

**Appendixes - Comparative Effectiveness of
Terbutaline Pump for the Prevention of Preterm
Birth**

Appendix A. Search Strategies

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1950 to 2009 Dec Week 1> (updated to 2010 April Week 3)

Search Strategy:

- 1 exp Obstetric Labor, Premature/ (14094)
- 2 (PTL or PTB or RPTL).ti,ab. (2396)
- 3 ((premature* or pre-mature* or preterm or pre-term or early) adj5 (labor* or labour* or birth* or deliver*)).ti,ab. (32212)
- 4 ((premature* or pre-mature* or preterm or pre-term or early) adj5 ((uterine or uterus) adj2 contract*)).ti,ab. (306)
- 5 Tocolysis/ or Tocolytic Agents/ (1876)
- 6 (tocolysis or tocolytic*).ti,ab. (2856)
- 7 1 or 2 or 3 or 4 or 5 or 6 (40062)
- 8 exp Terbutaline/ (2921)
- 9 (Terbutalin* or Brethaire or Brethine or Bricanyl or "BRN 2370513" or "EINECS 245-385-8" or "UNII-N8ONU3L3PG").ti,ab. (3089)
- 10 (23031 25 6 terbutaline or 23031 32 5 terbutaline sulfate).rn. (2921)
- 11 8 or 9 or 10 (3761)
- 12 exp Injections, Subcutaneous/ (31708)
- 13 exp Infusion Pumps/ (9822)
- 14 exp Home Infusion Therapy/ (555)
- 15 exp Infusions, Parenteral/ (75058)
- 16 (subcutaneous* or SubQ or sub-cutaneous* or pump or pumps or infuse or infused or infuses or infusing or infusion* or infuser*).ti,ab. (354453)
- 17 ((home adj3 therapy) or (home adj3 therapies) or (home adj3 tocoyl*) or (home-based adj3 therapy) or (home-based adj3 therapies) or (home-based adj3 tocoyl*)).ti,ab. (2249)
- 18 ((maintenance adj3 therapy) or (maintenance adj3 therapies) or (maintenance adj3 therapeutic) or (maintenance adj3 treatment*) or (maintenance adj3 tocoyl*) or (supportive adj3 therapy) or (supportive adj3 therapies) or (supportive adj3 treatment*) or (supportive adj3 tocoyls*) or (outpatient adj3 therapy) or (outpatient adj3 therapies) or (outpatient* adj3 treatment*) or (outpatient* adj3 tocoyl*)).ti,ab. (27705)
- 19 ((long-term adj therapy) or (long-term adj therapies) or (long-term adj therapeutic) or (long-term adj treatment*) or (long-term adj management) or (long-term adj tocoyl*) or (longterm adj therapy) or (longterm adj therapies) or (longterm adj therapeutic) or (longterm adj treatment*) or (longterm adj management) or (longterm adj tocoyl*)).ti,ab. (23491)
- 20 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 (457526)
- 21 11 and 20 (694)
- 22 7 and 21 (158)
- 23 from 22 keep 1-158 (158)

Database: EMBASE <1980 to 2009 Week 49> (Updated to 2010 Week 16)
Search Strategy:

-
- 1 exp premature labor/ (12859)
 - 2 (PTL or PTB or RPTL).ti,ab. (1981)
 - 3 ((Premature* or pre-mature* or preterm or pre-term or early) adj5 (labor* or labour* or birth* or deliver*)).ti,ab. (24223)
 - 4 ((Premature* or pre-mature* or preterm or pre-term or early) adj5 ((uterine or uterus) adj2 contract*)).ti,ab. (243)
 - 5 exp Tocolysis/ (2223)
 - 6 (tocolysis or tocolytic*).ti,ab. (2419)
 - 7 1 or 2 or 3 or 4 or 5 or 6 (30904)
 - 8 exp terbutaline/ (8346)
 - 9 exp terbutaline sulfate/ (492)
 - 10 (23031 25 6 or 23031 32 5).m. (8627)
 - 11 (Terbutalin* or Brethaire or Brethine or Bricanyl or "BRN 2370513" or "EINECS 245-385-8" or "UNII-N8ONU3L3PG").ti,ab. (2721)
 - 12 (Terbutalin* or Brethaire or Brethine or Bricanyl).tn. (1416)
 - 13 8 or 9 or 11 or 12 (8802)
 - 14 exp subcutaneous drug administration/ (72002)
 - 15 exp infusion pump/ (2755)
 - 16 exp infusion/ (26593)
 - 17 (subcutaneous* or SubQ or sub-cutaneous* or pump or pumps or infuse or infused or infuses or infusing or infusion* or infuser*).ti,ab. (285686)
 - 18 ((home adj3 therapy) or (home adj3 therapies) or (home adj3 tocoyl*) or (home-based adj3 therapy) or (home-based adj3 therapies) or (home-based adj3 tocoyl*)).ti,ab. (1578)
 - 19 ((maintenance adj3 therapy) or (maintenance adj3 therapies) or (maintenance adj3 therapeutic) or (maintenance adj3 treatment*) or (maintenance adj3 tocoly*) or (supportive adj3 therapy) or (supportive adj3 therapies) or (supportive adj3 treatment*) or (supportive adj3 tocoyls*) or (outpatient adj3 therapy) or (outpatient adj3 therapies) or (outpatient* adj3 treatment*) or (outpatient* adj3 tocoly*)).ti,ab. (23804)
 - 20 ((long-term adj therapy) or (long-term adj therapies) or (long-term adj therapeutic) or (long-term adj treatment*) or (long-term adj management) or (long-term adj tocoly*) or (longterm adj therapy) or (longterm adj therapies) or (longterm adj therapeutic) or (longterm adj treatment*) or (longterm adj management) or (longterm adj tocoly*)).ti,ab. (21021)
 - 21 14 or 15 or 16 or 17 or 18 or 19 or 20 (392514)
 - 22 13 and 21 (1163)
 - 23 7 and 22 (188)
 - 24 from 23 keep 1-188 (188)

