigen Eingriffsortes und, sofern zutreffend, der richtigen Lagerung des Patienten, der richtigen Implantate und der erforderlichen Spezialapparaturen/-instrumente.
   - **Prozess**: Aktive Kommunikation zwischen allen Mitgliedern des chirurgischen/Operationsteams, die von einem dazu bestimmten Teammitglied immer wieder initiiert und in einem fehlersicheren („Fail-Safe"-) Modus durchgeführt wird; d.h. der Eingriff beginnt erst nach Klärung etwaiger Fragen oder Bedenken.

Anhang 1 enthält ein detailliertes Flussdiagramm mit den einzelnen Schritten und Entscheidungspunkten bei der Vorbereitung eines chirurgischen oder anderen invasiven Eingriffs.

Kontext der standardisierten präoperativen Vorbereitung zur Vermeidung von Eingriffsverwechslungen

Die effektive und effiziente Implementierung des präoperativen Prozesses zur Gewährleistung des richtigen Eingriffsortes, des richtigen Eingriffs und des richtigen Patienten verlangt die Integration der einzelnen Schritte in die bestehenden Prozesse der Patientenbeurteilung und Diagnostik, der präoperativen Vorbereitung und des Patientenflusses, und nicht einfach nur die Einführung neuer Aufgaben.

Wichtig ist daher, die anderen Aspekte der Patientenversorgung zu identifizieren, an die eine präoperative Vorbereitung gekoppelt sein muss; dazu zählen:

- Patientenbeurteilung vor der Einweisung (durch niedergelassenen Arzt oder Klinik)
- diagnostische Untersuchungen (Laboruntersuchungen, bildgebende Verfahren, Biopsie etc.)
- Prozess der Einholung der Einverständniserklärung des Patienten
- Maßnahmen der Operationsplanung
- Prämedikationsvisite und präoperative pflegerische Beurteilungen
- Einweisung des Patienten/Aufnahme in die chirurgische Abteilung
- Vorbereitung des Eingriffsortes
- Prämedikation
- Vorbereitung des Operationssaales

- Pflegedokumentation
- Weitergabe von Informationen unter den Leistungserbringern

Angesichts der Erkenntnis, dass die Vermeidung von Eingriffsverwechslungen weitgehend eine Frage der Informationsbeschaffung und Weitergabe von Informationen unter den Mitgliedern des perioperativen Teams ist, werden sich die Details der Implementierung in erheblichem Umfang nach den in Ihrem Krankenhaus bestehenden Systemen und Prozessen zur Informationserhebung, -nutzung und -weitergabe richten, z.B. handschriftliche Patientenakten im Papierformat *versus* elektronische Patientenakten. Die Informationsmanagement-Aktivitäten, die diese SOP unterstützen, sollten daher so weit wie möglich in diese bestehenden Systeme und Abläufe integriert werden, indem Sie Ihre derzeit verwendeten Werkzeuge (Formulare, Checklisten, Datenerhebungsinstrumente etc.) anpassen und Ihre Arbeitsabläufe darauf abstimmen, um die Effizienz des integrierten Prozesses zu optimieren.

Schließlich hat auch die Kultur der jeweiligen Gesundheitseinrichtung im Hinblick auf interdisziplinäre Zusammenarbeit und Teamwork einen signifikanten Einfluss auf die Effizienz und Wirksamkeit des präoperativen Vorbereitungsprozesses. Dieser Prozess lässt sich am besten im Umfeld gemeinsam getragener Verantwortung durchführen, und genau in diesen Kontext ist das vorliegende Standard Operating Protocol eingebettet.

Beziehung zwischen der High 5s-SOP Vermeidung von Eingriffsverwechslungen und der WHO Surgical Safety Checklist

Beide Initiativen haben die Verbesserung der Sicherheit chirurgischer Eingriffe zum Ziel. Dementsprechend haben sie auch bestimmte Merkmale gemeinsam. Sie sind allerdings nicht identisch, aber miteinander kompatibel. Die **High 5s-SOP** zur Vermeidung von Eingriffsverwechslungen fokussiert auf eine Risikoreduktion für eine bestimmte Gruppe von chirurgischen Komplikationen, nämlich falscher Patient, falscher Eingriff oder falscher Eingriffsort. Um die Ziele des High 5s-Projekts zu erreichen, sollten die teilnehmenden Krankenhäuser die SOP befolgen und ihre Leistungen im Hinblick auf die SOP-Implementierung wie auch ihren Erfolg bei der Vermeidung von Eingriffsverwechslungen (Verwechslung von Patient, Eingriff und Eingriffsort) messen.

Im Gegensatz dazu befasst sich die **WHO Surgical Safety Checklist** mit einem viel breiteren Spektrum von perioperativen Risiken. Die Checkliste steht allen Einrichtungen zur Verfügung, die davon Gebrauch machen wollen, und kann auf Wunsch der Anwender an die jeweils vor Ort üblichen Vorgehensweisen angepasst werden.

Der **Anhang 2** beinhaltet die WHO Surgical Safety Checklist (Erste Auflage) vom Juni 2008, sowie die beiden deutschen Versionen der Deutschen Gesellschaft für Chirurgie (DGCH) und der Deutschen Gesellschaft für Allgemein- und Viszeralchirurgie (DGAV). Das Handbuch zur Implementierung der Checkliste im englischsprachigen Original steht zur Verfügung unter: http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html .

Wo sich die beiden Initiativen überschneiden – bestimmte präoperative Kontrollen, Markierung des Eingriffsortes und ein Team-Time-Out vor Operationsbeginn – sind die Erwartungen konsistent. Unterschiede bestehen im Umfang der jeweils damit verbundenen perioperativen Aktivitäten.

Bei der **High 5s-SOP** zur Vermeidung von Eingriffsverwechslungen wird der präoperative Verifikationsprozess stärker betont. Dieser Prozess beginnt, wenn der Eingriff terminiert wird, und setzt sich durch den gesamten präoperativen Prozess fort.

Dagegen wird die **WHO Surgical Safety Checklist** präoperativ am OP-Tag selbst angewendet. Zudem umfasst sie eine postoperative „Sign-out"-Phase, die nicht Bestandteil der High 5s-SOP ist.

Beide Initiativen mit ihren verschiedenen Schwerpunkten sind sinnvoll und ihre Implementierung wird daher auch für alle Einrichtungen empfohlen, die chirurgische Leistungen erbringen.

Anwendungsbereich des Standard Operating Protocols

Im Rahmen des High 5s-Projekts ist die SOP für alle Eingriffe anzuwenden, die im OP-Bereich eines Krankenhauses stattfinden, in dem stationäre Patienten operiert werden (ausgenommen sind: Endoskopie, Katheterlabore, rein geburtshilfliche Einrichtungen und Einrichtungen für ausschließlich ambulante Eingriffe). Als Mindestanforderung für eine Markierung gilt, dass der Eingriffsort durch Lateralität (z.B. bei Extremitäten, paarigen Organen) oder durch mehrere Körperflächen oder -ebenen (z.B. Beuge- oder Streckseite, oder bestimmte Wirbel) bzw. -strukturen (z.B. ein bestimmtes Finger- oder Zehenglied, oder eine bestimmte Hautläsion) gekennzeichnet

ist. In Absprache mit den Projektkrankenhäusern kann individuell festgelegt werden, dass eine Markierung für alle Eingriffe durchgeführt wird.

Beschreibungen der einzelnen Komponenten des präoperativen Vorbereitungsprozesses

Damit die drei grundlegenden Komponenten dieser SOP (präoperativer Verifikationsprozess; Markierung des Eingriffsortes; „Team-Time-Out“) konsistent umgesetzt werden, sollte Folgendes eingehalten werden:

1. Präoperativer Verifikationsprozess

Die Verifikation der richtigen Person, des richtigen Eingriffs und des richtigen Eingriffsortes erfolgt

- zum Zeitpunkt, zu dem die Operation bzw. der Eingriff angesetzt wird
- zum Zeitpunkt der Untersuchung und Beurteilung des Patienten vor seiner Einweisung
- zum Zeitpunkt seiner Einweisung oder Aufnahme in das Krankenhaus
- jedes Mal, wenn die Verantwortung für die Versorgung des Patienten auf eine andere Betreuungsperson übertragen wird (als formaler Bestandteil des Übergabeprozesses)
- wenn möglich unter Beteiligung des Patienten, solange er wach und bei Bewusstsein ist
- bevor der Patient den präoperativen Bereich verlässt bzw. vor Eintritt in den Operationssaal

Eine präoperative Verifikationscheckliste (High 5s OP-Checkliste) dient dazu, Vorhandensein und Überprüfung folgender Faktoren vor Operationsbeginn zu gewährleisten:

- relevante Dokumentation (z.B. Ergebnisse der Anamnese, der körperlichen Untersuchungen, Einwilligungserklärungen, pflegerische und anästhesiologische Beurteilungen)
- Ergebnisse der diagnostischen Untersuchungen einschl. Biopsieberichte
- relevante Aufnahmen, korrekt beschriftet und aufgehängt
- spezifische Größe und spezifischer Typ eventuell benötigter Implantate sowie Angaben zu benötigten Spezialinstrumenten

2. Markierung des Eingriffsortes

- Markieren Sie für die Inzision oder perkutane Instrumentierung alle Stellen, bei denen Körperseite, Körperfläche (Beugeseite, Streckseite) oder Körperebene (Wirbelsäule) eine Rolle spielen, oder den jeweiligen Finger/Zeh bzw. die Läsion, die behandelt werden soll.
- In Absprache mit den Projektkrankenhäusern kann individuell festgelegt werden, dass eine Markierung für alle Eingriffe durchgeführt wird.
- Die Markierung des Eingriffsortes sollte vorzugsweise von der Person vorgenommen werden, die den Eingriff durchführt (Operateur). Ist das nicht möglich, kann die Markierung des Eingriffsortes von einer zuständigen Person, die beim Eingriff direkt oder bei dessen Vorbereitung (z.B. aufklärender Arzt) beteiligt ist, durchgeführt werden.
- Das Krankenhaus legt die Mindestqualifikation der verantwortlichen Person (Arzt, Pflegende) und deren Rolle (direkt beteiligt am Eingriff / Vorbereitung des Eingriffs) fest, an die die Markierung des Eingriffsortes delegiert wird.
- Bei jedem zu markierenden Fall ist die zuständige Person über die Patientenakte (vorzugsweise über die High 5s OP-Checkliste) zu identifizieren.
- Der Eingriffsort wird vor Eintritt des Patienten in den Operationssaal markiert.
- Die Markierung erfolgt, wenn möglich, unter Beteiligung des Patienten und solange dieser wach und bei Bewusstsein ist.
- Die Markierung wird an oder in der Nähe der geplanten Inzisionsstelle gesetzt. Markieren Sie auf keinen Fall Stellen, die nicht zum Eingriffsort gehören, es sei denn, dies ist aus anderen medizinischen Gründen erforderlich.
- Die Markierung muss eindeutig sein. Empfohlen wird die Verwendung der Initialen des Operateurs mit oder ohne einer Linie, welche die beabsichtigte Inzision darstellen soll.
- Die Markierung wird so angebracht, dass sie nach der Hautdesinfektion und steriler Abdeckung des Patienten noch sichtbar ist.

- Die Markierung erfolgt mit Hilfe eines wischfesten Hautmarkers, damit sie auch nach Abschluss der Hautdesinfektion noch sichtbar bleibt. Die Verwendung von Aufklebern reicht zur Markierung der Operationsstelle allein nicht aus.
- Im gesamten Krankenhaus werden dieselbe Markierungsmethode und dieselbe Art von Markierung angewendet.
- Bei Eingriffen an der Wirbelsäule werden zusätzlich zur präoperativen Hautmarkierung der groben Spinalregion spezielle intraoperative radiographische Techniken zur Markierung der exakten Wirbelhöhe eingesetzt.
- Bei Verfahren mit Minimalzugang zur Behandlung eines lateralisierten inneren Organs (gleichgültig ob perkutan oder durch eine natürliche Körperöffnung) muss die vorgesehene Seite an oder nahe der Insertionsstelle markiert werden (zu alternativen Vorgehensweisen siehe unten).
- Die endgültige Verifizierung der Markierung des Eingriffsortes erfolgt während des „Team-Time-Outs".
- Für Patienten, die eine solche Markierung des Eingriffsortes verweigern, steht eine festgelegte Vorgehensweise zur Verfügung.
- Von der Markierungspflicht ausgenommene Fälle:
  - Frühgeborene, bei denen die Markierung eine dauerhafte Tätowierung verursachen kann
  - In Fällen, in denen die Markierung des Eingriffsortes technisch oder anatomisch nicht möglich oder unpraktisch ist (z.B. Schleimhäute, Perineum, Frühgeborene), wendet man alternative Verfahren zur visuellen Identifizierung der richtigen Seite an, z.B. kann auf der Seite, auf der der Eingriff erfolgen soll, vorübergehend ein Armband angebracht werden, auf dem der Name des Patienten, ein zweites Identifizierungsmerkmal, der vorgesehene Eingriff und der Eingriffsort vermerkt sind.
  - Lebensbedrohliche Notfälle, in denen die für die Markierung benötigte Zeit nach ärztlichem Ermessen ein inakzeptables Risiko darstellt.

3. Abschließende „Team-Time-Out"-Verifikation unmittelbar vor Operationsbeginn

- Die abschließende Verifizierung erfolgt kurz vor Operationsbeginn in dem Raum, in dem die Operation durchgeführt wird; dabei ist der Patient bereits korrekt für den bevorstehenden Eingriff gelagert.
- Am abschließenden „Team-Time-Out" muss das gesamte Operationsteam durch aktive Kommunikation teilnehmen.
- Das „Team-Time-Out" wird von einem qualifizierten Koordinator initiiert. Die Koordinatorenfunktion sollte in allen Fällen vom gleichen Mitglied des OP-Teams, z.B. vom Operateur oder Springer oder einer anderen Person, übernommen werden.
- Während des „Team-Time-Outs" ruhen alle anderen Aktivitäten, und zwar in dem Umfang, der möglich ist, ohne die Sicherheit des Patienten zu gefährden, damit alle Mitglieder des OP-Teams sich auf die aktive Verifizierung des richtigen Patienten, des richtigen Eingriffs, des richtigen Eingriffsortes sowie anderer kritischer Elemente konzentrieren können.
- Beim „Team-Time-Out" müssen mindestens folgende Punkte überprüft werden:
  - die richtige Identität des Patienten
  - die richtige Seite und der richtige Eingriffsort
  - Einigkeit hinsichtlich des vorgesehenen Eingriffs
  - die richtige Lagerung des Patienten
  - Vorhandensein der richtigen Implantate und Spezialinstrumente
- Die Klärung von Unstimmigkeiten in den Antworten während des „Team-Time-Outs" wie auch etwaiger Diskrepanzen zwischen den Antworten und der Einverständniserklärung (Informed Consent) sowie anderen verfügbaren Dokumenten folgt einem festgelegten Prozess.
- Das „Team-Time-Out" wird in einem fehlersicheren („Fail-safe"-) Modus durchgeführt, d.h. die Operation beginnt erst dann, wenn alle Unstimmigkeiten, Fragen oder Bedenken abgeklärt sind.
- Das „Team-Time-Out" wird auf der präoperativen Checkliste dokumentiert.

Beteiligung des Patienten und seiner Angehörigen

Die Wirksamkeit dieses Prozesses wird durch die Beteiligung des Patienten und seiner Angehörigen noch verstärkt. Eine solche Beteiligung sollte erwartet und gefördert werden, indem man die Betroffenen in den Prozess der Einverständniserklärung, in die Verifikation der Identität und die Markierung des Eingriffsortes einbezieht, indem man sie über den präoperativen Vorbereitungsprozess informiert, dem der Patient unterzogen wird, indem

man sie über die Risiken aufklärt und ihnen mitteilt, worauf sie achten sollen, und indem man sie ermutigt und ihnen die Möglichkeit gibt, etwaige Bedenken und Sorgen zu äußern. Patienten, die die Markierung des Eingriffsortes verweigern, sollten über die mit einem solchen Verzicht verbundenen Risiken aufgeklärt werden.

