Provincial Frozen Plasma (FP)/Prothrombin Complex Concentrate (PCC) Utilization Audit

Version 1. November 2013.

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You will find all the information needed to conduct your audit within this package.
If you require additional information or have any questions, please contact:

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On behalf of,

Ontario Regional Blood Coordinating Network

Provincial Frozen Plasma (FP)/Prothrombin Complex Concentrate (PCC) Utilization Audit – 2013

Purpose and Rationale

The goal of the FP/PCC utilization audit is to determine whether the introduction of the Ontario Recommendations for the Use of FP and the implementation of PCC have resulted in a reduction in the inappropriate use of FP. An initial baseline FP audit conducted in 2008, found that 54.8% of orders for frozen plasma were "appropriate", 28.6% "inappropriate" and 16.6% "indeterminate". A web-based audit tool has been created to for to audit the utilization of these blood products.

Following the provincial plasma audit in 2008, Ontario recommendations for the use of FP were developed and disseminated to all Ontario hospitals to provide guidance for the appropriate use of frozen plasma. Guidelines for the use of PCC were published by the National Blood Advisory Committee on Blood and Blood Products (NAC) and disseminated to Ontario hospitals in 2009.

At the time of the first provincial FP audit, PCC were being introduced into Ontario hospitals to be used for the urgent reversal of warfarin, therefore the initial audit did not capture PCC utilization data. The Plasma Audit Steering Committee has recommended that the use of PCC be captured in this subsequent provincial audit.

Population to be studied

This data collection project will focus on all patients being transfused with FP or PCC. There will be no interaction with patients to collect this data; the data elements required are listed below:

- Hospital site (coded)
- Patient care area
- Date of transfusion
- Patient identification by study code number
- Patient age (YOB)
- Gender
- Indication for FP/PCC transfusion including baseline coagulation results
- Number of units/vials ordered and transfused
- Ordering physician specialty

Each order will be assigned an order number for entry into a secure database. Other than the patient's year of birth and gender, there is no patient specific data that will be entered

in the electronic audit tool. The database is housed on a SQL secure server housed by the Ontario Regional Blood Coordinating Network portal.

Provincial FP/PCC Audit Methods

A prospective review of the clinical indications and laboratory data in all transfusion episodes of FP and PCC occurring in all participating Ontario hospitals will take place for any five days chosen by the site between Monday November 18th and Friday December 13th. The 5 day period does not need to be consecutive days. For the participating sites that utilize plasma or PCCs infrequently, please choose the days in which you receive orders for plasma or PCC to audit. (if possible).

Manual data entry forms have been included in this audit package for those sites that would find it easier to log the order data manually and subsequently enter the information into the electronic audit tool.

In addition, a **FP/PCC Audit Patient Tracking Log** is included for sites to log patient specific information. This information will not be entered into the electronic tool and can be used internally at each site. The purpose of the log is to maintain the patients' anonymity and allow for cross-referencing should there be a reason to investigate data discrepancies. The electronic audit tool will automatically assign an order number. Please record the order number on the FP/PCC Audit Patient Tracking Log.

At the conclusion of the provincial audit, a review of the utilization data will be used to determine whether or not ordering practices have improved since the baseline audit was conducted in 2008. This data will be used to determine future strategies to influence ordering and infusion practices of FP and PCC.

FP/PCC Audit- Manual Data Entry Form

Facility details (only needs to be completed once per facility)

1. a) Does your facility have institutional guidelines for the use of Frozen Plasma? ☐ Yes ☐ No

b) If yes, are the guidelines in line with the Ontario Recommendations for the Use of Frozen Plasma that were released in 2008? ☐ Yes ☐ No Link to Ontario Recommendations

2. Does your facility stock prothrombin complex concentrate (PCC)? ☐ Yes ☐ No

3. Does your facility have guidelines for the use of PCC? ☐ Yes ☐ No

FP/PCC Audit- Manual Data Entry Form

FP/PCC Transfusion Order

1. Patient age: _____ years/months

2. Transfusion date: _____

3. Patient sex: ☐ M ☐ F

4. a) Is the patient on anticoagulants? ☐ Yes ☐ No ☐ Don't know

b) If yes, which one (check all that apply)
☐ Heparin
☐ Low molecular weight heparin
☐ Fondoparinux (Arixta)
☐ Dabigatran (Pradaxa)
☐ Apixaban (Eliquis)
☐ Warfarin (Coumadin)
☐ Rivaroxaban (Xarelto)
☐ Don't know
☐ Other (please specify) _____

