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Pregnancy Care for women with Cystic Fibrosis Guideline

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Document Control

Ownership

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Contents

1. Introduction

With the improvement in the survival of women with cystic fibrosis (CF), many are in good health and wish to have a baby. Working within a multidisciplinary team within a specialised centre can improve the outcome for the woman and her baby with due attention towards pro-active management of multi-system needs and challenges posed by the physiological needs of pregnancy. CF can have adverse outcomes on the fetus and twenty five percent of the babies born to CF mothers are premature.

Wythenshawe hospital is the North West Centre for cystic fibrosis and women diagnosed with cystic fibrosis receive comprehensive care here with good outcomes.

This guideline outlines in brief the management of women with CF when they present to their nearest or local hospital with obstetric issues or if they go into labour.

2. Women presenting with Obstetric or other problems

Assess women at the Obstetric triage and treat for any immediate obstetric concern.
Arrange for further follow up at Wythenshawe hospital if no acute emergency.
If needs further obstetric input, CF team input or if in early labour transfer to Wythenshawe hospital if safe to do so.

3. Women presenting in advanced labour or unable to transfer to St Marys Hospital Wythenshawe

- Women with CF can have a spontaneous vaginal delivery if their lung function has been predicted to be at an optimal range this has been agreed during the antenatal period.
- When in established labour the woman should be transferred to the high dependency room on the delivery suite for continuous maternal and fetal monitoring.
- Adequate early analgesia in the form of low dose epidural analgesia during labour reduces cardiovascular and respiratory work associated with labour.
- It may be judicious to shorten the second stage of labour to prevent prolonged Valsalva manoeuvre using forceps or vacuum as per clinical need.
- Planned caesarean might be required in a proportion of women for example due to poor lung function that precludes vaginal delivery.

- Liaise with the cystic fibrosis team (Phone Pearce Ward 0161 291 4732 or 0161 291 4011) if advice needed.
  Liaise with anaesthetist, core midwife and neonatal team to plan the caesarean.
- Combined spinal epidural, epidural analgesia or general anaesthesia can be used for caesarean as dictated by the patient's CF status and anaesthetic input.
- If delivery is planned prior to 37 weeks antenatal corticosteroids should be administered to the mother for fetal lung maturity. Women with diabetes will need variable rate intravenous insulin infusion (VRIII) as per protocol.
- In situations where delivery is indicated prior to 34 completed weeks' magnesium sulphate should be administered for fetal neuroprotection (Refer to local guidelines preterm birth guidelines).
- Management of IV access (Appendix 1)
- Management of diabetes
  - For women with diabetes / gestational diabetes who are having a planned caesarean section, the need for a variable rate intravenous insulin infusion (VRIII) should be discussed on an individual basis – most have sufficient endogenous insulin to cover background requirements when nil by mouth.
  - Women having vaginal delivery who have required insulin during pregnancy are likely to require a VRIII.
  - Women whose diabetes is managed by insulin pump could continue to use this during labour/C section at discretion of diabetes team and the wishes of individual.

4. Management in the Postnatal period

- Women can be transferred for postnatal care to Wythenshawe hospital if they are stable enough.
- Extra help and support is needed for mothers with CF who have a new-born. This should be coordinated between the CF team, obstetricians and midwives.
- Postpartum care should be delivered in a High dependency room of the delivery suite for 24 hours.
- The woman then stays in a single room with the baby on the postnatal ward.
- Adequate rest is necessary for optimal maternal recuperation and care of the new-born.
- In many instances the women may need to continue IV antibiotics post-delivery to clear infections
  - Management of PORT access as per Appendix 1
  - Decision to transfer to oral antibiotics to be made in conjunction with CF team
- Early mobilisation and assisted physiotherapy helps in clearance of the lung and improve ventilation. Within first few hours of delivery support with active chest clearance, inhaled therapies and mobilisation in conjunction with adequate analgesia should be ensured.
- Postpartum analgesia helps with physiotherapy and early mobilisation.