Zulässige Abweichungen vom präoperativen Vorbereitungsprozess

Wie oben bereits erwähnt, wird die Implementierung zum einen durch das kulturelle Umfeld und die strukturellen Rahmenbedingungen beeinflusst, in die dieser Prozess implementiert wird, zum anderen auch durch die besonderen Merkmale und die Ressourcen der jeweiligen Gesundheitseinrichtung sowie die einzelnen Elemente bereits bestehender Prozesse, die an die präoperative Vorbereitung gekoppelt sind. Im vorliegenden Standard Operating Protocol bemühen wir uns um Einheitlichkeit in Bezug auf die grundlegenden Schritte des Prozesses, ihre Wechselbeziehungen, die Zuweisung von bestimmten kritischen Aufgaben an spezifische Fachdisziplinen/Berufsgruppen sowie Mindestanforderungen an die Dokumentation und Erfassung von Daten, wohingegen wir im Hinblick auf das Format von Dokumentation und Erfassung Flexibilität zulassen.

Ziel dieser SOP ist die Durchführung der präoperativen Vorbereitung als einer multidisziplinären Aktivität, wobei sich Chirurgen, Anästhesisten, Pflegende, technische Assistenten und andere an der präoperativen Versorgung des Patienten beteiligte Personen die Verantwortung teilen. Wird eine Aufgabe einem bestimmten Mitglied des Operationsteams übertragen, gilt jegliche Delegation dieser Aufgabe als Anpassung der SOP. Wie alle anderen Adaptationen muss ein solches Vorgehen gegenüber der Lead Technical Agency[2] (LTA) begründet und mit ihr abgesprochen werden. Die LTA muss eine Anpassung formal beantragen und nachweisen, dass diese Adaptation im Hinblick auf die Patientensicherheit dem in der vorliegenden SOP beschriebenen Prozess ebenbürtig ist. Alle einrichtungs- oder länderspezifischen Änderungen dieser SOP müssen von der High 5s Steering Group[3] zugelassen werden.

Implementierungsstrategie für die Durchführung des richtigen Eingriffs am richtigen Eingriffsort

Bei der präoperativen Vorbereitung handelt es sich um einen komplexen Prozess, an dem zahlreiche Fachdisziplinen/Berufsgruppen aus mehreren Versorgungsbereichen beteiligt sind - angefangen bei der diagnostischen Eingangsuntersuchung bis zum Beginn einer operativen Maßnahme. Während die grundlegenden Prinzipien der informationsbasierten Entscheidungsfindung und Kommunikation zwischen den Mitgliedern des Teams allgemein akzeptiert sind, lassen sich beim Prozess selbst oftmals große Unterschiede beobachten. Er ist anbieterzentriert (statt patientenzentriert) und hierarchisch strukturiert (statt teambasiert), und wird wahrscheinlich auf Widerstand stoßen, falls seine Implementierung nicht systematisch mit der angemessenen Überwachung und den erforderlichen Ressourcen sowie der frühzeitigen Einbindung der Betroffenen in den Prozess erfolgt.

Überwachung der Implementierung

1. Ernennen Sie für das Implementierungsprojekt ein Aufsichtsgremium (z.B. die Klinikleitung oder eine andere Führungsgruppe).
2. Ernennen Sie einen leitenden Mitarbeiter aus dem administrativen oder klinischen Bereich, um eine direkte Überwachung der Implementierungsaktivitäten, der Zuteilung des Personals, der Zuweisung von Zeit an das Personal zur Erledigung der Arbeiten sowie die Allokation anderer Ressourcen zu gewährleisten (die ärztliche Leitung der Implementierungsbemühungen kann die Gewinnung anderer Ärzte für das Projekt erleichtern).
3. Ernennen Sie einen oder mehrere Vertreter der am präoperativen Prozess beteiligten Berufsgruppen und klinischen Funktionsträger (wenigstens Chirurgen, Anästhesisten, Pflegepersonal, chirurgisch-technische Assistenten, MTA, MTRA, MLTA sowie OP-Planer), der/die die Planung, Testung und Einführung des neu gestalteten präoperativen Prozesses steuern und in seinem jeweiligen Fachgebiet als Vorbild und „Vorkämpfer" für den neuen Prozess wirken kann.

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[2] Verantwortliche, nationale Einrichtung für die Koordinierung des Projektes (in Deutschland: Ärztliches Zentrum für Qualität in der Medizin (ÄZQ) und Aktionsbündnis Patientensicherheit (APS))

[3] Steuergruppe auf internationaler Ebene bestehend aus Vertretern der Teilnehmerländer und der koordinierenden Institutionen

4. Ernennen Sie einen Moderator (eine Person, die sich mit dem präoperativen und dem operativen Prozess auskennt und über Fertigkeiten im Projektmanagement verfügt), um den Projektarbeitsplan zu erstellen und zu steuern.

Projektarbeitsplan

(alle oben genannten Berufsgruppen/Fachdisziplinen sollten an sämtlichen Schritten des Projektarbeitsplans beteiligt werden)

1. Erstellen Sie eine detaillierte Aufgabenliste für Planung, Testung, Schulung, Implementierung und Bewertung des präoperativen Vorbereitungsprozesses.
2. Legen Sie Meilensteine und ihre Zieldaten fest; dabei sollten mindestens folgende Aspekte erfasst werden:
    a) Genehmigung des Projektarbeitsplans durch das Aufsichtsgremium
    b) Genehmigung des Pilottestplans
    c) „Go-live"-Termin für den Pilottest
    d) Vorlage der Pilottestergebnisse beim Aufsichtsgremium
    e) „Go-live"-Termin für die Vollimplementierung (12–18 Monate nach dem Starttermin)
3. Legen Sie für jede der Projektaufgaben die jeweiligen Abhängigkeiten und einen realistischen zeitlichen Rahmen fest.
4. Legen Sie für jede der Projektaufgaben die auszuführenden Arbeiten und Fälligkeitsdaten fest.
5. Weisen Sie den einzelnen Aufgaben Ressourcen zu.

Detaillierte Informationen zur Erstellung eines Projektarbeitsplanes sind auch dem Getting Started Kit zu entnehmen.

Risikobewertung des präoperativen Vorbereitungsprozess

1. Beschreiben Sie den Prozess (verwenden Sie dazu z.B. ein Flussdiagramm, das auf der Grundlage des in **Anhang 1** vorgestellten Prototyps erstellt wurde).
2. Identifizieren Sie für jeden der Prozessschritte und für jede Verknüpfung zwischen den einzelnen Schritten die Stellen, an denen der Prozess fehlschlagen könnte oder an denen er die verlangte Funktion nicht erfüllt (**Anhang 3**).
3. Identifizieren Sie die potenziellen Wirkungen, die ein Fehlschlagen oder eine Fehlleistung des Prozesses auf die Patienten haben könnten, sowie den Schweregrad dieser Effekte.
4. Stufen Sie die potenziellen Fehlschläge bzw. Fehlleistungen nach ihrer Priorität ein.
5. Stellen Sie fest, warum es zu den Fehlschlägen bzw. Fehlleistungen höherer Priorität kommen konnte.
6. Implementieren Sie Kontrollen, Warnhinweise oder protektive Maßnahmen, um das Risiko einer Schädigung der Patienten zu minimieren.

Durchführung eines Pilottests zum präoperativen Vorbereitungsprozess

1. Ermitteln Sie eine oder mehrere Abteilungen, in denen ein Vorversuch (Pilottest) durchgeführt werden soll – üblicherweise handelt es sich dabei um eine allgemeinchirurgische Abteilung, die für alle prä- und intraoperativen Funktionen des Krankenhauses repräsentativ ist.
2. Erheben Sie die Ausgangsdaten, anhand derer sich Diskrepanzen in den aktuellen Prozessen der Abteilung/den Abteilungen feststellen lassen, in denen der Pilottest durchgeführt wird.
3. Beteiligen Sie Vertreter der Pilottest-Abteilung(en) an der Versuchsplanung und Implementierung.
4. Adaptieren Sie die vorgeschlagenen präoperativen Vorbereitungsprozesse an die Besonderheiten der jeweiligen Pilottest-Abteilung(en).
5. Schulen Sie das Personal, das an der Pilottestung des neuen Prozesses teilnehmen wird; berücksichtigen Sie dabei, dass diese Personen als Trainer des übrigen Krankenhauspersonals fungieren werden, wenn die Vollimplementierung des neuen Prozesses ansteht.
6. Implementieren Sie den neuen Prozess in der Pilottest-Abteilung / den Pilottest-Abteilungen.

7. Erfassen Sie, inwieweit die Implementierung der einzelnen Prozessschritte einheitlich, rechtzeitig und korrekt umgesetzt wurde (für spezifische Indikatoren siehe unten).
8. Erfassen Sie die Auswirkungen auf damit verwandte und verknüpfte Aktivitäten.
9. Erfassen Sie die Auswirkungen auf die Patienten.
10. Werten Sie die Pilottestdaten aus und legen Sie diese dem Aufsichtsgremium vor, damit die weiteren Schritte beschlossen werden können, darunter auch eine mögliche Umgestaltung des Prozesses.

Übertragung auf andere Bereiche

1. Legen Sie Reihenfolge und Zeitpunkt der Implementierung in allen anderen chirurgischen Abteilungen fest.
2. Empfohlen wird weniger die gleichzeitige als vielmehr eine sequentielle Implementierung, um vor der Implementierung eine adäquate Schulung, die Überwachung und ein Coaching während der Frühphasen der Implementierung sowie ein Monitoring des neuen Prozesses zu gewährleisten.

Kommunikationsplan

1. Bekanntmachung über die Entscheidung und Verpflichtung zur Implementierung eines Prozesses, der im Rahmen der Teilnahme der Einrichtung an der WHO-Initiative *Action on Patient Safety*: *High 5s* Eingriffsverwechslungen verhindern soll.
2. Begründung der Teilnahme an der Initiative:
    a) Beschreibung des zu lösenden Problems (Operation an der falschen Körperstelle, Durchführung des falschen Eingriffs, Operation der falschen Person)
    b) Lösungsvorschlag (Umgestaltung des präoperativen Vorbereitungsprozesses)
    c) Kosten und Nutzen der Teilnahme
    d) Mit der Teilnahme verbundene Anreize für das Klinikpersonal (verbesserte Patientensicherheit; Effizienzsteigerung und geringeres Risiko für das Personal)
3. Regelmäßige Information der Mitarbeiter über die Fortschritte des Projektarbeitsplans
4. Rückmeldungen an alle Mitarbeiter über die während des Pilottests und der Implementierungsphase des Projekts erhobenen und ausgewerteten Messdaten
5. Anerkennung der Beiträge und Erfolge aller an diesem Projekt beteiligten Mitarbeiter

Evaluationsstrategie

Die Implementierung und Auswirkungen der SOP werden analog zum Evaluationsplan des High 5s-Projekts wie folgt erfasst:

1. Strukturdaten: Damit eine vergleichende Bewertung aller diese SOP implementierenden Krankenhäuser durchgeführt werden kann, werden allgemeine Strukturdaten dieser Krankenhäuser sowie spezifischere Daten über ihre jeweiligen chirurgischen Einrichtungen erhoben.
2. Prozess- und Ergebnisparameter: Erhebung von definierten und standardisierten Datenelementen für jeden präoperativen Prozessschritt zur Bewertung der Wirkung der SOP-Einführung auf Versorgungsprozesse und Patientenoutcomes in den teilnehmenden Krankenhäusern im zeitlichen Verlauf und für den Vergleich mit anderen teilnehmenden Krankenhäusern und Ländern (für Details siehe **Anhang 4**). Das konsentierte Indikatorenset umfasst:
    - **H5sCS-1:** Vollständige präoperative Verifikation
      Der Anteil infrage kommender chirurgischer Fälle mit einer vollständigen präoperativen Verifikations-Checkliste. (Dieser Indikator ist nicht Teil der WHO „Safe Surgery Saves Lives"-Initiative).
    - **H5sCS-2:** Korrekt markierter Eingriffsort
      Der Anteil der für eine Seitenmarkierung infrage kommenden chirurgischen Fälle, deren Eingriffsorte korrekt markiert sind.
    - **H5sCS-3:** Vollständigkeit des „Team-Time-Out"
      Der Anteil der für ein „Team-Time-Out" infrage kommenden chirurgischen Fälle, in denen alle erforderlichen SOP-Elemente des „Team-Time-Outs" erfüllt wurden.

Präoperative pflegerische Beurteilung einschl. vollständiger aktueller Medikamentenliste.

- **H5sCS-4:** Fälle mit identifizierten Diskrepanzen während des „Team-Time-Outs“
  Der Anteil der für ein „Team-Time-Out“ infrage kommenden chirurgischen Fälle mit mindestens einer Diskrepanz, ob gelöst oder nicht, die beim abschließenden „Team-Time-Out“ identifiziert wurden.
- **H5sCS-5:** Fälle, die einem Eingriff unterzogen werden, mit ungelösten „Team-Time-Out“ Diskrepanzen
  Der Anteil chirurgischer Fälle mit mindestens einer Diskrepanz, die beim abschließenden „Team-Time-Out“ identifiziert und nicht gelöst wurde, bevor der Schnitt erfolgte.
- **H5sCS-6:** Abgesetzte operative Eingriffe bei Diskrepanzen
  Der Anteil chirurgischer Eingriffe, die auf Grund von Diskrepanzen, die zu irgendeinem Zeitpunkt der SOP-Anwendung identifiziert wurden, abgesetzt oder verschoben wurden.
- **H5sCS-7:** Eingriffsverwechslungen (falsche Seite, falscher Eingriff oder falscher Patient)
  Der Anteil chirurgischer Fälle mit einer Eingriffsverwechslung (falsche Seite, falscher Eingriff oder falscher Patient), unabhängig davon, ob ein Prozessfehler auftrat oder ob der Patient Schaden erlitt.

3. Das Krankenhaus wird Zwischenfallanalysen von tatsächlichen oder Beinahe-Ereignissen durch Eingriffsverwechslungen durchführen.
4. Die Lead Technical Agency wird die Implementierung der SOP durch eine Reihe direkter Beobachtungen und strukturierter Gespräche mit Personal und Leitung in einer kleinen Stichprobe von teilnehmenden Krankenhäusern evaluieren.
5. Das Krankenhaus übermittelt die gesammelten Daten anhand eines abgestimmten und festgelegten Vorgehens an die Lead Technical Agency APS.
6. Die Lead Technical Agency übermittelt die aggregierten und anonymisierten Daten an das Collaborating Centre (Joint Commission International) gemäß den Anforderungen im Evaluationsplan des High 5s-Projekts.
7. Das Collaborating Centre analysiert die übermittelten Daten und stellt der Lead Technical Agency regelmäßig Ergebnisberichte zur Überprüfung und Weiterleitung an die Krankenhäuser zur Verfügung.
8. Das Collaborating Centre entwickelt und führt ein interaktives web-basiertes Informationsmanagementsystem ein, um sämtliche Implementierungs- und Evaluationsaktivitäten des High 5s-Projekts zu unterstützen.

Erhaltungs- und Verbesserungsstrategie

1. Ist der neu gestaltete Prozess der präoperativen Vorbereitung in der gesamten Einrichtung erst einmal implementiert, sollte die regelmäßige Überwachung der Schlüsselparameter für vorerst ein Jahr fortgesetzt werden; anschließend ist geplant, mindestens einmal jährlich Compliance-Audits durchzuführen.
2. Möglichkeiten zur Verbesserung der Effizienz und Wirksamkeit des Prozesses sollten identifiziert, Prioritäten gesetzt und gegebenenfalls geeignete Maßnahmen ergriffen werden.
3. Hinweise auf Abweichungen von den vorgesehenen Abläufen sollten ausgewertet werden, um die Gründe dafür zu ermitteln und geeignete Gegenmaßnahmen festzulegen, beispielsweise zusätzliche Schulungen, Umgestaltung des Prozesses, technische Unterstützung.