5. a) Does the patient have a coagulopathy? ☐ Yes ☐ No ☐ Don't know

b) Is yes, which one?
☐ DIC
☐ Vitamin K deficiency
☐ Liver disease
☐ Sepsis
☐ Massive transfusion
☐ Clotting factor deficiency
☐ Trauma
☐ Unknown

6. Bleeding status: ☐ No Bleeding ☐ Minor Bleeding ☐ Major Bleeding ☐ Unknown

Major bleeding: defined as hemorrhage sufficient to require at least one RBC within 24 hours OR intracranial OR spinal bleeding OR hemoglobin drop to <80 g/L
Minor bleeding: defined as all other bleeding situations not meeting definition of major bleeding as above.

7. Specialty of ordering physician:

☐ Anesthesia	☐ Cardiology	☐ Critical care: cardiac	☐ Critical care: medicine	☐ Dermatology
☐ Emergency	☐ Gastroenterology	☐ General Practice/Family Medicine	☐ Hematology	☐ Immunology
☐ Infectious Disease	☐ Internal Medicine	☐ Neonatology	☐ Nephrology	☐ Neurology
☐ Obstetrics and Gynecology	☐ Oncology	☐ Pediatric-General	☐ Radiology	☐ Respirology
☐ Rheumatology	☐ Surgery: Cardiovascular	☐ Surgery: General	☐ Surgery: Neurosurgery	☐ Surgery: Orthopedic
☐ Surgery: Other	☐ Unknown	☐ Other (please specify)_____		

8. a) Was there a procedure/other indication? ☐ Yes ☐ No

b) If there was a procedure, select from the list below:

☐ Central line placement	☐ Exchange transfusion	☐ Fine needle aspirate	☐ Image guided therapy	☐ Kidney biopsy
☐ Liver Biopsy	☐ Paracentesis	☐ Plasma exchange (therapeutic apheresis)	☐ Surgery	☐ Thoracentesis
☐ Unknown	☐ Other (please specify)_____			

c) If there was a procedure, was the procedure to be performed within 6 hours of administration of the blood component?
☐ Yes ☐ No ☐ Unknown

9. If there was another indication, select from the list below:

☐ DIC (Disseminated intravascular coagulation)	☐ Vitamin K deficiency	☐ Liver Disease
☐ Sepsis	☐ Massive transfusion	☐ Clotting factor deficiency
☐ Trauma	☐ Unknown	☐ No other indication
☐ Other (please specify)_____		

Product ordered/transfused

10. Product ordered: FP _____ unit(s)
PCC_____vial(s)

11. Product transfused: FP_____unit(s)
Apheresis 250 mL _____unit(s)
Apheresis 500 mL _____unit(s)
Cryosupernatant plasma_____unit(s)
PCC _____vial(s)

12. Issued to location:

☐ Apheresis	☐ Coronary care unit	☐ Diagnostic imaging	☐ Dialysis
☐ Emergency room	☐ Endoscopy	☐ ICU	☐ ICU:Cardiovascular
☐ ICU:Neonatal	☐ Medical ward	☐ Operating room	☐ Outpatient clinic
☐ Recovery room	☐ Surgical ward	☐ Unknown	☐ Other- (please specify) _____

Pre-transfusion blood work:

13. a) Was a pre-transfusion INR ordered (within 24 hours)?

☐ Yes ☐ Yes-results pending ☐No

b) If yes, what was the INR result?

☐ 0-1.2	☐ 1.3-1.5	☐ 1.6-1.7	☐ 1.8-1.9
☐ 2.0-3.0	☐ 3.1-5.0	☐ 5.1-10.0	☐ >10.0

14. a) Was a pre-transfusion aPTT ordered (within 24 hours)?

☐ Yes ☐ Yes-results pending ☐ No

b) If yes, what was the aPTT result?

☐ Within normal range	☐ between upper limit of normal range and 1.5 X upper limit of normal range	☐ 1.6-2.0 X upper limit of normal range	☐ >2.0 X upper limit of normal range

Post-transfusion blood work:

15. a) Was a post-transfusion INR ordered (within 6 hours)?