CINAHL 2009 Dec 7

#	Query	Results
S24	S12 AND S23	32
S23	S13 OR S14 OR S16 OR S17 OR S18 OR S19 OR S22	30893
S22	(MH "Infusions, Parenteral+")	4186
S21	S12 AND S20	32
S20	S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19	30863
S19	TX (long-term W1 therapy) or (long-term W1 therapies) or (long-term W1 therapeutic) or (long-term W1 treatment*) or (long-term W1 management) or (long-term W1 tocoly*) or (longterm W1 therapy) or (longterm W1 therapies) or (longterm W1 therapeutic) or (longterm W1 treatment*) or (longterm W1 management) or (longterm W1 tocoly*))	4365
S18	TX (maintenance N3 therapy) or (maintenance N3 therapies) or (maintenance N3 therapeutic) or (maintenance N3 treatment*) or (maintenance N3 tocoly*) or (supportive N3 therapy) or (supportive N3 therapies) or (supportive N3 treatment*) or (supportive N3 tocoly*) or (outpatient* N3 therapy) or (outpatient* N3 therapies) or (outpatient* N3 therapeutic) or (outpatient* N3 treatment*) or (outpatient* N3 tocoly*)	4252
S17	TX (home N3 therapy) or (home N3 therapies) or (home N3 tocoly*) or (home-based N3 therapy) or (home-based N3 therapies) or (home-based N3 tocoly*)	2453
S16	TX subcutaneous* or SubQ or sub-cutaneous* or pump or pumps or infuse or infused or infuses or infusing or infusion* or infuser	21255
S15	(MH "Infusions, Parenteral")	276
S14	(MH "Infusion Pumps+")	1748
S13	(MH "Injections, Subcutaneous+")	1188
S12	S8 AND S11	63
S11	S9 or S10	206
S10	TX Terbutalin* or Brethaire or Brethine or Bricanyl or "BRN 2370513" or "EINECS 245-385-8" or "UNII-N8ONU3L3PG"	206
S9	(MH "Terbutaline")	137
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7	5924
S7	TX Tocolytic OR tocolysis	431
S6	"TX ((premature* N5 (uterine N2 contract*)) OR (pre-mature* N5 (uterine N2 contract*)) OR (preterm N5 (uterine N2 contract*)) OR (pre-term N5 (uterine N2 contract*)) OR early N5 (uterine N2 contract*))) or TX ((premature* N5 (uterus N2 contract*)) OR (pre-mature* N5 (uterus N2 contract*)) OR (preterm N5 (uterus N2 contract*)) OR (pre-term N5 (uterus N2 contract*)) OR (early N5 (uterus N2 contract*)))"	0
S5	TX (early N5 labor*) OR (early N5 labour*) OR (early N5 birth*) OR (early N5 deliver*)	1189
S4	TX ((preterm N5 labor*) or (preterm n5 labour*) or (preterm n5	3453

	birth*) or (preterm n5 deliver*)) or TX ((pre-term N5 labor*) or (pre-term n5 labour*) or (pre-term n5 birth*) or (pre-term n5 deliver*))	
S3	TX ((premature* N5 labor*) or (premature* n5 labour*) or (premature* n5 birth*) or (premature* n5 deliver*)) or TX ((pre-mature* N5 labor*) or (pre-mature* n5 labour*) or (pre-mature* n5 birth*) or (pre-mature* n5 deliver*))	2397
S2	TX PTL or PTB or RPTL	180
S1	(MH "Labor, Premature")	1539

Cochrane Library 2009, Issue 4 (updated to April 25, 2010)

ID	Search	Hits
#1	MeSH descriptor Obstetric Labor, Premature explode all trees	782
#2	(PTL or PTB or RPTL):ti,ab,kw	56
#3	(premature* NEAR/5 labor*) OR (premature* NEAR/5 labour*) OR (premature* NEAR/5 birth*) OR (premature* NEAR/5 deliver*):ti,ab,kw	1744
#4	(premature NEAR/5 (uterus NEAR/2 contract*)):ti,ab,kw or (premature NEAR/5 (uterine NEAR/2 contract*)):ti,ab,kw	15
#5	(pre NEXT mature* NEAR/5 labor*) OR (pre NEXT mature* NEAR/5 labour*) OR (pre NEXT mature* NEAR/5 birth*) OR (pre NEXT mature* NEAR/5 deliver*):ti,ab,kw	0
#6	((pre NEXT mature) NEAR/5 (uterus NEAR/2 contract*)):ti,ab,kw or ((pre NEXT mature) NEAR/5 (uterine NEAR/2 contract*)):ti,ab,kw	0
#7	(preterm NEAR/5 labor*) OR (preterm NEAR/5 labour*) OR (preterm NEAR/5 birth*) OR (preterm NEAR/5 deliver*):ti,ab,kw	1466
#8	(preterm NEAR/5 (uterus NEAR/2 contract*)):ti,ab,kw or (preterm NEAR/5 (uterine NEAR/2 contract*)):ti,ab,kw	15
#9	(pre NEXT term NEAR/5 labor*) OR (pre NEXT term NEAR/5 labour*) OR (pre NEXT term NEAR/5 birth*) OR (pre NEXT term NEAR/5 deliver*):ti,ab,kw	28
#10	((pre NEXT term) NEAR/5 (uterus NEAR/2 contract*)):ti,ab,kw or ((pre NEXT term) NEAR/5 (uterine NEAR/2 contract*)):ti,ab,kw	0
#11	(early NEAR/5 labor*) OR (early NEAR/5 labour*) OR (early NEAR/5 birth*) OR (early NEAR/5 deliver*):ti,ab,kw	602
#12	(early NEAR/5 (uterus NEAR/2 contract*)):ti,ab,kw or (early NEAR/5 (uterine NEAR/2 contract*)):ti,ab,kw	9