- If breast feeding is considered adequate nutritional supplementation of the mother should be ensured with additional intake of 500 kcal/day with addition of vitamin D, Calcium and optimal hydration.
- Any medications omitted during pregnancy can be recommenced if not contraindicated should the mother consider breast feeding (Appendix 2).
- Appropriate initiation of contraception should be considered as soon as possible.
- At discharge women with CF should have routine postnatal care with the community midwives, health visitors and other services and support systems available to new mothers.

Appendix 1: Management of Intravenous Access

There are three types of venous access devices that patients with Cystic Fibrosis (CF) may use as a means of delivering fluids and/or intravenous antibiotics during their stay in the maternity unit.

Cannula

A small thin flexible tube placed in a vein and taped into place with clear dressing. This gives intravenous access for 24-48 hours.

Midline

A thin flexible catheter up to 20 centimetres in length. The tip is advanced no further than the distal axillary vein in the upper arm. This type of line directs fluids/ antibiotics into a larger vein and meets the need of a patient who requires more than 5 days of intravenous therapy.

For most of the CF patients this is the preferred form of access to be used in the maternity department postnatally for the infusion of IV antibiotics. The Cystic Fibrosis Clinical Nurse Specialist (CFCNS) would be happy to assist with any education or training required in using this device.

Totally implantable venous access device

Commonly known as a Port are devices that are used long term for IV fluids, antibiotics and blood sampling. Ports are inserted when the patient has poor venous access and the above methods of access are no longer viable.
Under no circumstances should the ports be accessed without prior training as it is essential the system is accessed correctly using the specialist type needle and flushed according to protocol.

Training for maternity staff would have to be discussed with the Cystic Fibrosis Clinical Nurse Specialists (CFCNS).

If blood sampling is required for any CF patients via the port, CFCNS would be happy to assist with this request.

Appendix 2: Drug use in pregnant and breastfeeding women with Cystic Fibrosis

Table 1
Overview and recommendations on drug use in pregnant and breast feeding patients diagnosed with CF. New recommendations have been displayed in *italics*.

	Risk in first trimester	Risk in second/ third trimester	Risk at delivery	Recommendation	Breast feeding
Acid inhibitory drugs					
H2 antagonists	*No risk shown*	*Possible increased risk for asthma*	No	*Possible increased risk for asthma*[1]	*Possible compatible – low concentrations present in milk*
Proton pump inhibitors	No risk shown	Not shown	No	*PPI preferred*	Compatible - low concentration in milk
Prokinetics					
Metoclopramide	*No increased risk shown*[2]	*Monitor extrapyramidal syndrome in neonates in third trimester*	*Unknown*[3]	*Probably safe – first choice is meclozine second choice is metoclopramide*[5]	*Possible compatible*[4] *– passes blood-brain-barrier, short term use possible*
Domperidon	*Limited human data*	*Limited human data*	*No*	*Probably safe – meclozine preferred during pregnancy*	*Low dose present – does not cross Blood-Brain-Barrier, monitor QT-interval*
Constipation					
PEG +/− electrolytes	*No data – systemic exposure neglible*[6]	*No data – systemic exposure negligible*	*No*	*No absorption is taking place – probably safe*	*Compatible – no oral absorption*
Macrogol					
Lubiprostone	*Adverse effects in animals (fetal loss) – limited human data*[7]	*Adverse effects in animals (fetal loss) – limited human data*	*Unknown*	*Limited human data – avoid during pregnancy, Macrogol preferred*	*Avoid – no data*
Contact laxative					
Senna	*Limited human data shown no adverse effects*[8]	*Limited human data shown no adverse effects*[8]	*No*	*Short term use only*	*Possible compatible – low concentration in milk*[9]
Bisacodyl	*Animal studies show no adverse effects – limited human data*[10]	*Animal studies show no adverse effects – limited human data*	*No*	*Short term use only*[11]	*Compatible – no GI absorption*
Antibacterial drugs					
Aminoglycosides					
Gentamycin Tobramycin (i.v., inhal.)	Associated with fetal nephro- and ototoxicity	Associated with eighth cranial nerve damage in fetus but not in CF literature	No	Reserve for life threatening infections – inhaled causes minimal risk due to limited systemic absorption	Probably compatible[12] – monitor infant on GI flora effects i.e. diarrhea, candidiasis, beware of hypersensitivity
Cephalosporins					
Ceftazidim (and other cephalosporins)	*No risk shown*	No risk shown	No	Probably safe – only on strict indication	Compatible - excreted in low concentrations[13]
Fluoroquinolones					
Ciprofloxacin (and other fluorquinolones)	*Unknown*	Cartilage damage and arthropathy shown in animals[14]	No	Avoid during pregnancy, if needed ciprofloxacin drug of choice	Avoid - high concentration *Ciprofloxacin - probably compatible*[12]
Lincomycins					
Clindamycin	*No risk shown*	No risk shown	No	Probably safe – use in absence of safer alternative	*Possible Compatible – cases of bloody stool, monitor infant GI flora*[12,15]
Macrolides					
Erythromycin	*No risk shown*[16]	No risk shown	No	Use as first choice	Possible Compatible[12]
Azithromycin	*Probably no risk*	No risk shown	No	Erythromycin first choice	*Probably compatible*[12]
Roxithromycin	*No risk shown*[16]	Probably no risk	No	Erythromycin first choice	*Possible compatible*
Clarithromycin	*No risk shown*	No risk shown	No	Erythromycin first choice	*Possible compatible – low concentration in milk, monitor infant*
Penicillins					
Amoxicillin (and other penicillins + clavulanate or tazobactam)	*No risk shown*	No risk shown	No	Probably safe	Compatible – trace in milk, beware hypersensitivity
Polymyxins					
Colistin (i.v., inhal.)	*Limited human data*	*Limited human data*	No	IV avoid if possible - Inhalation probably safe	Inhaled -possible compatible IV – caution (poorly absorbed from gut)