☐ Yes ☐ Yes-results pending ☐ No

b) If yes, what was the INR result?

☐ 0-1.2	☐ 1.3-1.5	☐ 1.6-1.7	☐ 1.8-1.9
☐ 2.0-3.0	☐ 3.1-5.0	☐ 5.1-10.0	☐ >10.0

16. a) Was a post-transfusion aPTT ordered (within 6 hours)?

☐ Yes ☐ Yes-results pending ☐ No

b) If yes, what was the aPTT result?

☐ Within normal range	☐ between upper limit of normal range and 1.5 X upper limit of normal range	☐ 1.6-2.0 X upper limit of normal range	☐ >2.0 X upper limit of normal range

17. a) Was an adverse transfusion reaction (ATR) reported within 6 hours? ☐ Yes ☐ No

b) If yes, what were the symptoms?

☐ Chills	☐ Fever	☐ Hypotension
☐ Dyspnea	☐ Hives, urticaria	☐ Tachycardia
☐ Other (please specify)_____		

c) If yes, what was the ATR diagnosis?

☐ Acute hemolytic reaction	☐ Allergic reaction	☐ Febrile non-hemolytic
☐ TACO (Transfusion associated circulatory overload)	☐ TRALI (Transfusion related acute lung injury)	☐ Other (please specify)_____

Audit Question Instruction Sheet

Facility Details (facility questions will only need to be entered once into the audit tool)	
1. a) Does your facility have institutional guidelines for the use of Frozen Plasma?	**Answer Yes or No.** **If yes, proceed to question 1. b)** **If no, proceed to question 2.**
1. b) If yes, are the guidelines in line with the Ontario recommendations for the Use of Frozen Plasma that were released in 2008?	**Answer Yes or No.** ORBCoN released recommendations for the use of frozen plasma in 2008. View Ontario Recommendations **Proceed to question 2.**
2. Does your facility stock prothombin complex concentrate (PCC)?	**Answer Yes or No.** Prothrombin complex concentrates include Octaplex and/or Beriplex.
3. Does your facility have guidelines for the use of PCC?	**Answer Yes or No.** These could be the NAC guidelines or guidelines developed by your facility.

Plasma/Prothrombin Complex Concentrate Order	
1. Patient age	Enter the patient's age in years or months (if patient a neonate).
2. Order date	Enter the date of the transfusion order.
3. Patient sex	Select either Male (M) or Female (F).
4. a) Is the patient on anticoagulants?	**Select Yes or No or Unknown**. If yes, proceed to question 4. b) If no, proceed to question 5. If unknown, proceed to question 5.
4. b) Is yes, which one?	Choose all anticoagulants that apply. Proceed to question 5. a).
5. a) Does the patient have a coagulopathy?	Select Yes or No. If yes, proceed to question 5. b) If no, proceed to question 6.
5. b) If yes, which coagulopathy does the patient have?	Choose the coagulopathy the patient has. If this information is not known, select Unknown. Proceed to question 6. Note: Massive transfusion will appear down below as an indication. If there is a known coagulopathy related to the massive transfusion, choose Yes here
6. Bleeding status	Select either **No Bleeding, Minor bleeding, Major bleeding** or **Unknown**. Definition of minor and major bleeding on Manual form.
7. Specialty of ordering physician	Select the specialty of the ordering physician. Select "other" if specialty is not in list and

	record the specialty.
8. a) Was there a procedure/other indication?	Select **Yes** if the patient was going for a procedure or if there was another indication for the product. Proceed to 8 b). Select **No** if there wasn't a procedure or other indication. Proceed to question 9. Note: Massive transfusion also appears in the list of "other indications". It can be selected again as the indication, either with or without a coagulopathy.
b) If there was a procedure, which one?	Select the procedure. Proceed to 8. c)
c) If there was a procedure, was the procedure to be performed within 6 hours of administration of the blood component?	Select Yes, No or Unknown. Proceed to question 9. This question is included because the use of PCC is recommended for "urgent" (within 6 hours) reversal of warfarin, plasma should not be used for urgent reversal.
9. If there was another indication which one?	Select the indication. Proceed to question 10.