#13	MeSH descriptor Tocolysis explode all trees	92
#14	(tocolysis or tocolytic*):ti,ab,kw	479
#15	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)	3147
#16	MeSH descriptor Terbutaline explode all trees	686
#17	(Terbutalin* or Brethaire or Brethine or Bricanyl or "BRN 2370513" or "EINECS 245-385-8" or "UNII-N8ONU3L3PG"):ti,ab,kw	1220
#18	(#16 OR #17)	1220
#19	MeSH descriptor Injections, Subcutaneous explode all trees	2896
#20	MeSH descriptor Infusion Pumps explode all trees	806
#21	MeSH descriptor Home Infusion Therapy explode all trees	41
#22	MeSH descriptor Infusions, Parenteral explode all trees	9362
#23	(subcutaneous* or SubQ or (sub NEXT cutaneous*) or pump or pumps or infuse or infused or infuses or infusing or infusion* or infuser*):ti,ab,kw	38786
#24	((home NEAR/3 therapy) or (home NEAR/3 therapies) or (home NEAR/3 tocoyl*) or ((home NEXT based) NEAR/3 therapy) or ((home NEXT based) NEAR/3 therapies) or ((home NEXT based) NEAR/3 tocoyl*):ti,ab,kw	657
#25	((maintenance NEAR/3 therapy) or (maintenance NEAR/3 therapies) or (maintenance NEAR/3 therapeutic) or (maintenance NEAR/3 treatment*) or (maintenance NEAR/3 tocoyl*) or (supportive NEAR/3 therapy) or (supportive NEAR/3 therapies) or (supportive NEAR/3 treatment*) or (supportive NEAR/3 tocoyls*) or (outpatient NEAR/3 therapy) or (outpatient NEAR/3 therapies) or (outpatient* NEAR/3 treatment*) or (outpatient* NEAR/3 tocoyl*):ti,ab,kw	6598
#26	((long NEXT term NEXT therapy) or (long NEXT term NEXT therapies) or (long NEXT term NEXT therapeutic) or (long NEXT term NEXT treatment*) or (long NEXT term NEXT management) or (long NEXT term NEXT tocoyl*) or (longterm NEXT therapy) or (longterm NEXT therapies) or (longterm NEXT therapeutic) or (longterm NEXT treatment*) or (longterm NEXT management) or (longterm NEXT tocoyl*):ti,ab,kw	3944
#27	(#19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26)	49538
#28	(#15 AND #18 AND #27)	51

51 records

DSR – 3
DARE – 1
CENTRAL – 41
HTA – 1
NHS EED – 5

CRD Databases – 2010 Jan 2

	Search	<u>Matching records</u>
# 1	<u>MeSH Obstetric Labor, Premature EXPLODE 1</u>	146
# 2	<u>PTL OR PTB OR RPT</u>	13
# 3	<u>(premature* NEAR labor*) OR (premature* NEAR labour*) OR (premature* NEAR birth*) OR (premature* NEAR deliver*)</u>	153
# 4	<u>(premature NEAR contract*)</u>	11
# 5	<u>(pre NEAR mature* NEAR labor*) OR (pre NEAR mature* NEAR labour*) OR (pre NEAR mature* NEAR birth*) OR (pre NEAR mature* NEAR deliver*)</u>	1
# 6	<u>pre NEAR mature NEAR contract*</u>	0
# 7	<u>(preterm NEAR labor*) OR (preterm NEAR labour*) OR (preterm NEAR birth*) OR (preterm NEAR deliver*)</u>	342
# 8	<u>preterm NEAR contract*</u>	25
# 9	<u>(pre NEAR term NEAR labor*) OR (pre NEAR term NEAR labour*) OR (pre NEAR term NEAR birth*) OR (pre NEAR term NEAR deliver*)</u>	97
# 10	<u>(pre NEAR term NEAR contract*)</u>	7
# 11	<u>(early NEAR labor*) OR (early NEAR labour*) OR (early NEAR birth*) OR (early NEAR deliver*)</u>	281
# 12	<u>early NEAR contract*</u>	28
# 13	<u>MeSH Tocolysis EXPLODE 1</u>	14
# 14	<u>tocolysis OR tocolytic*</u>	67
# 15	<u>MeSH Terbutaline EXPLODE 1 2</u>	17
# 16	<u>Terbutalin* OR Brethaire OR Brethine OR Bricanyl OR "BRN 2370513" OR "EINECS 245-385-8" OR "UNII-N8ONU3L3PG"</u>	37
# 17	<u>#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14</u>	726
# 18	<u>#15 OR #16</u>	44

# 19	<u>#17 AND #18</u>	18
# 20	<u>MeSH Injections, Subcutaneous EXPLODE 1</u>	103
# 21	<u>MeSH Infusion Pumps EXPLODE 1 2</u>	89
# 22	<u>MeSH Home Infusion Therapy EXPLODE 1 2</u>	26
# 23	<u>MeSH Infusions, Parenteral EXPLODE 1</u>	359
# 24	<u>subcutaneous* OR SubQ OR (sub NEAR cutaneous*) OR pump OR pumps OR infuse OR infused OR infuses OR infusing OR infusion* OR infuser*</u>	1589
# 25	<u>(home NEAR therapy) OR (home NEAR therapies) OR (home NEAR tocoyl*)</u>	280
# 26	<u>(maintenance NEAR therapy) or (maintenance NEAR therapies) or (maintenance NEAR therapeutic) or (maintenance NEAR treatment*) or (maintenance NEAR tocoyl*) or (supportive NEAR therapy) or (supportive NEAR therapies) or (supportive NEAR treatment*) or (supportive NEAR tocoyls*) or (outpatient NEAR therapy) or (outpatient NEAR therapies) or (outpatient* NEAR treatment*) or (outpatient* NEAR tocoyl*)</u>	0
# 27	<u>(maintenance NEAR therapy) OR (maintenance NEAR therapies) OR (maintenance NEAR therapeutic) OR (maintenance NEAR treatment*) OR (maintenance NEAR tocoyl*)</u>	707
# 28	<u>(supportive NEAR therapy) OR (supportive NEAR therapies) OR (supportive NEAR treatment*) OR (supportive NEAR tocoyls*)</u>	350
# 29	<u>(outpatient NEAR therapy) OR (outpatient NEAR therapies) OR (outpatient* NEAR treatment*) OR (outpatient* NEAR tocoyl*)</u>	991
# 30	<u>#20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29</u>	3794
# 31	<u>#19 AND #30</u>	14

14 records

DARE - 7
NHS EED - 6
HTA - 1

Appendix B. Grey Literature Search

Search Dates: Nov. 27, 2009; Nov 29, 2009; Dec 31, 2009; Jan 2, 2010

Statistics

Canadian perinatal health report.