Table 1 (*continued*)

	Risk in first trimester	Risk in second/ third trimester	Risk at delivery	Recommendation	Breast feeding
Antibacterial drugs					
Rifamycins					
Rifampicin (and other rifamycins)	*Animal studies show adverse effect, no adequate human data*[17]	Associated with risk of bleeding by mother and neonate in last trimester	No	Avoid during pregnancy, if necessary, treatment with phytomenadione of mother and neonate	Excretion in milk – discontinue nursing or drug based on importance of therapy
Sulphonamide/ trimethoprim Sulphamethoxazole/ trimethoprim	Trimethoprim is associated with neural defects – reduced by folic acid	Sulphonamide use in the last trimester is associated with icterus of the neonate	Sulphonamide use at delivery associated with fetal hemolytic anemia	Avoid during first and third trimester and at delivery	Compatible in healthy term babies – avoid if G6PD deficient or jaundiced
Trimethoprim	Trimethoprim is associated with neural defects – reduced by folic acid	Probably no risk if have normal folate status	No	Avoid during first trimester if needed, ensure adequate folate supplementation	Probably compatible[12] – low concentration in milk
Tetracyclins					
Doxycycline (and other tetracylines)	Risk of neural defects, reduced by folic acid	Tetracyclines associated with tooth discolorations and delayed osteogenesis	Associated with tooth and bone discoloration	Avoid during 2nd/3rd trimester and at delivery should not be first choice (amoxicillin, cephalexin or erythromycin) – doxycycline possible safe	Possible compatible[12] – prolonged use tooth discoloration
Carbapenems					
Imipenem	*Limited human data*	No fetal damage in animals – limited humans studies[18]	No	Preferable drugs are penicillin, cephalosporin or erythromycin[19]	Possible compatible – present in milk, unlikely to be absorbed[20]
Meropenem	Fetal damage in animals – limited human studies[21]	*No fetal damage found in animals – limited human studies*[21]	Unknown	Preferable drugs are penicillin, cephalosporin or erythromycin[22]	*Possible compatible* – present in milk, unlikely to be absorbed[23,24]
Other antibacterials					
Chloramphenicol	*No fetal damage found in animals – limited human studies*[21]	Use in last trimester associated with neonatal cyanosis and hypothermia (grey-baby syndrome)	Associated with grey-baby syndrome	Avoid during last trimester and at delivery	Avoid – vomiting, excessive intestinal gas and falling asleep[25]
Metronidazole	*No increased risk*[26,27]	*No increased risk*[26,27]	No	*No proof for adverse effects on fetus*	Probably compatible[12] – discontinue for 12 h after intake
Phosphomycin	*Animal data show adverse effects at maternal dose - Limited human data show no risk*[28,29]	*Animal data show adverse effects at maternal dose - Limited human data show no risk*[28,29]	No	Drug of choice is nitrofurantoine (not during delivery) Second choice amox/clav[30]	Possible compatible – low levels in breastmilk[31]
Vancomycin	Unknown – no evidence of fetal damage	Unknown – no evidence of fetal damage	No	Avoid during pregnancy	Compatible – present in milk, but absorption unlikely
Teicoplanin	*Animal studies show reproductive toxicity – limited human data*[32]	*Animal studies show reproductive toxicity – limited human data*	Unknown	Avoid – no data	Possible compatible – limited data, poor oral availability due to high protein binding – monitor infant for GI problems[33]
Aztreonam (i.v./inhal.)	IV animal studies show no adverse reproductive effect – limited human studies[34]	IV administration crosses placenta and enter fetal circulation – limited human studies[35]	Unknown	Only give when potential benefit outweighs any potential risk – inhaled causes negligible systemic effect	Possible compatible[36] – inhaled poor systemic absorption
Antihistamines					