Product ordered/transfused	
10. Product ordered	Select the number of units of FP ordered or the number of vials of PCCs ordered. Note: the assumption here is that each unit of plasma ordered is equivalent to a 250ml bag
11. Product transfused	Select the number of units of FP transfused or the number of vials of PCCs transfused. ***Solvent detergent plasma should be entered as FP.** Note: The audit tool will automatically count 500ml apheresis units as "2" units of FP in the transfused data in the site report.
12. Issued to location	Select the location that the product(s) were issued to. If location is not listed, select "other" and specify the location.
Pre-transfusion blood work	
13. a) Was a pre-transfusion INR ordered (within 24 hours)?	Select **Yes** if an INR was ordered within 6 hours of the product order and if the results of the INR were available at the time of the product order. **Proceed to question 13.b)** Select **Yes-results pending** if an INR was ordered within 6 hours of the product order but the INR results were pending at time of product order. **Proceed to question 14 a)**. Select **No** if an INR was not ordered within 6 hours of the product order. **Proceed to question 14 a).**

13. b) If yes, what was the INR result?	If an INR was ordered within 6 hours of the product order and the results were available at time of order, select the range of the INR result. 0-1.2 1.3-1.5 1.6-1.7 1.8-1.9 2.0-3.0 3.1-5.0 5.1-10.0 >10.0
14. a) Was a pre-transfusion aPTT ordered (within 24 hours)?	Select **Yes** if an aPTT was ordered within 24 hours of the product order and if the results of the aPTT were available at the time of the product order. **Proceed to question 14.b)** Select **Yes-results pending** if an aPTT was ordered within 24 hours of the product order but the aPTT results were pending at time of product order. **Proceed to question 15. a)** Select **No** if an aPTT was not ordered within 24 hours of the product order. **Proceed to question 15. a).**
14. b) If yes, what was the aPTT result?	If an aPTT was ordered within 24 hours of the product order and the results were available at time of product order select the range of the aPTT result. -within normal range -1-1.5 X normal range -1.6-2.0 X normal range ->2.0 X normal range
Post-transfusion blood work	
15. a) Was a post-transfusion INR ordered (within 6 hours)?	Select **Yes** if an INR was ordered within 6 hours post-transfusion. **Proceed to question 15. b)** Select **Yes-results pending** if an aPTT was ordered within 24 hours of the product order but the aPTT results were pending at time of product order. **Proceed to question 16**. Select **No** if an INR was not ordered within 6 hours post-transfusion. **Proceed to question 16.**
15. b) If yes, what was the INR result?	If an INR was ordered within 6 hours post-transfusion select the range of the INR result. 0-1.2

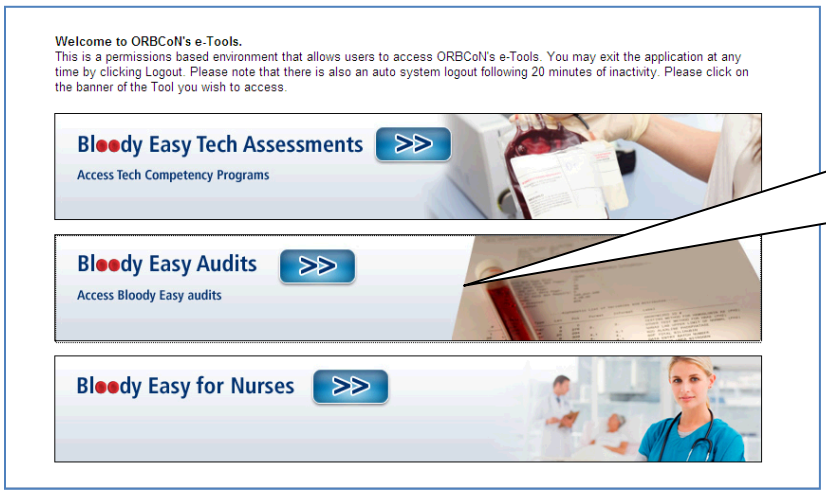
	1.3-1.5 1.6-1.7 1.8-1.9 2.0-3.0 3.1-5.0 5.1-10.0 >10.0
16. a) Was a post-transfusion aPTT ordered (within 6 hours)?	Select **Yes** if an aPTT was ordered within 6 hours post-transfusion. **Proceed to 16. b)** Select **Yes-results pending** if an aPTT was ordered within 24 hours of the product order but the aPTT results were pending at time of product order. **Proceed to question 17. a)** Select **No** if an aPTT was not order within 6 hours post-transfusion. **Proceed to question 17.a)**
16. b) If yes, what was the aPTT result?	If an aPTT was ordered within 6 hours post-transfusion select the range of the aPTT result. within normal range 1-1.5 X normal range 1.6-2.0 X normal range >2.0 X normal range
17. a) Was an adverse transfusion reaction (ATR) reported within 6 hours?	Select **Yes** if an adverse transfusion reaction was reported within 6 hours post-transfusion. **Proceed to question 17. b)** Select **No** if there was not an adverse transfusion reaction reported within 6 hours post-transfusion. **You have completed the data entry for this order. Click Save to save this order.**
17. b) If yes, what were the symptoms?	Select all the symptoms that apply to the adverse transfusion reaction. **Proceed to question 17. c)**
17. c) If yes, what was the adverse transfusion reaction (ATR) diagnosis?	Select the diagnosis for the adverse transfusion reaction. **You have completed the data entry for this order. Click Save to save this order.**