Literaturhinweise - Evidenzbasis und andere Quellen

(Anhang 5)

Action on Patient Safety: High 5s

SOP
Vermeidung von Eingriffsverwechslungen

Deutsche Version

Anhang 1

SOP-Prozessablauf zur Vermeidung von Eingriffsverwechslungen

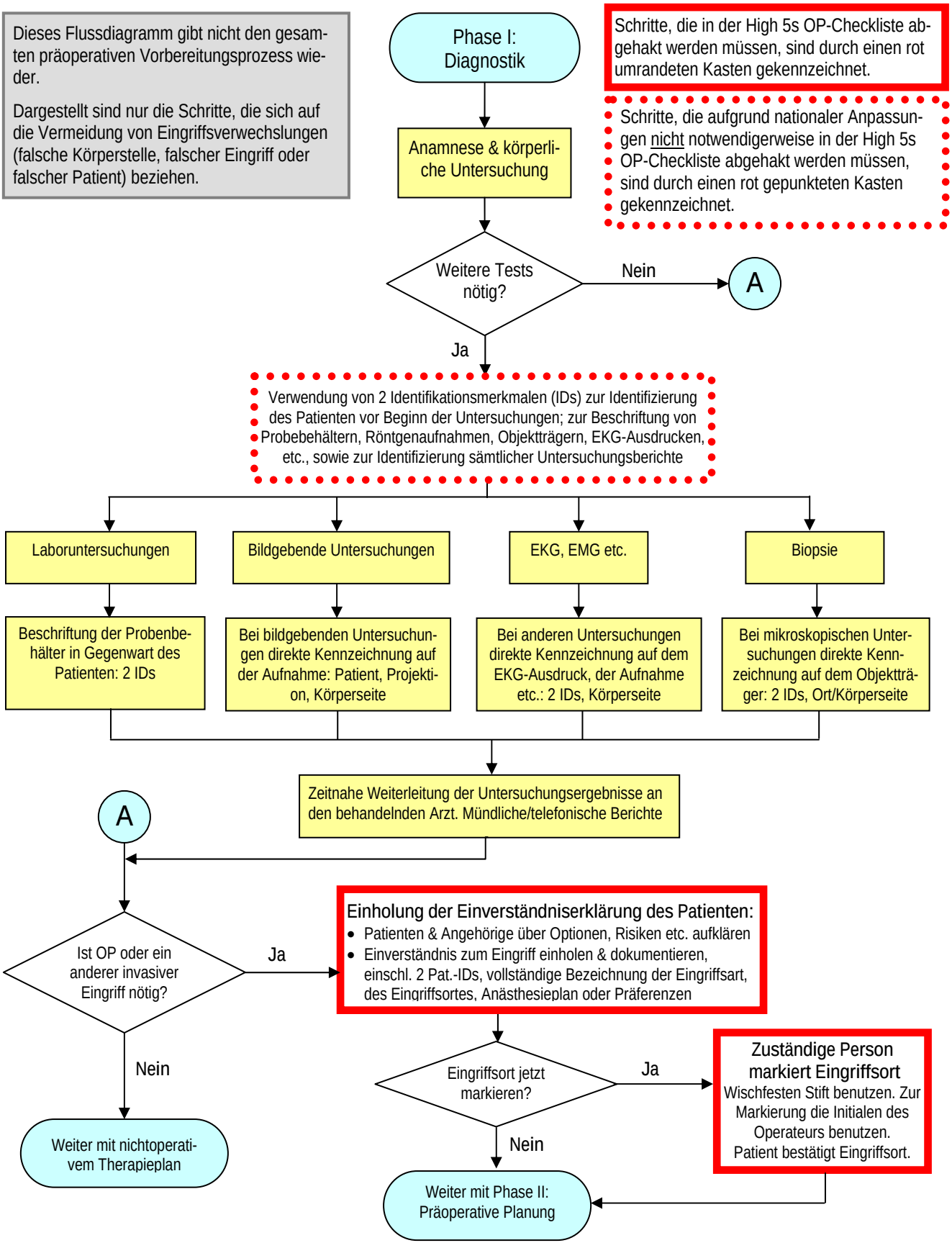
Präoperative Vorbereitung:

- Phase I
- Phase II & III
- Phase IV & V
- Phase VI

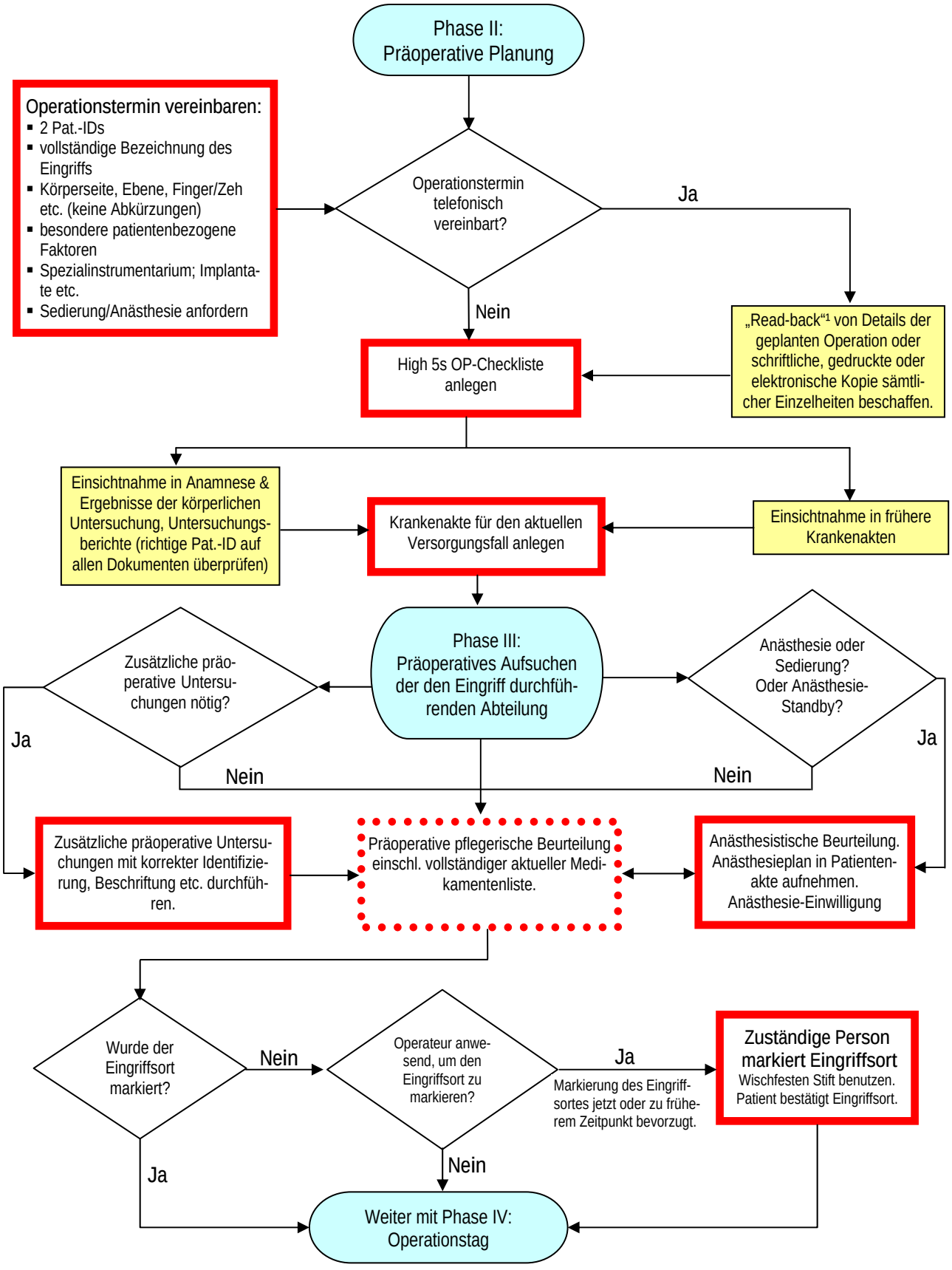
Stand der Überarbeitung (Original): Oktober 2009

Stand der deutschen Übersetzung: Mai 2010

Präoperative Vorbereitung bezüglich der Vermeidung von Eingriffsverwechslungen, Phase I:

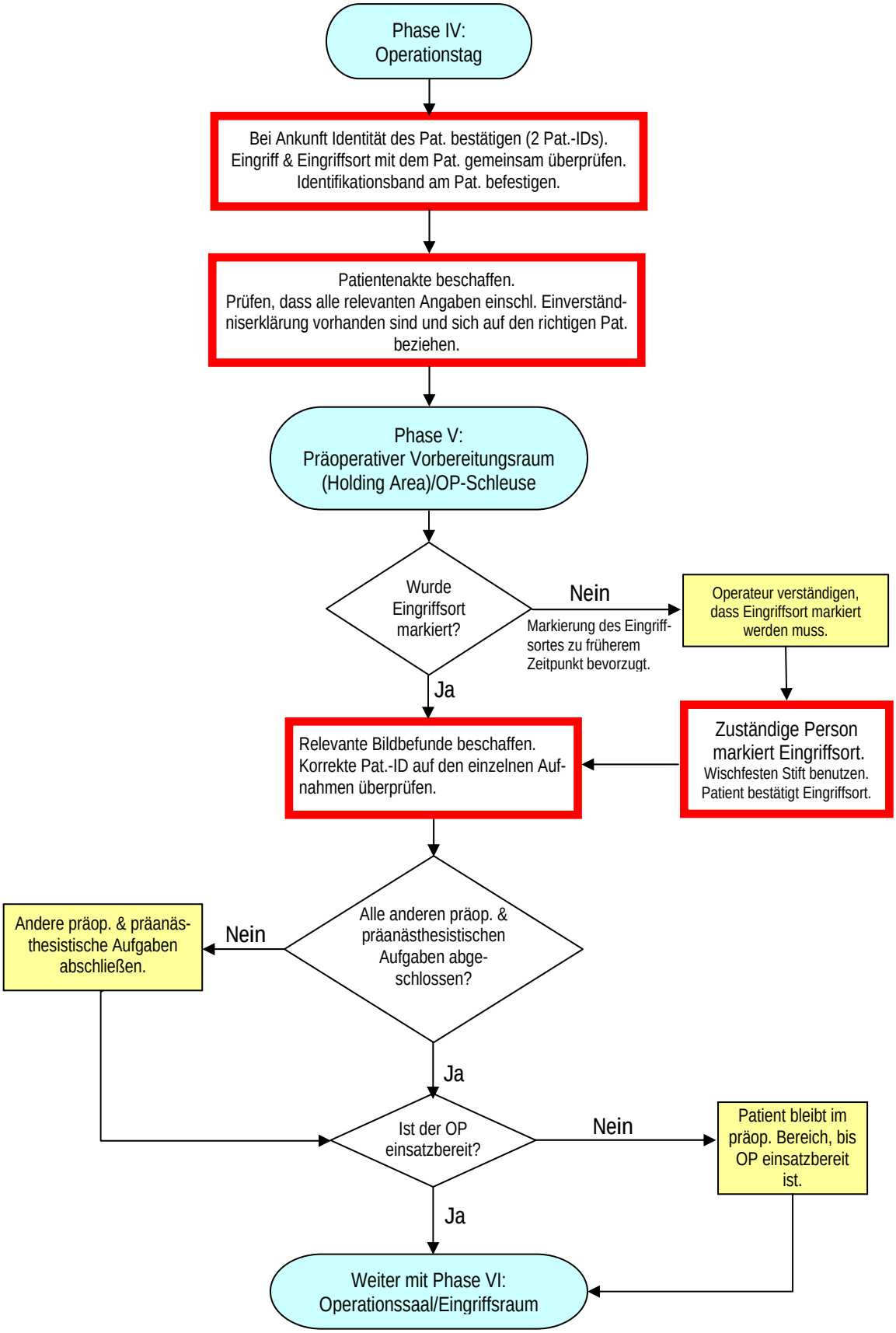


Präoperative Vorbereitung bezüglich der Vermeidung von Eingriffsverwechslungen, Phase II & III:

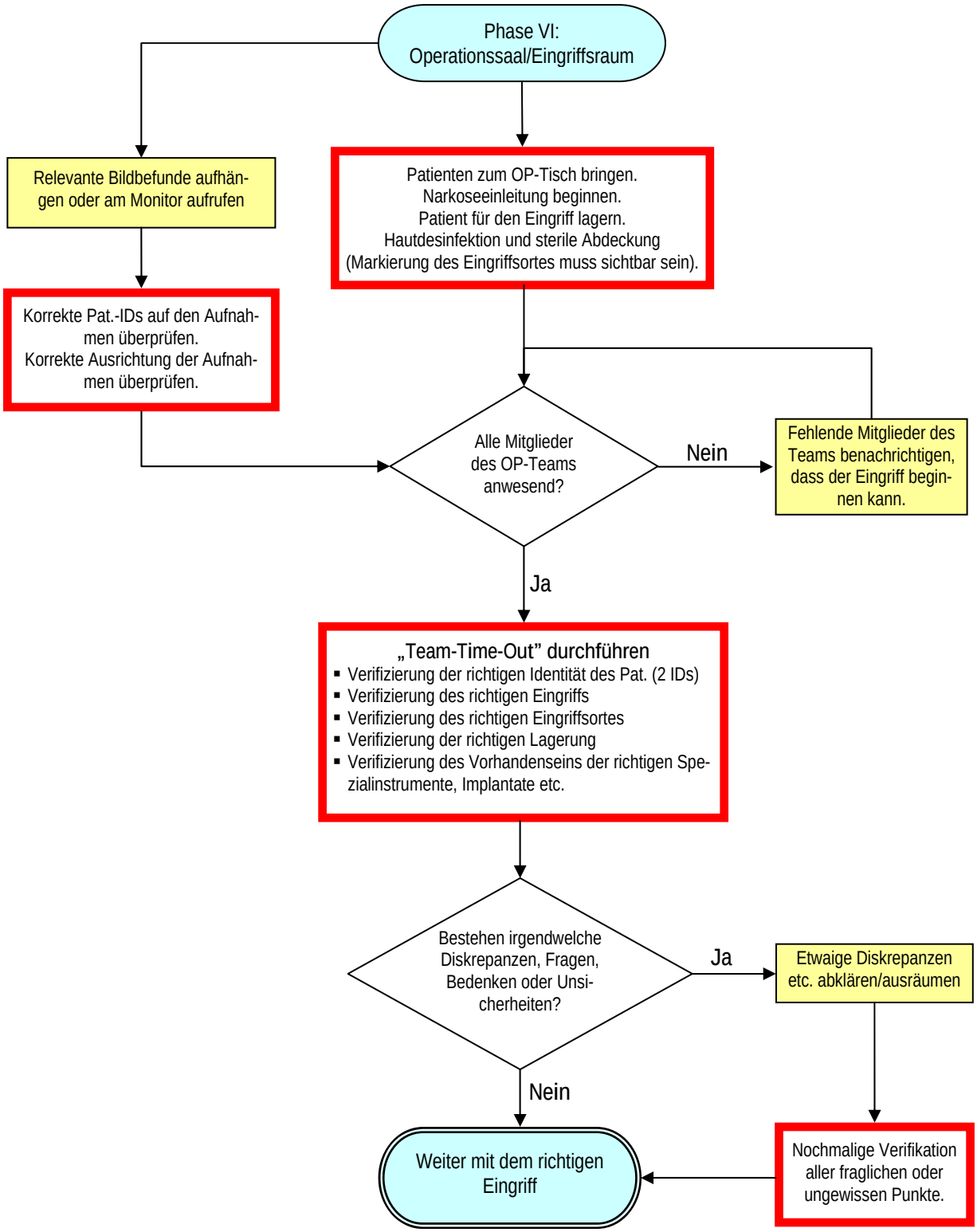


[1] „Read-back": Gemeint ist die verbale Bestätigung der kritischen Informationen