Cinnarizine (and other antihistamines)	No increased risk shown – meclozine drug of choice	No increased risk shown – meclozine drug of choice	No	Probably safe to use	Avoid – limited data, meclozine drug of choice
Antimycotic drugs					
Fluconazole	Animal studies show major congenital anomalies – limited human data shows the same[37]	*Increase of spontaneous abortion in human*[37]	Yes	*Dose > 300 mg contraindicated – lower doses avoid during first trimester*	Possible compatible – present in milk (less than neonatal dosage)[38]

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Table 1 (*continued*)

	Risk in first trimester	Risk in second/ third trimester	Risk at delivery	Recommendation	Breast feeding
Antihistamines					
Itraconazole, voriconazole	Animal studies show teratogenicity – limited human data show increased spontaneous abortion[37]	No data available	Unknown	Avoid	Avoid – limited data[38]
Posaconazole	Animal studies show toxicity – no human data[37]	Animal studies show toxicity – limited human data	Unknown	Avoid	Avoid – no data
Amphotericin	*Case reports show no increased risk*[39]	*Case reports show no increased risk*[39]	No	Drug of choice during pregnancy	*Possible compatible – high protein bound, poor oral absorption*
Nystatin	Probably safe	Probably safe	No	Probably safe	Compatible – no oral absorption
Anti-viral drugs					
Aciclovir	*No risk shown*	Use in second half of pregnancy to avoid transfer of virus to fetus	No	Drug of choice	Compatible[40]
Valaciclovir	No risk shown - limited human data	No risk shown – limited human data	No	Larger bioavailability – aciclovir preferred	Compatible
Ganciclovir	Animal studies reveal teratogenicity	No human data	Unknown	Contraindicated	Avoid – no data
Blood glucose lowering drugs					
Insulins/insulin analogues	No risk	No risk	No risk	Human insulins preferred	Compatible[12]
Glibenclamide	Animal studies reveal teratogenicity – limited human data	*Increased risk for respiratory distress, NICU, neonatal hypoglycemia, large for gestational age*[41]	Increased risk for neonatal hypoglycemia	Human insulins preferred	Possible compatible – monitor infant blood glucose
Tolbutamide, netaglinide, repaglinide	Animal studies reveal teratogenicity – Limited human data	*No adequate human studies – expected to cross placenta*	Increased risk for neonatal hypoglycemia	Human insulins preferred	Possible compatible – monitor infant blood glucose
Metformin	No increased risk[42]	Probably no risk but avoid – insulin preferred	Neonatal hypoglycemia	Human insulins preferred	Compatible[12]
Pioglitazone and other thiazolidinediones	Fetal toxicity in animals	Fetal toxicity in animals[43]	Neonatal hypoglycemia	Human insulins preferred	Avoid – no data
Bisphosphonates					
Risedronate etc.	*Limited human data show no substantial fetal risk*[44] *Animal reproduction studies shown adverse effect on fetus*	*Limited human data show no substantial fetal risk – marginal decrease gestational age, birth weight and transient neonatal electrolytes*[45]	Unknown	Limited human data shows no serious fetal or neonatal damage[45] – Use with caution	Avoid – no data[40]
Cholelithiasis drugs					
Ursodeoxycholic acid	No data	Human data show no increased risk[46]	No	Avoid during first trimester	Compatible – low levels in breast milk
Contrast media					
Gastrografin	No risk anticipated with oral use	No risk anticipated with oral use	No	Probably no risk	Possible compatible – poor oral absorption, unlikely to reach infant bloodstream
Corticosteroids					
Systemic	Fetal damage in animals (mainly schisis), not in humans – Prednisolone, hydrocortisone drugs of choice	Fetal damage in animals (intrauterine growth restriction in prolonged treatment, not in humans)	No	Systemic corticosteroids used for supplementation therapy in adrenal insufficiency. Neonate should be monitored for growth retardation, adrenal insuf., hypoglycemia	Compatible – monitor infant adrenal function if maternal dose exceeds 40 mg prednisolone – delay feeding for 4–6 h after dose