FP/PCC Audit Tool Quick Guide for Site Administrator

http://orbcon.transfusionontario.org/etools/index.php?c=security&m=login

Login

Enter Email address and Password and click Login. (this information will be provided to each hospital's site administrator)



Accessing Bloody Easy Audits application

Click anywhere on the Bloody Easy Audits box to open the audit programs.

Accessing Frozen Plasma Audit tool

Click on the Frozen Plasma Audit box to open the FP Audit Tool.

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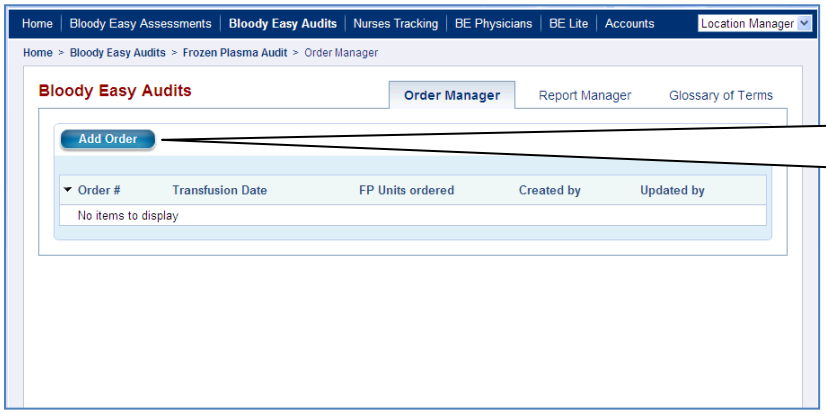
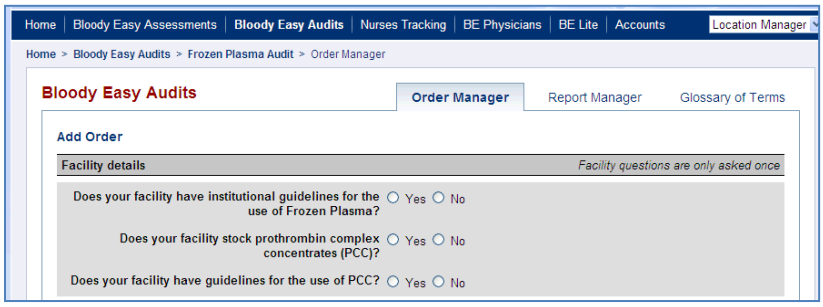


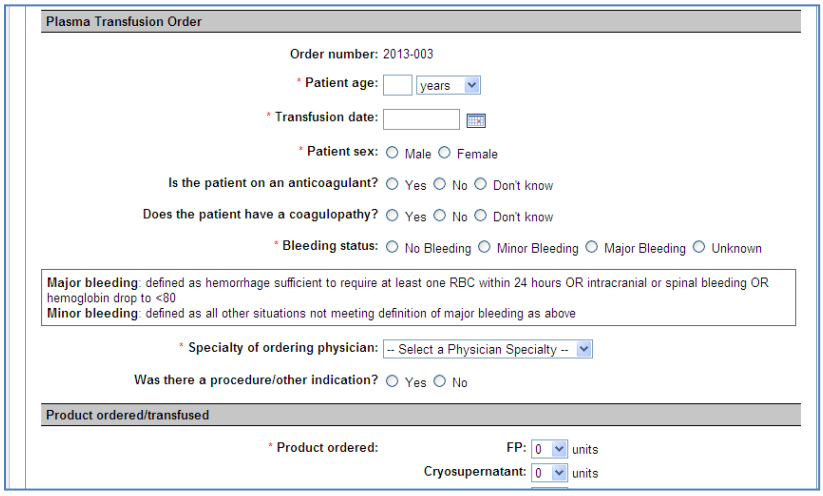
Entering audit data

Click on Add Order to enter the FP/PCC audit data for each order.