Präoperative Vorbereitung bezüglich der Vermeidung von Eingriffsverwechslungen, Phase IV & V:



Präoperative Vorbereitung bezüglich der Vermeidung von Eingriffsverwechslungen, Phase VI:



Action on Patient Safety: High 5s

SOP
Vermeidung von Eingriffsverwechslungen

Deutsche Version

Anhang 2

- WHO Surgical Safety Checklist
- Deutsche Versionen der WHO Surgical Safety Checklist

Stand der Bearbeitung: Mai 2010

World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ **PATIENT HAS CONFIRMED**
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ **SITE MARKED/NOT APPLICABLE**

☐ **ANAESTHESIA SAFETY CHECK COMPLETED**

☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ **ANAESTHESIA TEAM REVIEWS:** ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ **THE NAME OF THE PROCEDURE RECORDED**

☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)

☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)

☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

World Health Organization

Sicherheits-Checkliste Chirurgie
„Safe surgery saves live“
Globale Initiative für Patientensicherheit der WHO

1. *Initialer-Check (vor Narkoseeinleitung)*

- ☐ Patient bestätigt: seine Identität (Personalien), Eingriffsort, Art des Eingriffs und Zustimmung zum Eingriff
- ☐ Eingriffsort markiert/nicht anwendbar
- ☐ Anästhesie – Sicherheitscheck abgeschlossen
- ☐ Pulsoxymeter ist am Patienten angebracht und funktioniert

Hat der Patient:

Allergie	☐	nein	☐	ja
Intubationsschwierigkeit/ Aspirationsrisiko	☐	nein	☐	ja (notwendige Instrumente und Personal sind vorhanden)
Risiko von Blutverlust > 500 ml (> 7 ml/kg bei Kindern)	☐	nein	☐	ja

2. *Vor Hautschnitt (team time out)*

- ☐ alle Mitglieder des Teams haben sich mit Namen und Funktion vorgestellt
- ☐ Operateur, Anästhesist und Pflegepersonen bestätigen Identität des Patienten, von Eingriffsort und -art sowie korrekte Lagerung

Vorhersehbare kritische Ereignisse

- ☐ Operateur fasst entscheidende und mögliche kritische Schritte der Operation zusammen und nennt zu erwartende(n) OP-Zeit und Blutverlust
- ☐ Anästhesieteam definiert evtl. notwendigen Reanimationsplan und patientenspezifische Probleme
- ☐ Pflege nennt Ergebnisse der Sterilisations-Indikatoren und Funktionsweise spezieller Geräte

Wurde Antibiotika-Prophylaxe während der letzten Stunde gegeben?

☐ ja ☐ nicht sinnvoll

Wurden alle nötigen Bilder (Röntgen, MR usw.) sichtbar präsentiert?

☐ ja ☐ nicht sinnvoll

☐ andere Punkte ……..

3. *Finaler Check (bevor Patient OP Raum verlässt)*

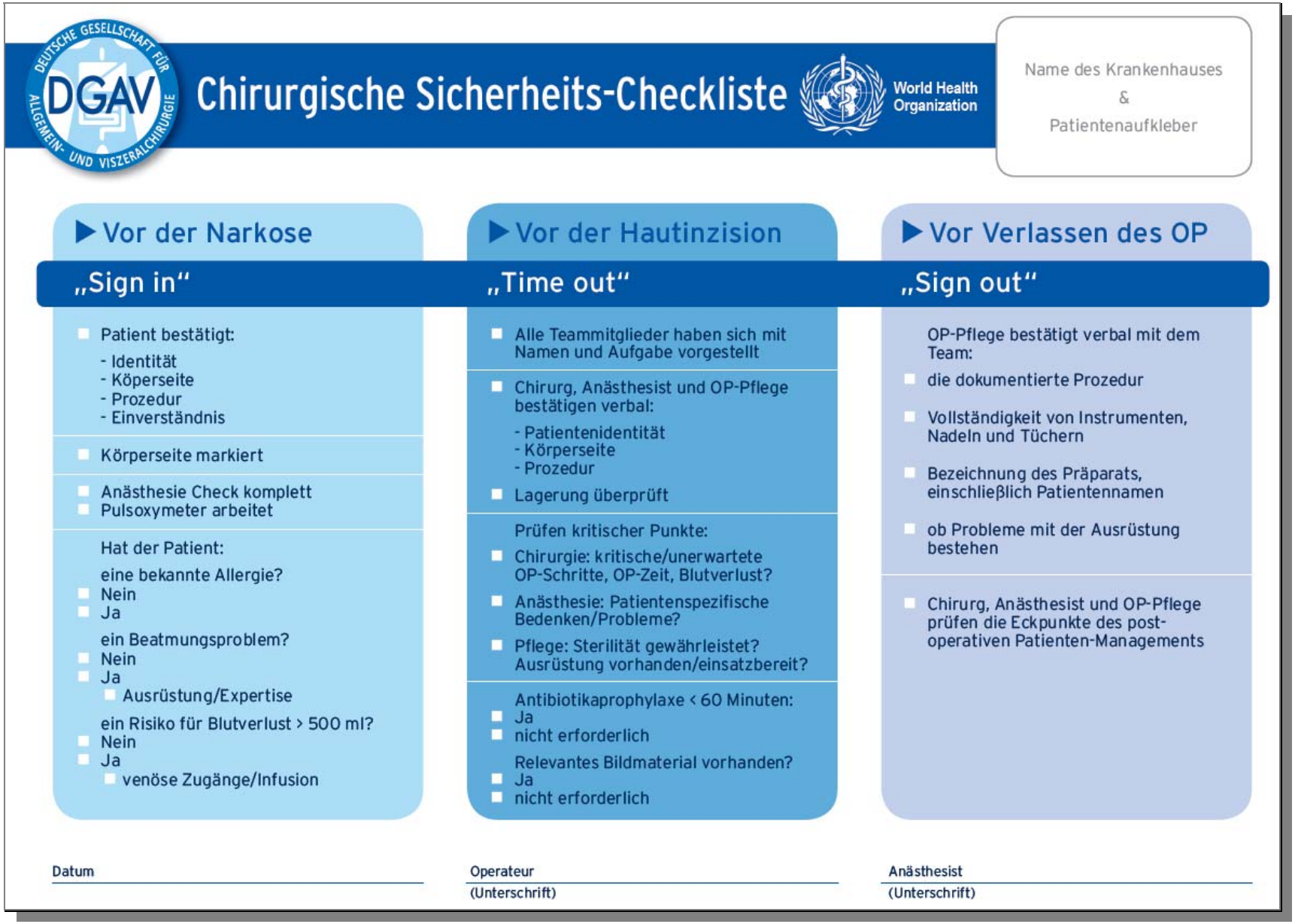
Pflege bestätigt mündlich:

- ☐ Art des Eingriffs
- ☐ vollständige Zahl von Instrumenten, Tupfern, Bauchtüchern etc., Nadeln
- ☐ Korrekte Beschriftung der Gefäße für Pathologie (entnommenes Gewebe)
- ☐ evtl. Fehlfunktion von Geräten

Operateur, Anästhesist und Pflege definieren:

- ☐ wichtigste Gesichtspunkte für Aufwachphase und postoperative Versorgung

(Unterschrift) (Datum)
Für das Team



DEUTSCHE GESELLSCHAFT FÜR ALLGEMEIN- UND VISZERALCHIRURGIE

DGAV

Chirurgische Sicherheits-Checkliste

World Health Organization

Name des Krankenhauses
&
Patientenaufkleber

▶ Vor der Narkose

„Sign in"

- Patient bestätigt:
  - Identität
  - Köperseite
  - Prozedur
  - Einverständnis
- Körperseite markiert
- Anästhesie Check komplett
- Pulsoxymeter arbeitet

Hat der Patient:

eine bekannte Allergie?
- Nein
- Ja

ein Beatmungsproblem?
- Nein
- Ja
  - Ausrüstung/Expertise

ein Risiko für Blutverlust > 500 ml?
- Nein
- Ja
  - venöse Zugänge/Infusion

▶ Vor der Hautinzision

„Time out"

- Alle Teammitglieder haben sich mit Namen und Aufgabe vorgestellt
- Chirurg, Anästhesist und OP-Pflege bestätigen verbal:
  - Patientenidentität
  - Körperseite
  - Prozedur
- Lagerung überprüft

Prüfen kritischer Punkte:
- Chirurgie: kritische/unerwartete OP-Schritte, OP-Zeit, Blutverlust?
- Anästhesie: Patientenspezifische Bedenken/Probleme?
- Pflege: Sterilität gewährleistet? Ausrüstung vorhanden/einsatzbereit?

Antibiotikaprophylaxe < 60 Minuten:
- Ja
- nicht erforderlich

Relevantes Bildmaterial vorhanden?
- Ja
- nicht erforderlich

▶ Vor Verlassen des OP

„Sign out"

OP-Pflege bestätigt verbal mit dem Team:
- die dokumentierte Prozedur
- Vollständigkeit von Instrumenten, Nadeln und Tüchern
- Bezeichnung des Präparats, einschließlich Patientennamen
- ob Probleme mit der Ausrüstung bestehen

- Chirurg, Anästhesist und OP-Pflege prüfen die Eckpunkte des post-operativen Patienten-Managements

Datum

Operateur
(Unterschrift)

Anästhesist
(Unterschrift)

Action on Patient Safety: High 5s

SOP
Vermeidung von Eingriffsverwechslungen

Deutsche Version

Anhang 3

Risikobewertung des präoperativen Vorbereitungsprozesses (Beispiel)

Stand der Überarbeitung (Original): Oktober 2009
Stand der deutschen Übersetzung: Mai 2010

Risikobewertung des Prozesses zur Vermeidung von Eingriffsverwechslungen
(unvollständiges Beispieldiagramm zur Veranschaulichung des Formats)

Prozessschritt (aus dem Flussdiagramm)	Potenzielle Fehlermöglichkeit	Potenzielle Wirkung	Fehlerhäufigkeit*	Auffindbarkeit*	Schweregrad des Effekts*	RPN **	Potenzielle Ursachen	Kontroll-/ protektive Maßnahmen
Diagnostische Abklärung; Eingang der Untersuchungsergebnisse	Untersuchungsergebnisse eines falschen Patienten	falsche Diagnose falsche Behandlung falsche Person oder falscher Eingriff	1	2	3	6	fehlerhafte Identifizierung des Probenbehälters; fehlerhafte Identifizierung des Untersuchungsberichts	Zwei Identifizierungsmerkmale (IDs) benutzen. Alle Probenbehälter in Gegenwart des Patienten beschriften. Sicherung der Probenidentität während aller Untersuchungsphasen.
Informierte Einverständniserklärung	Patient versteht den Therapieplan nicht	keine rechtskräftige Einverständniserklärung	2	2	2	8	Sprachbarrieren; geringe Gesundheitskompetenz	Verfügbarkeit von Übersetzern/mehrsprachige Einverständniserklärungen Beteiligung der Angehörigen Vermeidung von Fachjargon
	falsche oder nicht eindeutige Einträge auf der Einverständniserklärung	falscher Eingriff	2	2	3	12	unvollständige Angaben zum Eingriff; Verwendung von Abkürzungen	Vollständigen Namen des Eingriffs angeben sowie Eingriffsort, Körperseite, Ebene, Fläche etc. Keine Abkürzungen oder Akronyme verwenden
Vereinbarung des Eingriffstermins	Kommunikationsfehler bzgl. Eingriff oder Operationssitus	falsche Eingriffsart oder falscher Eingriffsort	2	3	3	18		
Einrichtung und Anwendung der präoperativen Verifikationscheckliste	Eingabe von Informationen zum falschen Patienten auf der Checkliste	falsche Person, falscher Eingriff oder falscher Eingriffsort						
	Punkte auf der Checkliste unvollständig							
…								

* Zu empfehlen ist eine einfache 3-Punkte- (hoch, mittel, niedrig) oder 5-Punkte-Skala.

** Risikoprioritätszahl (Risk Priority Number) = Häufigkeit x Auffindbarkeit x Schweregrad

Action on Patient Safety: High 5s

SOP
Vermeidung von Eingriffsverwechslungen

Deutsche Version

Anhang 4
in englischsprachiger Originalversion

Prozess- und Ergebnisparameter

- Measure Information Forms
- Measure Set Specific Data Elements

Stand der Überarbeitung: Oktober 2009

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-1

Performance Measure Name: Completed Preoperative Verification Check List

Description: The proportion of eligible surgical cases with a complete preoperative verification check list. (Please note, this measure is not part of the WHO "Safe Surgery Saves Lives" global challenge).

Value Statement: This measure focuses on one of the three necessary components of the correct surgery strategy: the preoperative verification process, which involves the collection, assembly, and cross-verification of information generated throughout the preoperative period. Tracking the consistency of performance of this early phase of the surgical process is important because errors in the scheduling, preoperative testing, admission, and other preoperative activities, if not recognized and corrected immediately, can propagate through to the surgery itself, resulting in incorrect surgery.

Data will be collected for each of the many steps in the preoperative process and for each step will differentiate between "no discrepancy," "discrepancy reconciled," "case canceled due to unreconciled discrepancy," and "unresolved discrepancy." This granularity of data collection will allow for multiple calculated sub-measures to evaluate the reliability of information that feeds into the preoperative process as well as to identify patterns of inconsistent compliance with the verification process as defined in the SOP. As such, this measure contributes to the determination of success in meeting Goal #1 of the Action on Patient Safety (High-5s) Initiative [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems]. The burden of detailed data collection for this measure will be mitigated by real-time integration of data collection with the verification process itself through the use of a check list. Cases that move forward with unresolved discrepancies will be subject to event analysis. Significant patterns of resolved discrepancies may undergo aggregate analysis.

Type of Measure: Process

Improvement Noted As: Increase in the rate

Numerator Statement: The number of eligible surgical cases with a complete preoperative verification check list.

Included Populations: Not applicable

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Complete Preoperative Verification Checklists*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Pre-Op Verification Checks Are Done When Surgery Is Scheduled*
- *Pre-Op Verification Checks Are Done at Pre-Op Testing*
- *Pre-Op Verification Checks Are Done When Patient Consent Is Obtained*
- *Pre-Op Verification Checks Are Done When Pre-operative Assessments are Performed*
- *Pre-Op Verification Checks Are Done on Entry to Pre-Op Holding*
- *Pre-Op Verification of Medical Record Entries*
- *Pre-Op Verification of Diagnostic Test Results*
- *Pre-Op Verification: Special Equipment [DUPLICATE]*
- *Pre-Op Verification Summary*

Notes: A Completed verification check list means all items listed on the check list under the category of Pre-Operative Verification are checked off as being having been done.

Denominator Statement: The number of surgical cases within the scope of the Correct Surgery Standard Operating Protocol

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment
- Emergency procedures and other late add-on procedures performed in a hospital in-patient operating room environment
- Surgical cases cancelled for potential incorrect surgery (for example, because of an unreconciled discrepancy)

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases cancelled reasons unrelated to the SOP

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-1*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Procedure Site*

Notes: Inpatient operating room environment is defined as the hospital surgical facility (group of operating rooms) that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).

Risk Adjustment: No.

Data Collection Approach: Retrospective data from operative records or concurrently through direct observation and recording on the preoperative verification check list.