Table 1 (*continued*)

	Risk in first trimester	Risk in second/ third trimester	Risk at delivery	Recommendation	Breast feeding
Corticosteroids					
Dermal	Not probable to cause fetal damage	Not probable to cause fetal damage	No	Class I and Class II dermatocorticoids are preferred. Intermittend use. Class III/IV max. 1 week in acute phase	Compatible
Nasal, tracheal steroid metered dose inhalers and drops	No increased risk shown[47]	No increased risk shown	No	Can be used in pregnancy	Compatible
Bronchodilator drugs					
Sympathicomimetics inhaled	LABA – limited data SABA – probably safe (data shows malformations – due to asthma?)	LABA – limited data SABA – probably safe (data shows malformations – due to asthma?)	No	SABA – salbutamol/albuterol LABA – Salmeterol/ formeterol	Compatible – limited systemic absorption
Anticholinergic inhaled	*Animal studies show no teratogenicity – limited human data*[48]	*Animal studies show no teratogenicity – limited human data*[48]	No	Ipratropium preferred	Probably compatible – limited systemic absorption
Aminophylline/ theophylline	Probably safe	Probably safe	Neonatal irritability, cardiac arrhythmias and apneas reported	*Control theophylline plasma level in third trimester*	Caution — present in milk: irritability in infants reported. Give modified release preparations after feeding
Pancreatic enzymes					
Pancreatic enzymes	*No animal/human data shown – probably no risk*[49]	*No animal/human data shown – probably no risk*	*No*	*Probably no risk since no maternal absorption*	*Compatible – no maternal absorption*
rhDNase					
Dornase alfa	*No fetal harm in animal studies, no human data*[50]	*No fetal harm in animal studies, no human data*[50]	*Unlikely/No*	*Due to inhaling no fetal harm expected – probably safe*[51]	*Possible compatible – due to large protein molecule absorption is low*[52]
Vitamins					
Vitamin A	Use of recommended dose of 800 RE safe[53]	Use of recommended dose of 800 RE safe[53]	No	Use of bètacarotene preferable – conversion rate adjusted to the amount of retinol is needed	Compatible – at prophylactic doses
Vitamin B group	Probably safe	Probably safe except high doses of B6 (neonatal convulsions)	No	Probably safe – use of high dose B6 contraindicated	Compatible
Vitamin C,E,K	Probably safe	Probably safe	No	Probably safe – High doses of vitamin C may cause paradoxical neonatal deficiency	Compatible
Vitamin D	Probably safe in prophylactic dose	Safe in prophylactic doses	No	Safe in prophylactic doses	Compatible – at prophylactic doses, high doses may cause hypercalcemia in infant
Immunosuppressant drugs					
Cyclosporine	*Adverse effects in animals – Human data show no increased risk of malformation*[54]	*Adverse effects in animals – Human data show no increased risk of malformation*[54]	*Risk of premature delivery - low birth weight*	Maybe not teratogen – risk of premature delivery, low birth weight, developmental delay, increased risk on development of auto-immune diseases	*Possible compatible – low levels in infant*[55] – monitor infant for liver and blood values, avoid breastfeeding 4–6 h after dose
Tacrolimus	Fetal damage in animals – limited human data show no increased risk[56]	Fetal damage in animals – limited human data show no increased risk[56]	*Risk of premature delivery - low birth weight*	Monitor infant on effect on kidneys, hyperkalemia	Possible compatible – present in low concentrations[57] monitor infant for liver and blood values, avoid breastfeeding 4–6 h after dose