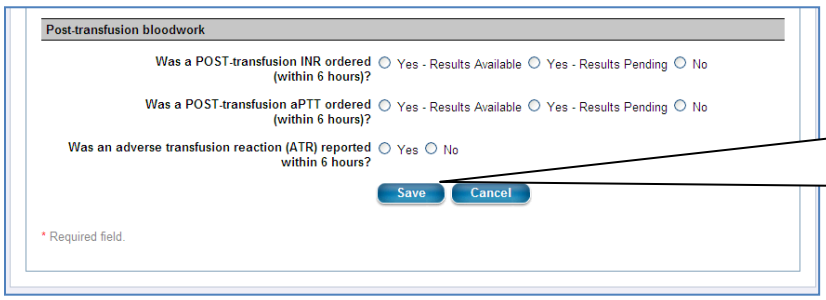
Facility Details

Enter the answers to the facility questions. (These questions only need to be answered once and will not appear again)



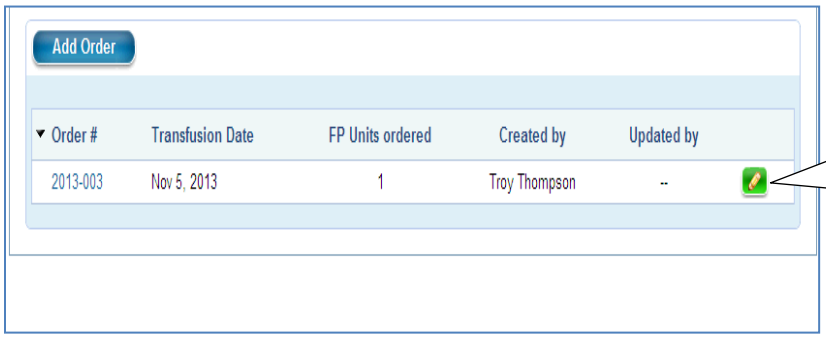
Subsequent audit data entry

Enter remaining audit data into application. (Instructions for audit questions can be found on Pg. 10)



Save audit data

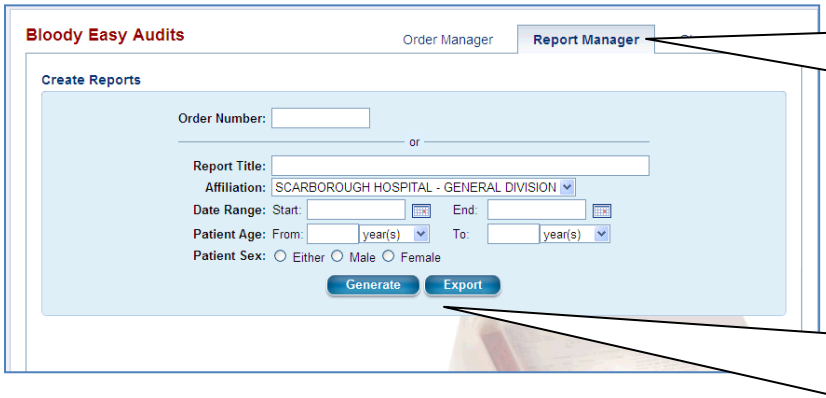
Upon data entry for each order click on the Save button to save audit data.



Editing existing audit data for specific order

Click on Green "pencil" button to edit audit data on a specific order.

Report Manager Function



Report Manager Function

To access site specific reports click on Report Manager tab.

Generating Site Specific Reports

To obtain site specific reports on your computer click on **Generate.**

To export site specific reports into Excel click on **Export**.

Form 1: FP/PCC Audit Patient Tracking Log

Order Number*	Order Date	Last Name	First Name	Hospital Identification Number	Data Entry Complete☑	Initials

The Order number is auto-generated by the electronic audit tool. Please record the number is this column.