It is recommended that baseline data from records be collected on the preceding 12 months.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: Hospitals may wish to do further analysis to identify cases where a verification check list was not done, or where all steps in the verification process were not completed, identifying trends in the areas not completed.

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. Correct site surgery alert. London: National Patient Safety Agency, 2 March 2005.
3. World Alliance For Patient Safety. Implementation Manual: Surgical Safety Checklist First edition) http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf accessed September 2008Lessons learned: wrong site surgery. Sentinel Event Alert, Issue 6, 28 August 1998. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm.
4. A follow-up review of wrong site surgery. Sentinel Event Alert, Issue 24, 5 December 2001. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm.
5. Statement on ensuring correct patient, correct site, and correct procedure surgery. Bulletin of the American College of Surgeons, 87:12, December 2002. ttp://www.facs.org/fellows_info/statements/st-41.html.
6. AAOS launches 2003 public service ad campaign. AAOS Bulletin, February 2003. American Academy of Orthopaedic Surgeons' "Sign Your Site" initiative.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-2

Performance Measure Name: Properly Marked Surgical Site

Description: The proportion of surgical cases that are eligible for site marking that have properly marked surgical sites.

Value Statement: This measure focuses on the second of the three necessary components of the correct surgery strategy: marking the surgical site. This visual cue provides necessary redundancy to the correct surgery strategy but can be effective only to the degree that it is performed consistently. By tracking consistency of the site marking process and, through analysis, by identifying barriers to consistent performance of this critical process, this measure will contribute to the determination of success in meeting Goal #1 of the Action on Patient Safety (high-5s) Initiative [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems].

Data collection for this measure is minimized by incorporating documentation of site marking into the preoperative check list. Cases that move forward without site marking (except those designated in the SOP as exemptions from this step) will be subject to event analysis.

Type of Measure:

Numerator Statement: The number of eligible surgical cases requiring site marking that had correct surgical site(s) marked properly.

Included Populations:

- Eligible surgical cases where both the correct site is marked and the site is marked properly

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Cases With Correct Surgical Site Marked Properly*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Correct Surgical Site Marked*
- *Surgical Site Marked Properly [DUPLICATE]*
- *Site Mark Summary*
- *Site Marking Requirements*

Denominator Statement: The number of surgical cases for which site marking is required.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment
- Emergency surgeries and other late add-on procedures performed in a hospital inpatient operating room environment
- Surgical cases canceled for potential incorrect surgery (for example, because of an unreconciled discrepancy)
- Surgical cases with incision or percutaneous instrumentation procedure that involves laterality, surface (flexor, extensor) level (spine), or specific digit or lesion to be treated.

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases that do not involve laterality, surface (flexor, extensor), level (spine), or specific digit or lesion to be treated.
- Surgical cases cancelled for reasons unrelated to the SOP
- Eligible surgical cases which, due to special circumstances, are exempt from the site marking requirement, for example: premature infants, life threatening emergencies in which even the minimal time required to mark the site introduces more risk to the patient than the possibility of a wrong site or wrong person procedure.
- Patient refused site marking

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-2*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Site Marking Requirements*
- *Procedure Site*

Notes: Inpatient operating room environment can be defined as procedures in the hospital operating room environment that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through direct observation and recording on the preoperative verification check list is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: Hospitals may wish to do further analysis to identify and study the following:

- Cases where although the procedure site was marked, proper procedure was not followed.
- The percentage of cases exempt from site markings.

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. Correct site surgery alert. London: National Patient Safety Agency, 2 March 2005.
3. World Alliance For Patient Safety. Implementation Manual: Surgical Safety Checklist First edition) http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf accessed September 2008Lessons learned: wrong site surgery. Sentinel Event Alert, Issue 6, 28 August 1998. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm.
4. A follow-up review of wrong site surgery. Sentinel Event Alert, Issue 24, 5 December 2001. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm.
5. Statement on ensuring correct patient, correct site, and correct procedure surgery. Bulletin of the American College of Surgeons, 87:12, December 2002. http://www.facs.org/fellows_info/statements/st-41.html.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-3

Performance Measure Name: Complete Final Time-Out

Description: The proportion of cases eligible for a final Time Out verification for which all required elements of the Time Out, as described in the Standard Operating Protocol, are documented as done.

Value Statement: This measure focuses on the third of the three necessary components of the correct surgery strategy; the final "time out" verification. This final step of verifying agreement among all members of the surgical team on the key aspects of the procedure they are about to undertake is arguably the most important and certainly the last opportunity to intercept a potential incorrect surgery. Measurement of the consistency of its performance is, therefore, critical, not only to identify whether or not the time out was completed but whether there were discrepancies identified and, if so, how they were resolved. In concert with CS-1 and CS-2, this measure contributes to the determination of success in meeting Goal #1 of the Action on Patient Safety (High-5s) Initiative [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems].

Data collection for this measure is minimized by incorporating the data elements for the final time out into the preoperative check list. Cases that move forward with unresolved time out discrepancies will be subject to event analysis. Significant patterns of resolved discrepancies may undergo aggregate analysis.

Type of Measure: Process

Improvement Noted As: Increase in the rate

Numerator Statement: The number of surgical cases eligible for a final Time Out verification for which all required elements of the Time Out are documented as done.

Included Populations:

- Surgical cases with one or more final Time Out discrepancies whether resolved or not as long as each step is documented as done.
- Only the Final Time Out verification occurring immediately before the incision is made.

Excluded Populations:

- Time out verifications that occur prior to the final Time Out verification, for example, prior to the delivery of anesthesia.

Aggregate Data Elements (Used for data entry):

- *Number of Surgical Cases With Complete Final Time-Out*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Final Time Out Verification Occurs Immediately Prior To The Procedure*
- *Final Time Out Initiated By Designated Coordinator*
- *Final Time Out Involves Entire Operative Team*
- *Final Time Out involves Active Communication*
- *Final Time Out: Activities Suspended*

- *Final Time Out Verifies Patient Identity*
- *Final Time Out Verifies Correct Procedure*
- *Final Time Out Verifies Correct Surgery Site*
- *Final Time Out Verifies Correct Patient Position*
- *Final Time Out Verifies Images Labeled Correctly*
- *Final Time Out Verifies Availability of Special Equipment*
- *Final Time Out Summary*

Notes: The time out verification of interest for this measure is the final time out occurring immediately prior to the incision. Other time outs that may occur during a surgical case prior to the final time out are not relevant to the numerator data collection or calculation.

Denominator Statement: *The number of surgical cases eligible for a final Time Out verification*.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment.
- Emergency surgeries and other late add-on procedures performed in a hospital in-patient operating room environment.

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases canceled due to incomplete pre-op verification or incorrect site marking.
- Surgical cases cancelled for reasons unrelated to the SOP

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-3*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Case Cancelled: Pre-Op Verification Unreconciled Discrepancy*
- *Case Cancelled: Site Marking Unreconciled Discrepancy*

Notes: Inpatient operating room environment is defined as the hospital surgical facility (group of operating rooms) that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through direct observation and recording on the preoperative verification check list is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: Hospitals may wish to do further analysis to determine which steps of the process were not completed or not completed correctly. This can be done through analysis of the allowable values used for the data element Final Time Out Verification Status.

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a ratio .

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. Correct site surgery alert. London: National Patient Safety Agency, 2 March 2005.
3. World Alliance for Patient Safety. Implementation Manual: Surgical Safety Checklist First edition) http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf accessed September 2008Lessons learned: wrong site surgery. Sentinel Event Alert, Issue 6, 28 August 1998. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm.
4. A follow-up review of wrong site surgery. Sentinel Event Alert, Issue 24, 5 December 2001. Joint Commission. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm.
5. Statement on ensuring correct patient, correct site, and correct procedure surgery. Bulletin of the American College of Surgeons, 87:12, December 2002. http://www.facs.org/fellows_info/statements/st-41.html.
6. AMOS launches 2003 public service ad campaign. AMOS Bulletin, February 2003. American Academy of Orthopaedic Surgeons' "Sign Your Site" initiative.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-4

Performance Measure Name: Cases with Discrepancy Noted at Final Time-Out

Description: The proportion of eligible surgical cases with at least one discrepancy, whether resolved or not, identified at the final Time Out verification.

Value Statement: This measure tracks the number of cases in which one or more discrepancies were identified in the final time out and how they were handled: discrepancies reconciled; case canceled due to unreconciled discrepancies; or case moved forward with unresolved discrepancy (see CS-5). As with the preceding measures, this measure contributes to the determination of success in meeting Goal #1 of the Action on Patient Safety (High-5s) Initiative [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems]. It also provides information relating to Goal #2 [To achieve significant, sustained, and measurable reduction in the occurrence of adverse events relating to these patient safety problems] because the reconciliation of discrepancies and cancellation of cases due to discrepancies represent successes in avoiding potentially incorrect surgery through effective application of the SOP.

Data collection burden for this measure is minimized by incorporating the data elements for the final time out into the preoperative check list. Patterns of specific types of discrepancies (for example, lateralization disagreement or needed implant not available) may be subject to aggregate analysis.

Type of Measure: Process

Improvement Noted As: Decrease in the rate

Numerator Statement: The number of surgical cases eligible for the final Time Out that have at least one discrepancy noted at the final Time Out.

Included Populations:

- Includes discrepancies whether resolved or not
- Includes any undocumented steps in the Time Out (discrepancy by omission)
- Includes cases that are eligible for the final Time Out but the final Time Out is not done (none of the steps are documented).

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Surgical Cases With Discrepancy at Final Time-Out*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Final Time Out Verifies Patient Identity*
- *Final Time Out Verifies Correct Procedure*
- *Final Time Out Verifies Correct Surgery Site*
- *Final Time Out Verifies Correct Patient Position*
- *Final Time Out Verifies Images Labeled Correctly*
- *Final Time Out Verifies Availability of Special Equipment*

Notes: The time out verification of interest for this measure is the final time out occurring immediately prior to the incision. Discrepancies noted in other time outs that may occur during a surgical case prior to the final time out are not relevant to the numerator data collection or calculation for this specific measure. If a discrepancy is noted during a previous time-out and noted again during the final time out, the discrepancy should be included in the count for this measure.

Denominator Statement: The number of surgical cases eligible for a final Time Out verification.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment.
- Emergency procedures and other late add-on procedures performed in an inpatient operating room environment.

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases canceled due to incomplete pre-op verification or site marking.
- Surgical cases cancelled for reasons unrelated to the SOP.

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-3*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Case Cancelled: Pre-Op Verification Unreconciled Discrepancy*
- *Case Cancelled: Site Marking Unreconciled Discrepancy*
- *Procedure Site*

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through direct observation and recording in the preoperative verification check llist is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: Hospitals are encouraged to perform sub analyses to distinguish between cases with undocumented items as discrepancies versus cases with unresolved discrepancies involving inconsistent or conflicting information in an otherwise complete Time Out. Data elements have been added to the recommended check list to facilitate such sub-analyses.

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. World Alliance for Patient Safety, World Health Organization. The Conceptual Framework for the International Classification for Patient Safety (unpublished)
3. Barach, P. & Small, S. (2007). Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. BMJ: British Medical Journal, 320, 759-63.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-5

Performance Measure Name: Cases Undergoing Surgery with Unresolved Time-Out Discrepancies.

Description: The proportion of surgical cases with at least one discrepancy identified at the final Time Out that is not resolved before the incision is made.

Value Statement: This measure isolates cases in which there were one or more discrepancies that were not or could not be resolved but proceeded to surgery nonetheless. Each of these cases is regarded as a potential incorrect surgery. As with the preceding, this measure contributes to the determination of success (or, in this case, lack of success) in meeting Goal #1 of the Action on Patient Safety (High-5s) Initiative [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems]and also provides information relating to Goal #2 [To achieve significant, sustained, and measurable reduction in the occurrence of adverse events relating to these patient safety problems]. Specifically, this measure identifies failures of the SOP since any case that proceeds to surgery with an unresolved discrepancy is a potential incorrect surgery.

Data collection burden for this measure is minimized by incorporating the data elements for the final time out into the preoperative check list. Each of these cases will undergo a comprehensive event analysis.

Type of Measure: Process

Improvement Noted As: Decrease in the rate

Numerator Statement: The number of eligible surgical cases with at least one discrepancy (either an omission or inconsistent/conflicting information) that is not resolved at the final Time Out before making before the incision.

Included Populations: Not Applicable

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Surgical Cases With Unresolved Discrepancy at Final Time-Out*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Final Time Out Verifies Patient Identity*
- *Final Time Out Verifies Correct Procedure*
- *Final Time Out Verifies Correct Surgery Site*
- *Final Time Out Verifies Correct Patient Position*
- *Final Time Out Verifies Images Labeled Correctly*
- *Final Time Out Verifies Availability of Special Equipment*

Denominator Statement: The number of eligible surgical cases with one or more discrepancies noted at the final Time Out.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment for which discrepancies are noted at the final Time Out.
- Emergency procedures and other late add-on procedures performed in a hospital in-patient operating room environment for which discrepancies are noted at the final Time Out.
- Includes discrepancies whether resolved or not
- Includes an undocumented step(s) (discrepancy by omission)

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases canceled due to incomplete pre-op verification or site marking.
- Surgical cases cancelled for reasons unrelated to the SOP.
- Surgical cases with a complete final Time Out with no discrepancies.

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Surgical Cases With Discrepancy at Final Time-Out*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Case Cancelled: Pre-Op Verification Unreconciled Discrepancy*
- *Case Cancelled: Site Marking Unreconciled Discrepancy*
- *Procedure Site*

Notes: The time-out verification of interest for this measure is the final time-out occuring immediately prior to the incision. Other time-outs that may occur during a surgical case prior to the final time-out are not relevant to the count of cases with discrepancies for this measure.

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through direct observation and recording in the preoperative verification check list is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions:

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. World Alliance for Patient Safety, World Health Organization. The Conceptual Framework for the International Classification for Patient Safety (unpublished)
3. Barach, P. & Small, S. (2007). Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. BMJ: British Medical Journal, 320, 759-63.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-6

Performance Measure Name: Case Cancellation Resulting from SOP Implementation

Description: The proportion of surgical cases that are cancelled or postponed due to discrepancies identified at any point in the conduct of the SOP.

Value Statement: This measure is an overall accounting of case cancellations and postponements due to discrepancies identified at any point in the conduct of the SOP. As such, it informs Goal #2 of the Action on Patient Safety (High-5s) Initiative [To achieve significant, sustained, and measurable reduction in the occurrence of adverse events relating to these patient safety problems] by measuring success in avoiding incorrect surgery through effective application of the SOP. It also provides information about the impact of ineffective communication (discrepancies) on the efficiency of the surgical processes and facilities.

Data collection burden for this measure is minimized by incorporating the data elements for all three key components of the SOP into the preoperative check list. Cases cancellations above a defined frequency may be subject to aggregate analysis.

Type of Measure: Outcome

Improvement Noted As: Either an increase or decrease in the rate depending on the context of the measure

Numerator Statement: Number of eligible surgical cases canceled due to discrepancies identified during any step of the SOP implementation.

Included Populations:

- Cases cancelled due to discrepancies identified at any point prior to conducting the final Time Out (for example: unreconcilable discrepancy during pre-op verification or improper site mark)
- Cases cancelled as a means of resolving Time Out discrepancies (resolved by not operating).

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Surgical Cases Cancelled for Discrepancies noted in SOP Implementation*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Pre-Op Verification Summary*
- *Site Mark Summary*
- *Final Time Out Summary*

Denominator Statement: Number of surgical cases within the scope of the Correct Surgery Standard Operating Protocol.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment.
- Emergency procedures and other late add-on procedures performed in a hospital inpatient operating room environment.
- Surgical cases cancelled for potential incorrect surgery.

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment.
- Surgical cases cancelled for reasons unrelated to the SOP.