Public Health Agency of Canada, 2008

<http://www.phac-aspc.gc.ca/publicat/2008/cphr-rspc/pdf/cphr-rspc08-eng.pdf>

Alberta Reproductive Health: Pregnancies and Births Table Update, 2005

Alberta Health & Wellness; Alberta Perinatal Health Program, 2005

<http://www.health.alberta.ca/documents/Reproductive-Health-2005.pdf>

Systematic Reviews/Health Technology Assessments

Screening to prevent spontaneous preterm birth: systematic reviews of accuracy and effectiveness literature with economic modelling *Health Technol Assess* 2009;13(43):1–627

Summary: <http://www.hta.ac.uk/execsumm/summ1343.shtml>

Full text: <http://www.hta.ac.uk/fullmono/mon1343.pdf>

Continuous subcutaneous terbutaline infusion for treatment of preterm labor. HAYES, Inc. Healthcare Technology Brief Publication. 2006

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32009100278>

Subscription required

Management of preterm labor, 2000

Evidence report/Technology assessment no 18

<http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=hserta&part=A26682>

Safety

Short-acting beta agonists and risk of myocardial ischaemia

Final SPC and PL wording agreed by PhVWP October 2009

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/Product_Information/PhVWP_Recommendations/SABAs/CMDh-PhVWP-008-2009-Rev0a.pdf

ICU MEDICAL, INC. ORBIT 90" SUBCUTANEOUS INFUSION SET

Device leak, 2006

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=795454

CADD-MICRO TERBUTALINE PUMP SHOWER BAG

Injury, 2005

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=578910

Warning on use of terbutaline sulfate for preterm labor

JAMA. 1998;279(1):9

<http://jama.ama-assn.org/cgi/content/extract/279/1/9-a>

Guidelines

Terbutaline pump for preterm labor

Aetna, 25 Aug 2009

http://www.aetna.com/cpb/medical/data/400_499/0468.html

Management of Labour

ICSI, May 2009

http://www.icsi.org/labor/labor_management_of_full_version_2.html

Obstetric and Medical Complications. In: Guidelines for perinatal care

ACOG, 2007

<http://www.acog.org/publications/guidelinesForPerinatalCare/gpc-175.pdf>

Management of preterm labor

<http://www.acog.org/publications/pdfs/pb043.pdf>

Tocolytic drugs for women in preterm labour

RCOG, 2002

<http://www.rcog.org.uk/files/rcog-corp/GT1BTocolyticDrug2002revised.pdf>

Conference Literature

Continuous Subcutaneous Terbutaline Therapy Improves Outcome in Pregnancies

Complicated by Preterm Labour: Presented at ACOG. 11 May 2009

[Presentation title: *Using Meta-Analysis Methodology to Evaluate Treatment of Preterm Labor. Abstract 79*]

<http://www.peerviewpress.com/continuous-subcutaneous-terbutaline-therapy-improves-outcome-pregnancies-complicated-preterm-labour-presented-acog>

Economics

Ambrose S, Rhea DJ, Istwan NB, Collins A, Stanziano G. Clinical and economic outcomes of preterm labor management: inpatient vs outpatient. *J Perinatol* 2004;24(8):515-9.

Economic evaluation:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22004009091>

Fleming A, Bonebrake R, Istwan N, Rhea D, Coleman S, Stanziano G. Pregnancy and economic outcomes in patients treated for recurrent preterm labor. *J Perinatol* 2004;24(4):223-7.

Economic evaluation:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22004006413>

Morrison JC, Chauhan SP, Carroll CS, Sr., Bofill JA, Magann EF. Continuous subcutaneous terbutaline administration prolongs pregnancy after recurrent preterm labor. *Am J Obstet Gynecol* 2003;188(6):1460-5.

Economic evaluation :

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22003009556>

Lam F, Istwan NB, Jacques D, Coleman SK, Stanziano GJ. Managing perinatal outcomes: the clinical benefit and cost-effectiveness of pharmacologic treatment of recurrent preterm labor. *Manag Care* 2003;12(7):39-46.

Full text: http://www.managedcaremag.com/archives/0307/0307.peer_terbutaline.pdf

Economic evaluation:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22003006379>

Lam F, Bergauer NK, Jacques D, Coleman SK, Stanziano GJ. Clinical and cost-effectiveness of continuous subcutaneous terbutaline versus oral tocolytics for treatment of recurrent preterm labor in twin gestations. *J Perinatol* 2001;21(7):444-50.

Economic evaluation:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22002006321>

General/Miscellaneous

Note: Oregon Centre for Evidence-Based Policy appears to have done an evaluation on this topic but I can't find it on their Web site. You may wish to follow up with Mark Gibson, Deputy Director, gibsomar@ohsu.edu

Source info

http://docs.google.com/viewer?a=v&q=cache:0swFA5nHTqwJ:www.ecri.org/Documents/CERC/Gibson_Slides.pdf+Terbutaline+%2Bpreterm&hl=en&pid=bl&srcid=ADGEESiy9CSSqC5hjZLxayoNVAQI9eIrd2xxfdEr86KQ-f_S6EVImVX1HF3z_k9eThgxJc0N2Mr9thxd1UbF8WzucHgJszLh5oVxaKLX2Hy9tIDXcSOsNAY29X5E3yKXPmqAcVXLNvE&sig=AHIEtbSsSIQGqbdzwHPWmw2u5XB-ZwzDnA

Parenteral tocolytic therapy

Cigna Medical Coverage Policy, Sep 2009

http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0379_coverageposition_terbutaline_pump_and_tocolytic_therapy.pdf

After arrest of preterm labor, is continuous subcutaneous infusion of terbutaline effective treatment to prevent preterm birth?

<http://www.infopeoms.com/search/?query=terbutaline>

Subscription required

Preterm labor

Medscape, 2009

<http://emedicine.medscape.com/article/260998-overview>

Determinants and prevention of low birth weight: a synopsis of the evidence

Institute for Health Economics, Dec 2008

<http://www.ihe.ca/documents/IHE%20Report%20LowBirthWeight%20final.pdf>

Tocolysis with intravenous or subcutaneous terbutaline

Blue Cross, North Carolina, Dec 2008

http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/tocolysis_with_intravenous_or_subcutaneous_terbutaline.pdf

Born too soon: the continuing challenge of preterm labor and birth in the United States

J Midwifery Womens Health 2007;52(3):281-90.

PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/17467595>

Preterm labour and birth: a survey of clinical practice regarding use of tocolytics, antenatal corticosteroids, and progesterone

JOGC, 2007

http://www.sogc.org/jogc/abstracts/full/200702_Obstetrics_1.pdf

Preterm labour

Merck, 2005

<http://www.merck.com/mmpe/sec18/ch264/ch264f.html>

Frequently asked questions on tocolytics

BJOG 2005;112 Suppl 1:94-6.

http://www.porodnice.cz/upload/predcasny-porod/literatura/Frequently_askd_Q_on_tocolytics.pdf

Sanchez-Ramos L, Huddleston J. The therapeutic value of maintenance tocolysis: an overview of the evidence. Clinics Perinatol 2003;30(4):841-54.

PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/14714925>

Terbutaline studies, 2003

<http://www.twinslist.org/tablest.html>

Subcutaneous terbutaline pump in triplet gestation, In: Keith & Blickstien, editors. Triplet pregnancies and their consequences. Parthenon Publishing Group, 2002. p. 181-202.

<http://books.google.com/books?hl=en&lr=&id=1aAt14zt5SMC&oi=fnd&pg=PA181&dq=%22Terbutaline+pump%22+%2Bpreterm&ots=9rflddzapK&sig=PKMAevXgDOtDdcCcn7vj9Kasjy8#>

Management of preterm labour

JAOA 2001;101(2 Suppl):S14-8

http://www.jaoa.org/cgi/reprint/101/2_suppl/14S.pdf

Discusses terbutaline pump therapy

Gyetzvai K, Hannah M E, Hodnett E D, Ohlsson A. Tocolytics for preterm labor: a systematic review. Obstetrics and Gynecology 1999; 94(5 Part 2): 869-877

PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/10546776?dopt=Abstract>

Critical Appraisal:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=11999002142>

Meirowitz N B, Ananth C V, Smulian J C, Vintzileos A M. Value of maintenance therapy with oral tocolytics: a systematic review. Journal of Maternal-Fetal Medicine 1999; 8(4): 177-183

PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/10406302?dopt=Abstract>

Critical Appraisal:

<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=11999004436>

Shellhaas et al. Ambulatory management of preterm labour. Clin Obstet Gynecol 1998;41(3):491-502

<http://www.ncbi.nlm.nih.gov/pubmed/9742347>

FDA Advisory Cttee for Reproductive Health Drugs, 1998

<http://www.fda.gov/OHRMS/DOCKETS/AC/98/transcpt/3407t1.rtf>

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http://journals.lww.com/mcnjournal/Citation/1993/03000/Home_Care_Of_the_Pregnant_Woman_Using_Terbutaline.8.aspx

Women's experiences using terbutaline pump therapy for the management of preterm labor (Dissertation, 1993)

<http://nursinglibrary.org/Portal/main.aspx?pageid=4024&sid=9372>

Comanagement of the patient on subcutaneous terbutaline pump therapy

J Nurse Midwifery;1991:36(3):204-8

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T8N-4G0105T-15B&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1150447764&_rerunOrigin=scholar.google&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=1424a1cfe166517951e6cc1113e16f96

Regulatory
Canada

Licence No.: 7709
Type: Device Group Family

Licence Section			
Device Class	First Issue Date	Licence Name	
2	1999-07-12	SOF-SET INFUSION SET	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
1999-07-12	SOF-SET INFUSION SET	1999-07-12	MMT-112
		2002-05-06	MMT-111
		2009-03-10	MMT-111T
		2009-03-10	MMT-112T

Licence No.: 13631
Type: Single Device

Licence Section			
Device Class	First Issue Date	Licence Name	
2	1999-11-02	SOF-SET MICRO QR INFUSION SET	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
1999-11-02	SOF-SET MICRO QR	1999-11-02	MMT-320
		1999-11-02	MMT-321
		2009-03-10	MMT-320T
		2009-03-10	MMT-321T

Licence No.: 14508
Type: Device Group

Licence Section			
Device Class	First Issue Date	Licence Name	
2	1999-11-23	MINIMED SOF-SET ULTIMATE QR INFUSION SET	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier

1999-11-23	MINIMED SOF-SET ULTIMATE QR	1999-11-23	MMT-315
		1999-11-23	MMT-316
		2009-03-10	MMT-315T
		2009-03-10	MMT-316T

Licence No.: 37241
Type: Single Device

Licence Section			
Device Class	First Issue Date	Licence Name	
2	2002-04-05	MINIMED PARADIGM SOF-SET ULTIMATE QR MODEL NO. 317, 318	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
2002-04-05	MINIMED PARADIGM SOF-SET ULTIMATE QR INFUSION SET	2002-04-05	MMT-317
		2002-04-05	MMT-318
		2009-03-16	MMT-317T
		2009-03-16	MMT-318T

Licence No.: 37244
Type: Single Device

Licence Section			
Device Class	First Issue Date	Licence Name	
2	2002-04-05	MINIMED PARADIGM SOF-SET ULTIMATE QR MODEL NO. 324, 325	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
2002-04-05	MINIMED PARADIGM SOF-SET ULTIMATE QR INFUSION SET	2002-04-05	MMT-324
		2002-04-05	MMT-325
		2009-03-16	MMT-325T

Licence No.: 11270
Type: Device Family

Licence Section			
Device Class	First Issue Date	Licence Name	

2	1999-09-02	DISETRONIC CARTRIDGES FOR MICRODOSE INFUSION PUMPS	
Device Section		Identifier Section	
First Issue Date	Device Name	First Issue Date	Device Identifier
2005-07-06	DISETRONIC PLASTIC CARTRIDGES	2007-08-28	04567463001
		2007-08-28	04567528001
		2007-08-28	04923707001
		2008-04-16	04854047001
		2008-04-24	04949064001
		2008-04-24	04949935001
		2008-04-24	05206073001

Grey Literature Search: SRC

Search Date: April 8, 2010

Regulatory Information

FDA

Health Canada

Authorized Medicines for EU

Clinical Trial Registries

ClinicalTrials.gov

Current Controlled Trials

Clinical Study Results

WHO Clinical Trials

Abstracts and Conference Papers

Conference Papers Index

Scopus

Grants and Federally Funded Research

NIH RePORTER (a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions)

HSRPROJ (a database providing access to ongoing grants and contracts in health services research)

Other Miscellaneous Sources

Hayes, Inc. Health Technology Assessment

NY Academy of Medicine's Grey Literature Index

Appendix C. Scientific Information Packet Request

Requests for SIPs were made from the following companies:

M Infusion Therapy
AAIPharma Inc
Akorn, Inc.
Akorn, Inc.
Abraxis Pharmaceuticals (APP Pharmaceuticals)
AstraZeneca Pharmaceuticals, LP
AstraZeneca Pharmaceuticals, LP
Becton, Dickinson and Company
Becton, Dickinson and Company
Bedford Laboratories Inc
BREG, Inc
C.R. Bard, Inc.
Disetronic Medical Systems AG
Disetronic Medical Systems AG
Disetronic Medical Systems Inc
Hikma Pharmaceuticals (USA) Ltd.
I-Flow Corporation
Impax Laboratories, Inc.
International Infusion, LLC (Intra Pump Infusion Systems)
Lannett Company, Inc.
MarCal Medical, Inc.
Medtronic Diabetes
Medtronic MiniMed, Inc
Novartis Pharmaceuticals Corporation
RMS Medical Products
Roche Diagnostics
Sanofi Aventis US
Sorenson Medical Inc
Tandem Medical Equipment Inc.
Teva Pharmaceuticals USA
Baxter Healthcare Corp
C.R. Bard, Inc.