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Table 1 (*continued*)

	Risk in first trimester	Risk in second/ third trimester	Risk at delivery	Recommendation	Breast feeding
Immunosuppressant drugs					
Azathioprine	Small increase of fetal malformations in animals	Small risk of neonatal immune and bone marrow suppression, premature delivery and low birth weight – monitor, weigh benefit for mother against possible effect on fetus	*Risk of premature delivery - low birth weight*	Conflicting outcomes studies - monitor blood during third trimester for leukopenia and pancytopenia	Possible compatible – avoid breastfeeding 4–6 h after dose, monitor infant for liver and blood values
Mycophenolate	Animal studies show reproductive toxicity – *teratogen in humans*[59]	Animal studies show reproductive toxicity – *teratogen in humans*	Risk of spontaneous abortions	Avoid – contraindicated[59]	Avoid – no data[60]
CFTR modulators					
Class II modulator					
Lumacaftor	*No adverse effects in animal studies*[61]	*No adverse effects in animal studies*	*Unknown*	*Avoid – limited human data*	*Avoid – no human data*
Class III modulator					
Ivacaftor	*Limited human data – no adverse effects in animal studies*	*Limited human data – no adverse effects in animal studies*	*Unknown*	*Avoid – limited human data*	*Avoid – no human data*
Class IV modulator					
Ivacaftor	*See Class III CFTR modulators*	*See Class III CFTR modulators*	*See Class III CFTR modulators*	*See Class III CFTR modulators*	*See Class III CFTR modulators*
Osmotic agents					
Mannitol (inhal.)	*Animal studies show no malformations – limited human data*[63,64]	*Animal studies show no malformations – limited human data*[63,64]	*Unknown*	*Due to local absorption, limited systemic effect - Possible hyper reactive response unknown*[64]	*Avoid - unknown*
Anti-inflammatory agents					
Ibuprofen	*Human data show no significant increase in birth defect risk*[65]	*Avoid – contraindicated due to increased risk of renal failure and premature closing ductus arteriosus and cryptorchism*[66]	*Yes*	*Can be used during first trimester – avoid during second/third trimester*	*Compatible*
Vaccines					
Influenza	*No known adverse effects found*[67]	*Limited data show no adverse effects*[67]	*No*	*Limited data suggest vaccination is safe in the first trimester*	*Compatible*[68] *- antibodies present in milk, vaccinate child in routine schedules*
Pneumococcal	*Animal studies show no adverse effects – limited human data suggest also no adverse effects*[69]	*Animal studies show no adverse effects – limited human data suggest also no adverse effects*[69]	*No*	*Use with caution*	*Compatible*[68] *– antibodies present in milk, vaccinate child in routine schedules*

References

1) Journal of Cystic Fibrosis, MAGM Kroon et al (2018) 17-25

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