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-1*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Procedure Site*

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through direct observation and recording in the preoperative verification check list is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy requires that all definitions must be used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: The significance of an increase or decrease in the value of CS-6 will depend on the values of CS-4, CS-5 and CS-7. If any of these three measures are high, then an increase in the number of case cancellations due to identified discrepancies (CS-6) could be considered evidence of improvement in patient safety. However, with continued implementation of the SOP, it is anticipated that the values of CS-4, CS-5 and CS-7 will decrease. At that point, a decrease in the rate of cancellations would be considered improvement from an operational efficiency point of view.

Sampling: No

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. World Alliance for Patient Safety, World Health Organization. The Conceptual Framework for the International Classification for Patient Safety (unpublished)
3. Barach, P. & Small, S. (2007). Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. BMJ: British Medical Journal, 320, 759-63.

Measure Set: High 5s Correct Site Surgery(H5sCS)

Set Measure ID: H5sCS-7

Performance Measure Name: Incorrect Surgery (Wrong Site, Procedure or Person Cases)

Description: The proportion of surgical cases that are incorrect (NOTE: an incorrect surgery is determined strictly by the fact that the surgery involved the wrong patient, wrong procedure, wrong site or wrong implant whether or not harm may have resulted or an error was identified in the process of care leading to the incorrect surgery).

Value Statement: This measure identifies cases of actual incorrect surgeries - the specific type of adverse surgical events that the SOP is intending to prevent. Because all cases identified by this measure will undergo a comprehensive event analysis, it will help to identify barriers to consistent implementation of the SOP (for example, improper implementation of the SOP in the organization or inconsistent adherence to a properly implemented SOP) as well as potential inadequacies of the SOP itself (the SOP was properly implemented and followed but an incorrect surgery still occurred). The results of these event analyses will inform the evaluation of High-5 Goal #1 [To demonstrate the feasibility of implementing innovative, standardized operating protocols for three specific patient safety problems]. Further, tracking this measure over time will address Goal #2 [To achieve significant, sustained, and measurable reduction in the occurrence of adverse events relating to these patient safety problems] by providing evidence of the effectiveness of the SOP in preventing incorrect surgery. Insofar as adverse surgical events and complications are routinely tracked in hospitals, this measure should not increase the existing burden of measurement.

Type of Measure: Outcome

Improvement Noted As: Decrease in the rate

Numerator Statement: The number of eligible surgical cases where an incision was made and the case was subsequently determined to have been performed on the wrong patient or at the wrong site or to have employed the wrong procedure.

Included Populations:

- The category of "wrong procedure" includes cases of incorrect implant placement (for example, an intraocular lens that was intended for another patient).

Excluded Populations: None

Aggregate Data Elements (Used for data entry):

- *Number of Incorrect Surgery Cases*

Unit-Level Data Elements (Used to calculate aggregate data elements):

- *Level of Harm (Unit-level data element)*
- *Incorrect Surgery Classification*
- *Time of Error Identification*
- *Case Outcome*

Denominator Statement: The number of surgical cases within the scope of the Correct Surgery Standard Operating Protocol.

Included Populations:

- All surgical cases scheduled to be performed in a hospital in-patient operating room environment.
- Emergency procedures and other late add-on procedures performed in a hospital in-patient operating room environment.
- Cases cancelled because they were potential incorrect surgeries

Excluded Populations:

- Surgical cases not performed in an inpatient operating room environment
- Surgical cases cancelled for reasons unrelated to the SOP.

Aggregate Data Elements (Used for data entry):

- *Month*
- *Year*
- *Number of Eligible Surgical Cases CS-1*

Unit-level Data Elements (Used to calculate aggregate data elements):

- *Procedure Name*
- *Procedure Date*
- *Schedule Type*
- *Location of Surgery*
- *Cancellation for Reasons Unrelated to SOP*
- *Procedure Site*

Risk Adjustment: No.

Data Collection Approach: The concurrent method of data collection through observation is recommended to collect data most accurately and to facilitate point of care intervention when necessary to promote optimal patient outcome.

Data Accuracy: * Data accuracy is enhanced when all definitions are used without modification.

- Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Measure Analysis Suggestions: Hospitals may wish to analyze the data with respect to the type of error (wrong surgical site, wrong patient, or wrong procedure). Such surgical incidents may be analyzed with respect to the degree of harm that the patient incurred.

Note: Although improvement is indicated by a decrease in the percentage, the initial trend observed may be a sharp increase in the value, as staff begins to report these occurrences.

Sampling: No.

Data Reported As: Aggregate rate generated from count data reported as a proportion.

Selected References:

1. Performance of Correct Procedure at Correct Body Site. Patient Safety Solutions, volume 1, solution 4. May 2007 (http://www.ccforpatientsafety.org/fpdf/presskit/PS-Solution4.pdf accessed September 2008)
2. World Alliance for Patient Safety, World Health Organization. The Conceptual Framework for the International Classification for Patient Safety (unpublished)

Measure Set Specific Data Elements

Data Element Name:	*Number of Complete Preoperative Verification Checklists*
Collected For:	H5sCS-1,
Definition:	A complete verification check list is one in which all items on the check list are documented as done (checked for completion, availability, and possible discrepancy). The required items to be checked in the pre-op verification process include: • Surgery schedule • Pre-op testing • Relevant images • Consent form • Pre-op nursing assessment • Pre-anesthesia assessment • History & physical exam • Site mark • Medical record • Special equipment and implants • Patient identity • Procedure • Site
Suggested Data Collection Question:	What is the total number of eligible cases with a complete pre-op verification check list?
Format:	**Length:** 4 **Type:** Numeric **Occurs:** 1
Allowable Values:	0-9999
Notes for Abstraction:	An individual item is counted as "complete" if the pre-op check list indicates the item has been checked for completeness, availability and consistency with other documents, whether discrepancies have been noted or not.
Suggested Data Sources:	Pre-op verification check list
Additional Notes:	• If any one of the items on the pre-operative verification check list is not completed (left blank or not completed properly), the case cannot be counted in the total count of completed verification check lists.

Data Element Name:	*Pre-Op Verification Checks Are Done When Surgery Is Scheduled*
Collected For:	H5sCS-1,
Definition:	At the time the surgery is scheduled, sufficient information is obtained to assure that all aspects of the surgical procedure are carried out as intended; specifically that the correct procedure is done on the correct patient at the correct surgical site, and with all necessary equipment and implants available at the start of the procedure. This includes two separate and distinct forms of patient identification, the full name of the intended procedure (without abbreviations), identification of the intended surgical side/site (without abbreviations), and any necessary special equipment or implants.
Suggested Data Collection Question:	What aspects of the pre-op verification process took place at the time of surgery scheduling?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply. • 1 Patient identity was confirmed by two separate and distinct forms of identification. • 2 The procedure was recorded unambibously, without abbreviations • 3 The surgical site was recorded unambiguously, without abbreviations • 4 Special equipment and/or implants that are required are identified and specified. • 5 None of the above were done
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the Surgery Scheduling Log.
Suggested Data Sources:	• Preoperative check list • Surgical scheduling log

Data Element Name:	*Pre-Op Verification Checks Are Done at Pre-Op Testing*
Collected For:	H5sCS-1,
Definition:	At the time of pre-op testing, pre-op verification checks are done to assure that the correct procedure is done at the correct surgical site on the correct patient.
Suggested Data Collection Question:	What aspects of the pre-op verification process took place at the time of pre-op testing?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply • 1 Test requisitions are verified, by two separate and distinct forms of identification, for correct patient identity • 2 Test requisitions are verified by correct procedure • 3 Test requisitions are verified for correct site of surgery • 4 None of the above were verified
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original pre-op test requisitions.
Suggested Data Sources:	• Preoperative check list • Requisitions for pre-op lab testing, imaging, etc.

Data Element Name:	*Pre-Op Verification Checks Are Done When Patient Consent Is Obtained*
Collected For:	H5sCS-1,
Definition:	When informed consent for surgery is obtained, pre-op verification checks are done to assure that the correct procedure is done at the correct surgical site on the correct patient.
Suggested Data Collection Question:	What aspects of the pre-op verification process took place when the consent for surgery was obtained?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply • 1 The consent form was verified, by two separate and distinct forms of identification, for the correct patient identity • 2 The consent form was verified for the correct procedure • 3 The consent form was verified for the correct surgical site • 4 None of the above were verified
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original informed consent document.
Suggested Data Sources:	• Informed consent form • Preoperative verification check llist

Data Element Name:	*Pre-Op Verification Checks Are Done When Pre-operative Assessments are Performed*
Collected For:	H5sCS-1,
Definition:	Whe pre-operative patient assessments (nursing, anesthesia, and medical history and physical [H & P]) are performed, the pre-op verification process takes place to assure that the correct procedure is done at the correct surgical site on the correct patient.
Suggested Data Collection Question:	What aspects of the pre-op verification process took place when the pre-operative assessments were performed?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply • 1 The nursing assessment includes verification of patient identity using two separate and distinct forms of identification. • 2 The nursing assessment includes verification of the correct procedure. • 3 The nursing assessment includes verification of the correct surgical site. • 4 The pre-anesthesia assessment includes verification of patient identity using two separate and distinct forms of identification. • 5 The pre-anesthesia assessment includes verification of the correct procedure. • 6 The pre-anesthesia assessment includes verification of the correct surgical site. • 7 The medical H & P includes verification of patient identity using two separate and distinct forms of identification. • 8 The medical H & P includes verification of the correct procedure. • 9 The medical H & P includes verification of the correct surgical site.
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original nursing and pre-anesthesia assessments and the medical H&P.
Suggested Data Sources:	• Pre-op nursing assessment • Pre-anesthesia assessment • Medical history and physical • Preoperative verification check list

Data Element Name:	*Pre-Op Verification Checks Are Done on Entry to Pre-Op Holding*
Collected For:	H5sCS-1,
Definition:	When the surgical patient arrives in the pre-op holding unit, pre-op verification checks are done to assure that the correct procedure is done at the correct surgical site on the correct patient.
Suggested Data Collection Question:	What aspects of the pre-op verification process took place when the patient entered the pre-op holding unit?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply • 1 Patient identity was confirmed by two separate and distinct forms of identification • 2 The correct procedure was verified with the patient • 3 The correct site of surgery was verified with the patient • 4 None of the above were done
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original Holding Unit clinical notes.

Data Element Name:	*Pre-Op Verification of Medical Record Entries*
Collected For:	H5sCS-1,
Definition:	The patient's medical record is assembled prior to surgery and information with respect to patient identity, planned procedure and intended site are consitent throughout the medical record and are verified to be consistent with other preoperative documentation.
Suggested Data Collection Question:	Does the documentation in the patient's medical record display the correct patient identity, correct surgery, and the correct surgical site on all appropriate documents?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	* Each document in the medical record may not necessarily contain information relative to the surgical procedure and site, for example, a vital sign graphic, however such documents should be verified for patient identity.
Suggested Data Sources:	☐ Anesthesia record ☐ Consultation notes ☐ History and physical ☐ Laboratory report ☐ Vital signs graphic record ☐ Face sheet ☐ Nursing admission assessment ☐ Progress notes ☐ Preop checklist ☐ Diagnostic test reports ☐ Medication administration record (MAR) ☐ Preoperative check list

Data Element Name:	*Pre-Op Verification of Diagnostic Test Results*
Collected For:	H5sCS-1,
Definition:	Prior to the patient's surgery, diagnostic test results and relevant images are obtained, and the reports and labels are verified for the correct patient identity, procedure and site.
Suggested Data Collection Question:	Do the reports of all diagnostic tests and labels on all relevant images obtained prior to surgery contain the correct patient identity, procedure and site information?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	Primary data collection can be based on documentation of this pre-op verification step on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original pre-op test report and image labels.
Suggested Data Sources:	☐ Laboratory report ☐ Preoperative check list ☐ Diagnostic images ☐ Test reports

Data Element Name:	*Pre-Op Verification: Special Equipment [DUPLICATE]*
Collected For:	H5sCS-1,
Definition:	Prior to the patient's surgery, all required special equipment and implants if appropriate, are verified to be available for the surgical procedure.
Suggested Data Collection Question:	If special equipment or implants are required for the patient's procedure, were the items required verified to be avaialibe for the surgery?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1 Yes, all items verified and available • 2 No, items were not verified • 3 No, items were verified but not available • 4 No special equipment or implants required

Data Element Name: *Pre-Op Verification Summary*

Collected For: H5sCS-1, H5sCS-6,

Definition: During the pre-operative period specific processes and verification of specific documents must be undertaken. Prior to surgery, the surgery is scheduled and recorded in the OR log, pre-operative testing is done, surgical consent is obtained, pre-operative assessments are completed, the medical record is assembled and diagnostic test results and images, special equipment and implants are obtained when required. At these specific points, the patient identity is confirmed, and correct procedure and surgical site is verified.

Suggested Data Collection Question: At the conclusion of the pre-operative period, what is the status of this patient's preoperative verification?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

Select all that apply

- 1. The pre-op verification is complete (with or without discrepancies)
- 2. The surgical case was cancelled due to unreconciled discrepancy
- 3. The surgical case was advanced with unresolved discrepancy
- 4. Not applicable (out of SOP scope)

Notes for Abstraction:

* The pre-op verification process is considered complete if all elements listed on the check list have been checked, whether or not any discrepancies have been identified. In this situation select Value 1.

- Any items on the pre-op verification check list that are left blank are considered "discrepancies." As with other discrepancies, they must be reconciled, or the case cancelled (check Value 2), or the case moves forward with unresolved discrepancies (check Value 3).
- If the case is cancelled due to unreconciled discrepancies, all subsequent steps on the Preoperative Verification Check List should be checked "not applicable." As a result, if there are no remaining blanks, the pre-op verification can be considered complete and Value 1 can be selected along with Value 3.

Suggested Data Sources:

- Pre-op Verification Check List

Data Element Name:	*Month*
Collected For:	H5sCI-O1, H5sCI-O2, H5sCI-O3, H5sCI-P1, H5sCI-P1a, H5sCI-P1b, H5sCI-P1c, H5sCI-P2, H5sCI-P2a, H5sCI-P2b, H5sCI-P2c, H5sCI-P3, H5sCI-P3a, H5sCI-P3b, H5sCI-P3c, H5sCI-P4, H5sCI-P4a, H5sCI-P4b, H5sCI-P4c, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7, H5sMR-1, H5sMR-1a, H5sMR-1b, H5sMR-2, H5sMR-2a, H5sMR-2b, H5sMR-3, H5sMR-3a, H5sMR-3b, H5sMR-4, H5sMR-4a,
Definition:	The 2 digit month during which the measure specific episode occurred or for which data were collected.
Suggested Data Collection Question:	What was the month for which data were collected or during which the measure specific episode occurred?
Format:	**Length:** 2 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 01 January • 02 February • 03 March • 04 April • 05 May • 06 June • 07 July • 08 August • 09 September • 10 October • 11 November • 12 December
Notes for Abstraction:	None

Data Element Name:	*Year*
Collected For:	H5sCI, H5sCI-O1a, H5sCI-O1b, H5sCI-O1c, H5sCI-O2, H5sCI-O2a, H5sCI-O2b, H5sCI-O2c, H5sCI-O3, H5sCI-O3b, H5sCI-O3c, H5sCI-P1, H5sCI-P1a, H5sCI-P1b, H5sCI-P1c, H5sCI-P1d, H5sCI-P1f, H5sCI-P2, H5sCI-P2a, H5sCI-P2b, H5sCI-P2c, H5sCI-P3, H5sCI-P3a, H5sCI-P3b, H5sCI-P3c, H5sCI-P4, H5sCI-P4a, H5sCI-P4b, H5sCI-P4c, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7, H5sMR-1, H5sMR-1a, H5sMR-1b, H5sMR-2, H5sMR-2a, H5sMR-2b, H5sMR-3, H5sMR-3a, H5sMR-3b, H5sMR-4, H5sMR-4a,
Definition:	The 4-digit year during which the measure specific episode occurred.
Suggested Data Collection Question:	What was the year during which the measure specific episode occured?
Format:	**Length:** 4 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	YYYY (0-9999)
Notes for Abstraction:	None
Suggested Data Sources:	• Preop checklist • Operating room notes • Operative report

Data Element Name: *Number of Eligible Surgical Cases CS-1*

Collected For: H5sCS-1, H5sCS-6, H5sCS-7,

Definition: The total number of surgical cases scheduled to be performed in the hospital in-patient operating room including emergency and other late "add-on" cases minus those cases that were cancelled for convenience or where the patient expired prior to arriving in the surgical suite.