Responses were received from the following companies:

AAIPharma Inc
Abraxis Pharmaceuticals (APP Pharmaceuticals)
BREG, Inc
C.R. Bard, Inc.
Impax Laboratories, Inc.
International Infusion, LLC (Intra Pump Infusion Systems)
RMS Medical Products
Roche Diagnostics
Sanofi Aventis US
Baxter Healthcare Corp

Appendix D. Excluded Studies

Level 1 Exclusions (n=210):

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Full-Text: Excluded for another reason (no patient data, clearly not relevant to SQ terbutaline pump, betamimetic treatment not specified) (n=13)

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Full-Text: Abstract or full-text not in English (either no or cannot tell)/Insufficient information provided in abstract (full-text not in English) (n=12)

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Full-Text: Does not assess one of the specified outcomes (n=3)

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Full-Text: Companion article with no additional data (n=2)

Ambrose S, Jacques D, Stanziano. Clinical and economic outcomes of continuous subcutaneous tocolysis. *Obstet Gynecol* 2001;97:47

Wenstrom K, Weiner C, Merrill D, et al. A placebo-controlled trial of the terbutaline (T)

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Full-Text: Study design does not allow for an evaluation of SQ terbutaline pump as the sole maintenance tocolytic therapy (n=1)

Viscarello R, Griffith S, Charney. Outpatient management of higher order multiples with a comprehensive care plan improves outcome. *Obstet Gynecol* 2002;99:71

Appendix E. Screening, Data Extraction, Risk of Bias & Applicability Forms

Level 1 Screening Form (Titles and Abstracts):

1. Does the record describe a study for which an abstract and/or a full-text article has been published in English?
 No
 Yes
 Unsure

2. Does the record describe a review article?
 No
 Yes
 Unsure

3. Does the record describe a single case study?
 No
 Yes
 Unsure
 N/A

4. Does the record describe a study that includes pregnant women >24 weeks and <37 weeks gestation?
 No
 Yes
 Unsure
 N/A

5. Does the record describe a study that includes pregnant women with arrested preterm labor?
 No
 Yes
 Unsure

N/A

Does the record describe a study that includes at least one treatment group administered subcutaneous (SC) terbutaline by infusion pump as maintenance tocolytic therapy (i.e. primary tocolytic therapy)?

No

Yes

Unsure

N/A

7. Has the study assessed at least one of the following outcomes?

Neonatal Health Outcomes: bronchopulmonary dysplasia, necrotizing enterocolitis, significant intraventricular hemorrhage (grade III/IV), periventricular leukomalacia, seizures, retinopathy of prematurity, sepsis, stillbirth, death within initial hospitalization, neonatal death.

Other Health Outcomes: gestational age at delivery, incidence of delivery at <28 weeks, <34 weeks and <37 weeks gestational age, prolongation of pregnancy, birthweight, need for assisted ventilation, need for oxygen per nasal cannula, NICU admission

Maternal Harms: pulmonary edema, heart failure, arrhythmia, myocardial infarction, refractory hypotension, hypokalemia, hyperglycemia, maternal withdrawal due to adverse effects, maternal discontinuation of therapy

Neonatal Harms: hypoglycemia, hypocalcemia, ileus

Pump Failure: missed doses, dislodgment, overdose

No

Yes

Unsure

N/A

8. Should this record be excluded for any other reason that has not yet been captured with the above questions? If yes, please describe that reason.

No

Yes

N/A

Level 2 Screening Form (Full-text):

1. Does the record describe a study for which an abstract and/or a full-text article has been published in English?

No

Yes

Can't tell, abstract and/or full-text article not available

2. Does the record describe a review article?

No

Yes

3. Does the record describe a single or multiple (individual) case reports?

No

Yes

N/A because record already excluded by a prior question

4. Does the record describe a study that includes pregnant women >24 weeks and <37 weeks gestation?

No

Yes

N/A because record already excluded by a prior question

5. Does the study include only women with ruptured membranes?

No

Yes

Data not reported

N/A because record already excluded by a prior question

6. Does the record describe a study that includes pregnant women with arrested preterm labor after primary tocolytic treatment?

- No
- Yes
- N/A because record already excluded by a prior question

7. Has subcutaneous (SC) terbutaline by infusion pump been administered as a maintenance tocolytic therapy in at least one treatment group (i.e. not primary tocolytic treatment)?

- No
- Yes
- N/A because record already excluded by a prior question

8. Has the study assessed at least one of the following outcomes?

- Neonatal Health Outcomes: bronchopulmonary dysplasia, necrotizing enterocolitis, significant intraventricular hemorrhage (grade III/IV), periventricular leukomalacia, seizures, retinopathy of prematurity, sepsis, stillbirth, death within initial hospitalization, neonatal death
- Other Health Outcomes: gestational age at delivery, incidence of delivery at <28 weeks, <34 weeks and <37 weeks gestational age, prolongation of pregnancy period, birthweight, need for assisted ventilation, need for oxygen per nasal cannula, NICU admission
- Maternal Harms: pulmonary edema, heart failure, arrhythmia, myocardial infarction, refractory hypotension, hypokalemia, hyperglycemia, maternal withdrawal due to adverse effects, maternal discontinuation of therapy
- Neonatal Harms: hypoglycemia, hypocalcemia, ileus
- Harms or adverse events related to the pump device, but not necessarily terbutaline: for example missed doses, pump dislodgment, overdose or infection, allergic reaction or thrombosis at the infection site

- No
- Yes
- N/A because record already excluded by a prior question

9. Should this study be excluded for any other reason that has not yet been captured with above questions?

- No
- Yes. If yes, please indicate reason
- N/A because record already excluded by a prior question

Level 3 Screening Form (Further assessment of study design and outcomes for those citations that passed through Level 2 screening):

1. Which of the following categories of outcomes has the study assessed (check all that apply)?
- Neonatal Health Outcomes: bronchopulmonary dysplasia, necrotizing enterocolitis, significant intraventricular hemorrhage (grade III/IV), periventricular leukomalacia, seizures, retinopathy of prematurity, sepsis, stillbirth, death within initial hospitalization, neonatal death
 - Other Health Outcomes: gestational age at delivery, incidence of delivery at <28 weeks, <32 weeks, <34 weeks and <37 weeks gestational age, prolongation of pregnancy period, birthweight, need for assisted ventilation, need for oxygen per nasal cannula, NICU admission
 - Maternal Harms: pulmonary edema, heart failure, arrhythmia, myocardial infarction, refractory hypotension, hypokalemia, hyperglycemia, maternal withdrawal due to adverse effects, maternal discontinuation of therapy
 - Neonatal Harms: hypoglycemia, hypocalcemia, ileus
 - Harms or adverse events related to the pump device, but not necessarily terbutaline: for example missed doses, pump dislodgment, overdose or infection, allergic reaction or thrombosis at the infection site
 - N/A – the study has not assessed any of the above outcomes
 - Long-term childhood outcomes such as childhood development, neurobehavioural testing, long-term lung function, long-term vision or other long-term childhood outcomes

Based on the answer to the above question, citations were directed to one of the subsequent Level 3 screening forms:

If option 5 was the only one chosen (i.e harm or adverse events related to the pump device):

1. Are incidence data (versus prevalence) available for any outcome related to pump failure?
- No
 - Yes

If options 1, 2, 3, or 4 were the only ones chosen (i.e. maternal or neonatal outcomes):

1. Does the study include at least one comparison group receiving placebo, standard treatment or another intervention?
- No

Yes

2. Please specify the study design:

Randomized controlled trial

Non-randomized controlled trial

Prospective cohort

Retrospective cohort

Case-control

Cross-sectional

Other (please specify):

N/A - because record already excluded by question 1

3. Does the study design allow for an evaluation of the effectiveness or harms of subcutaneous (SC) terbutaline by infusion pump as the sole maintenance tocolytic therapy?

Note: study designs which are (treatment X + terbutaline pump vs. X alone) or (X + terbutaline pump vs. treatment X + treatment Y) are not to be excluded. Study designs that are (terbutaline pump + treatment X vs. terbutaline pump alone or in conjunction with treatment Y) are to be excluded (unless there is pump failure data)

No

Yes

N/A - because record already excluded by question 1

If a combination of pump related outcomes and maternal/neonatal outcomes were chosen:

1. To be included in the review, either condition (1) and/or (2) below must be met:

(1) For outcomes related to pump failure incidence data (versus prevalence data) must be available

(2) For neonatal or other outcomes, maternal harms or neonatal harms, the study must:

- include at least one comparison group receiving placebo, standard treatment or another intervention **AND**
- be a controlled trial (randomized or non-randomized), a prospective or retrospective cohort study, a case-control study or a cross-sectional study **AND**
- allow for an evaluation of the effectiveness or harms of subcutaneous terbutaline by infusion pump as the sole maintenance tocolytic therapy (*note: study designs which are (treatment X + terbutaline pump vs. X alone) or (X + terbutaline pump vs. treatment X + treatment Y) are to be included. Study designs that are (terbutaline pump + treatment X vs. terbutaline pump alone or in conjunction with treatment Y) are to be excluded (unless there is incident pump failure data, as above)*)

Is condition (1) and/or (2) above met?

No

Yes

2. Which of the following categories of outcomes has the study assessed AND met the above eligibility criteria (select all that apply)?

- Neonatal Health Outcomes: bronchopulmonary dysplasia, necrotizing enterocolitis, significant intraventricular hemorrhage (grade III/IV), periventricular leukomalacia, seizures, retinopathy of prematurity, sepsis, stillbirth, death within initial hospitalization, neonatal death
- Other Health Outcomes: gestational age at delivery, incidence of delivery at <28 weeks, <32 weeks, <34 weeks and <37 weeks gestational age, prolongation of pregnancy period, birthweight, need for assisted ventilation, need for oxygen per nasal cannula, NICU admission
- Maternal Harms: pulmonary edema, heart failure, arrhythmia, myocardial infarction, refractory hypotension, hypokalemia, hyperglycemia, maternal withdrawal due to adverse effects, maternal discontinuation of therapy
- Neonatal Harms: hypoglycemia, hypocalcemia, ileus
- Harms or adverse events related to the pump device, but not necessarily terbutaline: for example missed doses, pump dislodgment, overdose or infection, allergic reaction or thrombosis at the infection site

If option 7 has been chosen (long-term outcomes):

Please indicate which long-term outcomes have been assessed in the study (check all that apply)

- Childhood Development. Please provide details.
 - Neurobehavioural Testing. Please provide details
 - Long-term Lung Function. Please provide details
 - Long-term Vision. Please provide details
 - Other. Please describe
-

Risk of Bias Assessment

1. Are the treatment and comparison groups similar in terms of baseline characteristics and prognostic factors?

- Yes
- No. If no, please explain the differences
- Unclear
- N/A - there is no comparison group (studies of pump failure only)

2. Did participants in the treatment and comparison groups receive the same (or a similar distribution of) primary tocolytic to control their acute episode of preterm labor?

- Yes
- No. If no, please describe the differences.
- Unclear (data not reported)
- N/A - there is no comparison group (studies of pump failure only)

3. If this is an experimental study, were patients blinded to treatment allocation?

- Yes
- No
- Unclear (data not reported)
- N/A (not an experimental study)

4. If this is an experimental study, were healthcare providers blinded to treatment allocation?

- Yes
- No
- Unclear (data not provided)
- N/A (not an experimental study)

5. If this is an experimental study, were healthcare providers blinded to the frequency and intensity of maternal contractions? (Select all that apply)

- At initiation of maintenance therapy with the subcutaneous terbutaline pump (at treatment allocation)
- During maintenance therapy with the subcutaneous terbutaline pump
- When assessing treatment outcomes (of interest to this review)
- Health care providers were at no point blinded to the frequency and intensity of maternal contractions
- Unclear (data not reported)
- N/A (not an experimental study)

6. If this is an experimental study, was the outcome assessor blinded to treatment allocation?

- Yes
- No
- Unclear (data not reported)
- N/A (not an experimental study)

Was an intention-to-treat analysis conducted?