Suggested Data Collection Question: What is the total number of eligible surgical cases for the month?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

- Surgical cases cancelled for potential incorrect surgery are included in the count of eligible surgical cases.
- Ambulatory or "day surgery" cases that are performed in the inpatient operating room environment are included in the count of eligible surgical cases.
- The number of eligible surgical cases for measure CS-1 will also be the same number of eligible cases for CS-6 and CS-7.
- The definition of "inpatient operating room environment" is the hospital's operating room environment (suite of ORs) that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).

Suggested Data Sources: Operating Room Scheduling Log

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• Emergency cases and other late additions to the OR schedule	• Dedicated obstetrical operating room procedures • Procedures performed in Endoscopy and other Special Procedure Units • Procedures performed in facilities used exclusively for ambulatory surgery • Cancelled cases for convenience • Cases in which the patient expired before arriving in the OR

Data Element Name: *Procedure Name*

Collected For: H5sCS, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,

Definition: The name of the eligible procedure that is scheduled to be performed in the hospital inpatient operating room including emergency and other late add-on cases.

Suggested Data Collection Question: What is the name of the eligible surgical procedure?

Format:

Length: 100

Type: Alphanumeric

Occurs: 1?

Allowable Values: Name of any surgical procedure

* Only include procedures that are scheduled to be performed in the hospital inpatient operating room.

Notes for Abstraction:

- Primary data collection can be based on documentation of this on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original entries in the surgery scheduling log and medical record.

Suggested Data Sources:

- Preoperative check list
- Surgery Scheduling log
- Surgery Consent Form
- Surgeon's preoperative note

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• Emergency cases and othe late additions to the OR schedule	• Dedicated obstetrical operating room procedures • Procedures performed in Endoscopy and other Special Procedure Units • Procedures perfromed in facilities used exclusively for amublatory surgery

Data Element Name: *Procedure Date*

Collected For: H5sCS, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,

Definition: The month, day, and year when the eligible procedure was performed.

Suggested Data Collection Question: What was the date the procedure was performed?

Format:

Length: 10 - MM-DD-YYYY (includes dashes) or UTD
Type: Date
Occurs: 10??

Allowable Values:

MM = Month (01-12) DD = Day (01-31) YYYY = Year (2000-9999) UTS = Unable to Determine

* If the procedure date cannot be determined from the surgery scheduling log or medical record documentation, enter UTD.

Notes for Abstraction:

- The medical record must be abstracted as documented (taken at face value). When the date documented is obviously in error (not a valid date/format or is outside of the parameters of care [after discharge date]) and no other documentation is found that provides this information, the abstractor should select UTD.
- An eligible procedure is one that is scheduled to be performed in the hospital inpatient operating room including emergency and other late add on cases.
- If a scheduled case is cancelled, enter the date the case was scheduled to be performed.

Suggested Data Sources:

- ☐ Consultation notes
- ☐ Progress notes
- ☐ Discharge summary
- ☐ Operative notes
- ☐ Operating room notes
- ☐ Operative report
- ☐ Procedure notes
- ☐ Surgery scheduling log
- ☐ Preoperative check list

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
None	None

Data Element Name: *Schedule Type*

Collected For: H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,

Definition: The classification of the surgery that represents the time frame during which the case came to be placed on the surgery schedule, for example, planned or emergency surgery.

Suggested Data Collection Question: Which classification represents the time frame for which the surgical case was placed on the surgery schedule?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

- 1. Scheduled greater than or equal to 48 hours before the planned surgery.
- 2. Late add-on (scheduled less than 48 hours before surgery)
- 3. Emergency Case
- 4 UTD (unable to determine)

Notes for Abstraction: * Include only cases schedule to be performed in a hospital in-patient operating room environment

Suggested Data Sources:

- Preoperative check list
- Operating Room Scheduling Log

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• Cases performed in a hospital inpatient operating room	• Dedicated obstetrical operating room procedures • Procedures performed in Endoscopy and other special procedure units • Procedures performed in facilities used exclusively form ambulatory surgery

Data Element Name:	*Location of Surgery*
Collected For:	H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,
Definition:	The physical location of the place where the surgery is to take place.
Suggested Data Collection Question:	Where did the surgery take place?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Inpatient hospital operating room • 2. Dedicated obstetrical operating room • 3. Endoscopy or Special Procedure Unit • 4. Ambulatory surgery facility/room • 5. UTD unable to determine
Notes for Abstraction:	
Suggested Data Sources:	• Operating Room Scheduling Log • Operating room record

Data Element Name: *Cancellation for Reasons Unrelated to SOP*

Collected For: H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,

Definition: The surgical case was withdrawn for reasons not related to the Standard Operating Protocol (SOP). For example, the case is cancelled because the patient expired prior to arriving to the OR, or the operating room or surgeon was not available.

Suggested Data Collection Question: Was the surgical case cancelled for reasons unrelated to the SOP?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

- Y = Yes
- N = No

Notes for Abstraction:

Check "Yes" if the case was cancelled and none of the reasons for cancellation were related to the SOP.

Check "No" if the case was cancelled and one or more of the reasons for cancellation were related to the SOP

Check "No" if the case was not cancelled.

Suggested Data Sources:

- Surgery scheduling log

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
	* Case cancelled for reason related to SOP (discrepancy noted at Final time out, etc)

Data Element Name:	*Procedure Site*
Collected For:	H5sCS, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6, H5sCS-7,
Definition:	The location, on or in the body, of the procedure including laterality or level (spinal surgery), etc.
Suggested Data Collection Question:	What is the site of the surgical procedure?
Format:	**Length:** 50 **Type:** Alphanumeric **Occurs:** 1?
Allowable Values:	The name of the surgical site.
Notes for Abstraction:	The site generally refers to the place where the incision will be made. However, in cases of surgery in a body cavity involving a paired organ, the specific side must be identified even though the incision may be in the midline. Primary data collection can be based on documentation of the site on the Pre-op Verification Check List. Data quality review may be conducted on a sample of cases by comparing the Pre-op Verification Check List documentation with the original entries in the surgical scheduling log or the medical record.
Suggested Data Sources:	• Preoperative check list • Surgery Schedule • Surgery Consent Form • Surgeon's pre-op note

Data Element Name: *Number of Cases With Correct Surgical Site Marked Properly*

Collected For: H5sCS-2,

Definition:

The number of eligible surgical cases for the month (cases for which site marking is required) that have the correct surgical site marked and the surgical site is marked properly. Proper site marking includes the following:

- Person performing the procedure marks the site
- Site is marked before the patient is moved to the location where the procedure will be done.
- Site marking takes place with the patient involved, awake and aware, if possible.
- Mark is made at or near the intended incision site.
- The mark is unambiguous (for example, do not use an X as this may be misinterpreted).
- The site mark is sufficiently permanent to remain visible after completion of the skin prep. Adhesive markers are not used as the sole means of marking the site.
- The method of marking is consistent with hospital policy
- For procedures that intend to treat a lateralised internal organ, whether by midline or minimal access percutaneous incision or through a natural orifice, the intended side must be indicated by a mark at or near the incision/insertion site.

Suggested Data Collection Question: What is the total number of surgical cases for the month for which site marking is required that had the correct surgical site(s) marked properly?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

- If multiple sites are to be marked for one episode of surgery, and one surgical site was not marked properly (following all applicable requirements) the case will not be included in the numerator count.
- All applicable steps in the process of site marking must be followed in order to count the case as correctly and properly marked (numerator count).

Suggested Data Sources:

- Pre-op verification check list
- Observation

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
	• Adhesive site markers as a sole means of marking the site • An "X" cannot be the site mark

Data Element Name:	*Correct Surgical Site Marked*
Collected For:	H5sCS-2,
Definition:	The correct surgical site is properly marked prior to moving the patient to the location where the surgical procedure will be done. The placement of the surgical site mark is consistent with the intended surgical site as noted preoperatively on the surgical schedule, the signed consent form, pre-operative assessments and diagnositic test results.
Suggested Data Collection Question:	Is the correct surgical site properly marked?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	Check "Yes" if site marking is not required for this type of case and no mark has been made. Check "Yes" if the correct site has been marked AND if all the requirements for "properly" marking the site have been met. Check "No" if site marking is required but the wrong site has been marked. Check "No" if all the requirements for "properly" marking the site have not been met.
Suggested Data Sources:	• Diagnostic test reports • Preoperative check list • Surgery Schedule • Pre-Op Assessments • Diagnostic and Imaging Test Results • Surgical Consent Form • Observation

Data Element Name: *Surgical Site Marked Properly [DUPLICATE]*

Collected For: H5sCS-2,

Definition:

The surgical site is marked according to processes and criteria outlined in the SOP so as to identify unambiguously the intended site of incision or insertion. Proper site marking includes the following.

- Person performing the procedure marks the site
- Site is marked before the patient is moved to the location where the procedure will be done.
- Site marking takes place with the patient involved, awarke and aware, if possible
- The mark is made at or near the intended incision site
- The mark is unambiguous (for example, an X is not to be used as this may be imiinterpreted)
- The site mark is sufficiently permanent to remain visible after completion of the skin prep. Adhesive markers are not used as the sole means of marking the site.
- The method of marking is consistent with hospital policy; this requirement relates to the tyoe of site mark that may be used.
- For procedures that intend to treat a lateralized internal organ, whether by midline or minimal access percutaneous incision or through a natural orifice, the intended side must be indicated by a mark at or near the incision/insertion site.

Suggested Data Collection Question: What criteria were adhered to in carrying out the process of surgical site marking?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

Check all that apply

- 1 The person performing the procedure marked the site
- 2 The mark is made before the patient moved to the procedure site
- 3 The Patient is aware and involved in the marking if possible
- 4 The mark was made at or near the intended incision site
- 5 The mark was unambiguous
- 6 The mark was made using permanent skin marker
- 7 The marking method was consistent with hospital policy
- 8 The mark indicates the correct side for midline access to lateral site

* An "X" to mark the intended site may not be used as it mayb be interpreted as "do not operate here".

Notes for Abstraction:

 For cases in which it is technically or anatomically impossible or impractical to mark the site, an alternative method for visually identifying the correct side is used: for example, a temporary unique wrist band on the side of the procedure which contains the patient's name, a second identifier, the intended procedure and site.

 All applicable steps in the process of site marking must be followed in order to consider the site as properly marked.

Suggested Data Sources:

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• permanent site marker	• Adhesive marker used as the sole means of marking • "X" as the site mark

Data Element Name:	*Site Mark Summary*
Collected For:	H5sCS-2, H5sCS-6,
Definition:	This data element provides a synopsis or status of the site marking specifications that are listed on the surgery check list indicating whether or not discrepancies were noted during the site marking process: • Person performing procedure marks site • Mark is made before patient moved to procedure site • Patient aware and involved in marking if possible • Mark is made at or near the intended incision site • Mark is unambiguous • Mark made using permanent skin marker • Marking method consistent with hospital policy • Mark indicates correct side for midline access to lateral site
Suggested Data Collection Question:	For cases in which site marking is required by the SOP, was the site marked and, if so, was it marked properly?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancies noted or all discrepancies have been reconciled • 2. Case cancelled due to unreconcilled discrepancy • 3. Case advanced with unresolved discrepancy • 4. Not applicable as site marking is not required for this procedure
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Site Marking Requirements*
Collected For:	H5sCS-2,
Definition:	The following are minimum requirements for surgical site marking: • The case involves laterality such as extremities, paired organs, etc. • There is a specific surface such as flexor or extensor to be marked • There is a specific level to be marked as for spine surgery • The case involves a digit or lesion to be marked When these requirements are not present, the site does not require marking. There are some cases that meet the inclusion criteria but for clinical reasons they do not require site marking. These inclue premature infants, cases in which site marking is not technically feasible, and life threatening emergencies for which the clinical judgment is that the time to mark the site is an unacceptable risk. These cases, while meeting the above requirements for site marking, are considered exempt from the site marking requirement.
Suggested Data Collection Question:	What is the requirement for site marking in this surgical case?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Case meets minimum requirements for site marking • 2. Case does not meet minimum requirements for site marking • 3. Case is exempt from site marking • 4. Case meets minimum requirements but patient refused site marking
Notes for Abstraction:	
Suggested Data Sources:	☐ Preop checklist ☐ Operating room notes

Data Element Name: *Number of Eligible Surgical Cases CS-2*

Collected For: H5sCS-2,

Definition:

The total number of surgical cases scheduled to be performed in the hospital in-patient operating room including:

- Emergency and other late "add-on" cases
- Cases cancelled for potential incorrect surgery

minus

- Cases that were cancelled for reasons unrelated to the SOP
- Cases that are exempt from the site marking requirement
- Cases that do not involve laterality, surface (flexor, extensor) level (spine), or specific digit or lesion to be treated.
- Patients that refused site marking

Suggested Data Collection Question: What is the total number of eligible surgical cases for the month for which site marking is required?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

- Examples of cases that do not involve laterality, surface, level, or specific digit or lesion might be cholecystectomy or cardiac surgery
- Do not include cases that are not performed in an in-patient OR
- The definition of "inpatient operating room environment" is the hospital's operating room environment (suite of ORs) that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).
- Cases exempt from site marking include premature infants, life threatening emergencies, etc. * Life threatening emergencies are those in which even the minimal time required to mark the site may, in the surgeon's judgment, introduce more risk to the patient than the possibility of a wrong site or wrong person procedure due to lack of site marking.

Suggested Data Sources: Operating Room Scheduling Log

Data Element Name:	*Number of Surgical Cases With Complete Final Time-Out*
Collected For:	H5sCS-3,
Definition:	The total number of surgical cases for the month where all required steps for the final time-out verification as indicated on the surgery check list in the section for Final Time-Out Verification are documented as done. This includes discrepancies whether resolved or unresolved as long as they are documented as done.
Suggested Data Collection Question:	What is the total number of cases in which all required steps of the final time out verification are documented as done?
Format:	**Length:** 4 **Type:** Numeric **Occurs:** 1
Allowable Values:	0-9999
Notes for Abstraction:	• The time-out verification of interest for this measure is the final time-out occuring immediately prior to the incision. Other time-outs that may occuring during a surgical case prior to the final time-out are not relevant to the numerator data collection or calculation. • All steps in the final time-out verification must be checked/documented as complete in order to be included in the numerator count. If one step is not checked off, the case cannot be included in the count. • If all steps in the final time-out verification are checked/documented as complete, that case will be included in the numerator count whether or not there are discrepancies and, if there are discrepancies, whether or not they are resolved.
Suggested Data Sources:	• Pre-op verification check list • Observation

Data Element Name:	*Final Time Out Verification Occurs Immediately Prior To The Procedure*
Collected For:	H5sCS-3,
Definition:	The final time out verification is conducted in the location where the procedure will be done, with the patient properly positioned for the procedure, just before the incision is made.
Suggested Data Collection Question:	Did the final time out verification occur immediately prior to the incision?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	This data element addresses only the timing of the final time out; not whether it was complete or properly done. These are addressed in other data elements.
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Initiated By Designated Coordinator*
Collected For:	H5sCS-3,
Definition:	The final time out is initiated by a designated coordinator (for example, a qualified circulating nurse).
Suggested Data Collection Question:	Was the final time out initiated by a qualified designated coordinator?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Involves Entire Operative Team*
Collected For:	H5sCS-3,
Definition:	The final time out verification involves the entire operative team (at a minimum, includes the surgeon, surgical assistants, anesthesia provider, circulating nurse, and scrub nurse or technician).
Suggested Data Collection Question:	Did the entire operative team participate in the final time out?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	This data element addresses only the presence of all members of the team when the final time out is conducted; not whether they used "active communication." "Active communication" is addressed in another data element.
Suggested Data Sources:	• Observation • Preoperative check list • Operating room record

Data Element Name:	*Final Time Out involves Active Communication*
Collected For:	H5sCS-3,
Definition:	The final time out verification includes active communication by all members of the operative team. "Active communication" means each person indicates agreement (or not) by word or gesture for each element of the time out.
Suggested Data Collection Question:	Did the final time out verification include active communication by all members of the operative team?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out: Activities Suspended*
Collected For:	H5sCS-3,
Definition:	During the final time out, other activities are suspended to the extent possible without compromising the safety of the patient, so that all members of the team are focused on the active verification of the correct patient, procedure, site, and other critical elements.
Suggested Data Collection Question:	Were other activities suspended during the final time out verification?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name: *Number of scheduled eligible procedures*

Collected For: H5sCS, H5sCS-1, H5sCS-2, H5sCS-3, H5sCS-4, H5sCS-5,

Definition: The number of(in scope) surgical operations scheduled at the participating organization to be performed in a recognized operating room. In-scope procedures include orthopedic, neurosurgical and paired internal organ procedures performed in an inpatient or outpatient operating room environment.

Suggested Data Collection Question: What was the number of eligible procedures scheduled at the facility during the reporting month?

Format:

Length: 4 ?

Type: Numeric

Occurs: 1

Allowable Values: 1 to 9999

Notes for Abstraction: Should we define recognized operating room? and should we craft a table of the procedure names we are interested in for abstractor reference, a table for orthopedic, one for neuro, and one for paired organ procedures

Suggested Data Sources:

- Surgery Scheduling Logs

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
See Table X, Y, Z for reference on in-scope procudures%ENDRED%	

Data Element Name:	*Final Time Out Verifies Patient Identity*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include at a minimum verification of six specific points. One of the six is verification of patient identity. Patient identity should be confirmed with at least two separate and distinct forms of identity.
Suggested Data Collection Question:	Which best describes the status of the final time out verification of patient identity?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Verifies Correct Procedure*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include at at a minimum verification of six specific points. One of the six is verification of the correct procedure to be done. Thus the procedure to be done must match the consent and other documentation that identifies the procedure.
Suggested Data Collection Question:	Which best describes the status of the final time out verification of the correct surgical procedure?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Verifies Correct Surgery Site*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include at a minimum verification of six specific points. One of the six is verification of the correct side and site of surgery. This verification is accomplished by visualizing the site mark after the patient has been prepped and draped.
Suggested Data Collection Question:	Which best describes the status of the final time out verification of the correct side and site of surgery?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	If site marking is not required for this particular case, the person leading the Time Out must verbalize the intended site and note agreement of the other members of the operative team. If site marking is required but the mark is not visible after prepping and draping, that is considered to be a discrepancy, which must be addressed.
Suggested Data Sources:	• Observation • Operative team acknowlegement

Data Element Name:	*Final Time Out Verifies Correct Patient Position*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include at a minimum verification of six specific points. One of the six is verification of the correct patient position for the intended procedure and site.
Suggested Data Collection Question:	Which best describes the status of the final time out verification of the correct patient position?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Verifies Images Labeled Correctly*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include, at a minimum, verification of six specific points. One of the six is verification that images are correctly labelled and properly displayed.
Suggested Data Collection Question:	Which best describes the status of the final time out verification of correctly labelled and displayed images?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Verifies Availability of Special Equipment*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5,
Definition:	The final time out must include, at a minimum, verification of six specific points. One of the six is that all needed special equipment and implants are available at the time of the surgical procedure. Even if no special equipment or implants are needed for the case, the final time out should include a verification that none are needed.
Suggested Data Collection Question:	Which best describes the status of the final time out verification with respect to the availability of implants and special equipment at the time of surgery?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. No discrepancy • 2. Discrepancy Reconciled • 3. Case Cancelled due to unreconciled discrepancy • 4. Discrepancy Unresolved • 5. Not applicable
Notes for Abstraction:	
Suggested Data Sources:	• Preoperative check list • Observation

Data Element Name:	*Final Time Out Summary*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6,
Definition:	This data element provides the results of the final time out procedure with respect to completeness and management of identified discrepancies.
Suggested Data Collection Question:	What findings did the final time out verification identify?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	Check all that apply • 1. The final time out process is complete (all items documented as done). • 2. One or more discrepancies have been identified (regardless of how they have been managed) • 3. All discrepancies have been reconciled • 4. Case cancelled due to unreconciled discrepancy • 5. One or more discrepancies remain unresolved
Notes for Abstraction:	* The final time out is considered "complete" if all SOP requirements for the timing, participation, and method are met AND all six items requiring verification are addressed (includes patient identity; correct procedure; surgical site; patient position; labelling of images; and availability of implants and/or special equipment. • If an identified discrepancy remains unresolved and advances to surgery (case is not cancelled), select allowable value 4.
Suggested Data Sources:	• Preoperative check list

Data Element Name: *Number of Eligible Surgical Cases CS-3*

Collected For: H5sCS-3, H5sCS-4,

Definition: The total number of surgical cases scheduled for a hospital in-patient operating room including emergency and other late add-on cases added to the schedule minus those cases cancelled for any reason prior to the final time out (for example, cancellations for OR/surgeon convenience; incomplete or discrepant pre-op verification; missing or improper site mark; or cases where the patient expired before arriving in the OR).

Suggested Data Collection Question: What is the total number of surgical cases for the month that are eligible for a final time out?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

- Surgical cases cancelled due to incomplete or discrepant pre-op verification or missing/improper site marking will not be included in the count of eligible surgical cases. (These cases are included in the count for CS-1, CS-6, CS-7 but will not be included for CS-3 or CS-4) because the never progresses to the point at which a final time out can be conducted.
- The definition of inpatient operating room environment relates to procedures in the hospital operating room environment that serves the hospital's inpatients (excludes procedure units such as endoscopy and catheterization labs, as well as dedicated obstetrical operating rooms and facilities used exclusively for ambulatory surgery).

Suggested Data Sources:

- Operating Room Scheduling Log
- Pre-op verification check list

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• Emergency and other late add-on cases added to the OR schedule	• Procedures performed in dedicated obstetrical operating rooms • Procedures performed in Endoscopy or other special procedure units • Procedures performed in facilities used exclusively for ambulatory surgery • Cases cancelled for convenience • Cases cancelled for incomplete/discrepant pre-op verification • Cases cancelled for missing/improper site mark

Data Element Name:	*Case Cancelled: Pre-Op Verification Unreconciled Discrepancy*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6,
Definition:	The surgical case was cancelled as a result of an unreconciled discrepancy noted during the pre-operative verification process. This includes pre-op verification at the following points: • Surgery scheduled • Pre-op testing • Informed Consent • Pre-op assessments • Entry into pre-op holding • Assembling of the medical record • Procurement of diagnostic and imaging test results • Verification of availability of special equipment and implants
Suggested Data Collection Question:	Was the surgical case cancelled due to a pre-op verification unreconciled discrepancy?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	
Suggested Data Sources:	• Surgical check list

Data Element Name:	*Case Cancelled: Site Marking Unreconciled Discrepancy*
Collected For:	H5sCS-3, H5sCS-4, H5sCS-5, H5sCS-6,
Definition:	The surgical case was cancelled as a result of an unreconciled discrepancy noted during the site marking process. The discrepancy can be related to either the correct site not being marked or to the process of properly marking the surgical site.
Suggested Data Collection Question:	Was the surgical case cancelled due to an unreconciled discrepancy identified during the site marking process?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• Y = Yes • N = No
Notes for Abstraction:	Check "No" if site marking is required for this type of case but the site was not marked; or if the placement of the site mark was inconsistent with the intended site as identified on any of the preoperative documents; or if any aspect of the site marking process was not consistent with the SOP requirements.
Suggested Data Sources:	• Surgical check list

Data Element Name:	*Number of Surgical Cases With Discrepancy at Final Time-Out*
Collected For:	H5sCS-4, H5sCS-5,
Definition:	The total number of cases with one or more discrepancies noted at the final time-out verification. This includes all discrepancies, whether resolved or not.
Suggested Data Collection Question:	What is the total number of cases for the month with at least one discrepancy at the final time-out?
Format:	**Length:** 4 **Type:** Numeric **Occurs:** 1
Allowable Values:	0-9999
Notes for Abstraction:	• A discrepancy is any undocumented step in the Final Time-Out section of the Pre-op Verification Check List, or any Time Out information that is inconsistent with the corresponding information in other relevant documents or which any member of the surgical team questions or disagrees. • Both resolved and unresolved discrepancies contribute to this count. • Cancellation of surgery because of a discrepancy noted at the final time out is considered a resolution of that discrepancy.
Suggested Data Sources:	• Pre-op verification check list

Data Element Name:	*Number of Surgical Cases With Unresolved Discrepancy at Final Time-Out*
Collected For:	H5sCS-5,
Definition:	The number of cases with one or more unresolved discrepancy noted at the final time-out occuring immediately before the incision is made. (Need more of a definition, what is considered unresolved and give examples)
Suggested Data Collection Question:	What is the total number of cases for the month with one or more unresolved discrepancies noted at the final time-out?
Format:	**Length:** 4 **Type:** Numeric **Occurs:** 1
Allowable Values:	0-9999
Notes for Abstraction:	• The final time out is the time-out occuring immediately before the incision is made. Discrepancies noted at time-out verifications that occur prior to the Final Time Out verification, for example, prior to the delivery of anesthesia, would not be included in this count. • Cancellation of surgery because of a discrepancy is considered a resolution and would not be included in this count. • "Resolution" means that any undocumented steps are completed AND any discrepant information is reconciled such that all relevant documents and all members of the surgical team are in agreement OR the case is cancelled.

Data Element Name: *Number of Surgical Cases Cancelled for Discrepancies noted in SOP Implementation*

Collected For: H5sCS-6,

Definition: The number of surgical cases scheduled to be performed in a hospital in-patient operating room that were cancelled due to discrepancies identified during implementation of the Standard Operating Protocol (SOP). For example, cases cancelled at any point prior to starting the surgical procedure (making the initial incision) for reasons relating to the provisions of the SOP. For example, case cancelled because the patient is discovered to be the wrong patient at the time of entry to the pre-op holding area; or case cancelled as a means of resolving a time out discrepancy (resolved by not operating). Not included in this number of cases are those that were cancelled for convenience (for example, operating room or surgeon not available) or where the patient expired before arriving to the OR.

Suggested Data Collection Question: What is the total number of surgical cases cancelled for discrepancies noted in SOP Implementation?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

Suggested Data Sources:

- Pre-op verification check list
- Operating room scheduling log

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
• Cases cancelled because of discrepancies in the pre-op verification process • Cases cancelled because of a missing or improper site mark • Cases cancelled because of discrepancies in the time out process	• Cases cancelled for convenience of the OR or surgical team

Data Element Name: *Number of Incorrect Surgery Cases*

Collected For: H5sCS-7,

Definition: The total number of surgical cases performed in a hospital in-patient operating room where an incision was made and the case was found to be the wrong site, procedure or person whether or not the error resulted in harm.

Suggested Data Collection Question: What was the total number of surgical cases where an incison was made and the case was found to be the wrong procedure, site, or person?

Format:

Length: 4

Type: Numeric

Occurs: 1

Allowable Values: 0-9999

Notes for Abstraction:

Suggested Data Sources:

- Operating room notes
- Operative report
- Incident Report
- Surgical Safety Form/Checklist

Additional Notes:

Guidelines for Abstraction:

Inclusion	Exclusion
Wrong site, procedure or person cases performed (initial incision made) in an inpatient operating room environment.	

Data Element Name:	*Level of Harm (Unit-level data element)*
Collected For:	H5sCI-O1, H5sCI-O2, H5sCI-O3, H5sCS-7,
Definition:	The harm scale is intended to measure an event's impact on a patient's functional ability, including quality of life and is to be applied after any attempt to prevent, reduce, or halt the progression of harm following the event (24 hours following the time of the event is recommended). Scale points are arranged in order of degree of permanence and severity of impact.
Suggested Data Collection Question:	What is the level of harm sustained by the patient as a result of the event/incident?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Death • 2. Severe Permanent Harm: Severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life. • 3. Permanent Harm: Life-long bodily or psychological injury or increased susceptibility to disease • 4. Temporary Harm: Bodily or psychological injury, but likely not permanent • 5. Additional Treatment: Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury. • 6. Emotional distress or inconvenience: Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation, physical examination, laboratory testing, including phlebotomy, and/or imaging studies). • 7. No Harm * Select the first applicable category, in descending order.
Notes for Abstraction:	This is a unit level data element collected for the outcome measures so as to understand the adverse event impact on the patient. The data element is not used in the calculation of the outcome measures.
Suggested Data Sources:	• Incident Reports • Operative report • Progress notes

Data Element Name:	*Incorrect Surgery Classification*
Collected For:	H5sCS-7,
Definition:	For any case in which an incorrect surgery was identified at any time after the incision was made, the type of error(s) involved. An incorrect surgery could be any one of the following: a procedure performed on the wrong patient, performed at the wrong site, the wrong implant placed, or the wrong procedure performed.
Suggested Data Collection Question:	Which of the following describes the type of incorrect surgery?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Wrong Patient • 2. Wrong Procedure • 3. Wrong Site • 4. Wrong Implant
Notes for Abstraction:	* Allowable values for this data element should be selected only if there was an actual incorrect surgery. Check all that apply. • The phrase "incorrect surgery" applies only to the types of errors noted above. For purposes of the High 5s project, it does not include cases determined to be incorrect based on clinical judgment; for example, a subsequent determination that the surgery was not necessary.
Suggested Data Sources:	• Observation • Preoperative check list • Operating room record • Operative report

Data Element Name:	*Time of Error Identification*
Collected For:	H5sCS-7,
Definition:	The time at which the surgical error was first noticed, including actual or potential incorrect surgeries.
Suggested Data Collection Question:	When was the actual or potential incorrect surgery first noticed?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Intra-operatively • 2. Immediately post-op • 3. In the PACU • 4. In a hospital patient-care unit post-PACU • 5. Post discharge from the hospital
Notes for Abstraction:	
Suggested Data Sources:	☐ Preop checklist ☐ Operating room notes ☐ Operative report ☐ PACU/recovery room record

Data Element Name:	*Case Outcome*
Collected For:	H5sCS-5, H5sCS-6, H5sCS-7,
Definition:	A determination of the outcome of the surgical case; for example, the case was completed uneventfully and no SOP-related discrepancies were identified, an incorrect surgery was identified, or a potential incorrect surgery was noted (case progressed to surgery with unresolved discrepancy but an actual incorrect surgery did not occur).
Suggested Data Collection Question:	Which best describes the outcome of this surgical case?
Format:	**Length:** 1 **Type:** Alphanumeric **Occurs:** 1
Allowable Values:	• 1. Case cancelled due to SOP-related unreconciled discrepancy • 2. Case cancelled for reasons other than SOP-related discrepancy • 3. Incorrect surgery identified • 4. Potential incorrect surgery (unresolved discrepancy) • 5. None of the above
Notes for Abstraction:	
Suggested Data Sources:	Surgical scheduling log Preoperative check list Operating room record Operative report

Action on Patient Safety: High 5s

SOP
Vermeidung von Eingriffsverwechslungen

Deutsche Version

Anhang 5

Ausgewählte Referenzen und Ressourcen

Stand der Bearbeitung: Mai 2010

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