7. *Note: An intention-to-treat (ITT) analysis aims to include all participants randomized into a trial irrespective of what happened subsequently. Indicate "yes" if participants were analyzed in the intervention groups to which they were assigned, regardless of the intervention they actually received. To receive a "yes" response, all participants must be included in the analysis (i.e. missing data has been imputed by some means).*

- Yes
- No

Unclear (data not reported)

N/A (case series)

8. Was there either: i) a differential loss to followup between the compared groups; or ii) an overall high loss to followup?

Yes. If yes, please provide details:

No

Unclear (data not reported)

9. Was the sample size adequate to determine a difference in outcomes between comparison groups or between pre and post intervention?

Yes

No

Unclear

N/A

10. Was there a differential level of care (e.g., home uterine contraction monitoring, education, nurse visits, individualized dosing schedules, other co-interventions) between the treatment and comparison groups?

Yes

No

Unclear (data not reported)

N/A - there is no comparison group (studies of pump failure only)

11. Are the study funders likely to have had any influence on study outcomes that might have biased the study results?

Yes

No

Unclear (data not reported)

12. Is there any indication of selective outcome reporting?

Note: to assess selective outcome reporting, please compare the outcomes listed in the methods section of the report to the reported results. Indicate "yes" if all measured outcomes are accounted for in the results section, and are adequately reported.

Yes. If yes,
please describe:

No

Unclear

13. If multiple outcome assessors were used, is it likely there was high reliability in outcome assessment between all assessors? (e.g., inter-rater reliability testing was conducted and adequate)

Please note, if you are unclear how to answer this question, please ask Laura or Mohammed for clarification.

Yes

No. If no, please describe

Unclear (data not reported)

N/A - multiple assessors were not used

14. Was compliance with the study protocol (i.e. treatment or comparator intervention) adequate in all study groups?

Yes

No. If no, please describe:

Unclear (data not reported)

15. If this is a randomized controlled trial, was the allocation sequence adequately generated?

Note: Indicate "yes" if the method of randomization to treatment groups is likely to produce comparable groups, for example through use of a random number table or a computerized random number generator.

- Yes
- No
- Unclear (data not reported)
- N/A - this is not a randomized controlled trial

16. If this is a randomized controlled trial, was the process of concealing the random allocation sequence adequate?

Note: Indicate "yes" if a process was in place to adequately conceal future intervention allocations from study personnel, for example through pharmacy controlled randomization, or the use of sequentially numbered, sealed and opaque envelopes.

- Yes
- No
- Unclear (data not reported)
- N/A - this is not a randomized controlled trial

17. If this is a randomized controlled trial, at the time of study enrollment is there any indication that study personnel were able to predict future intervention assignments?

Note: Indicate "yes" if any reported baseline imbalances are likely to have resulted from study personnel selectively enrolling patients into the study based on their prediction of future intervention assignments.

- Yes
- No
- Unclear (data not reported)
- N/A - this is not a randomized controlled trial

18. If this is an observational study or a nonrandomized trial, is the sample population from which the comparison group(s) was drawn the same as the sample population from which the treatment group was drawn?

- Yes
- No. If no, please describe:
- Unclear
- N/A - this is not an observational study/nonrandomized trial or there is no comparison group (studies of pump failure only)

19. If this is an observational study or a nonrandomized trial, were appropriate methods undertaken to control for important confounders (e.g., matching)?

- Yes
- No
- Unclear
- N/A - this is not an observational study/nonrandomized trial or there is no comparison group (studies of pump failure only)

20. If this is a retrospective study that used multiple data sources, is it likely there was consistency in outcome definition across those data sources?

- Yes
- No. If no, please describe:
- Unclear (data not reported)
- N/A - this is not a retrospective study that uses multiple data sources

21. For studies assessing maternal or neonatal harms: If the harm outcomes assessed in the study are not generally known to have standard definitions, then were these harms pre-defined using standardized or precise definitions?

- Yes
- No
- Unclear (data not reported)
- N/A - this is not a study assessing maternal or neonatal harms
- N/A - this study measured harms with standardized definitions. If so, please specify these harms

22. If this is a study assessing maternal or neonatal harms, was the mode of harms collection specified as active (versus passive)?

Note: Active harms assessment is when participants are asked about the occurrence of specific harms in structured questionnaires or interviews or pre-defined laboratory or diagnostic tests, usually performed at pre-specified time intervals.

Passive assessment of harms occurs when study participants spontaneously report (on their own initiative) or are allowed to report harmful events not probed with active ascertainment.

- Yes
- No
- Unclear (data not reported)
- N/A - this is not a study assessing maternal or neonatal harms

23. If this is a study assessing maternal or neonatal harms, did the report specify who collected harms data, including their training and background?

- Yes
- No
- Unclear
- N/A - this is not a study assessing maternal or neonatal harms

24. Were the subjects who were included in the study representative of the source population? For instance, subjects would be representative if the entire source population was recruited for the study, if a sample of consecutive patients was recruited, or if a random sample was obtained.

- Yes. Please explain
- No. Please explain
- Unclear (e.g. sampling methodology is not reported). Please explain

25. Were the primary outcomes in the study defined by either prespecified or standardized clinical definitions?

- Yes. Please list what these outcomes are and any definitions provided in paper
- No. Please list what these outcomes are

- Unclear
- N/A - the study does not list any primary outcomes

Overall Risk of Bias (study quality) Assessment

For each outcome assessed within this study, please provide an overall assessment of the risk of bias associated with measurement of that outcome based on your answers to the above questions.

26. Please specify study outcome:

Select an Answer

Overall risk of bias assessment

Please select one of either good, fair or poor and provide an explanation for your response.

- Good (low risk of bias)
- Fair
- Poor (high risk of bias)
- Please explain your response

Applicability Assessment Form:

POPULATION

Please consider each of the following criteria and indicate which, if any, might limit applicability:

1. Inclusion/exclusion criteria

A condition that might limit applicability is narrow eligibility criteria

- Yes. If yes, please explain:
- No
- Unclear

2. Exclusion rate

A condition that might limit applicability is a high exclusion rate

Yes. If yes, please
explain:

No

Unclear (data not reported)

3. Demographic characteristics

A condition that might limit applicability is a large difference between demographics of study population and that of patients in the community

Yes. If yes, please
explain:

No

Unclear

4. Run in period, considering attrition before randomization and reasons (if reported)

A condition that might limit applicability is a run in period with high-exclusion rate for non-adherence or side effects

Yes. If yes, please
explain:

No

Unclear

N/A - non-randomized study

INTERVENTION

Please consider each of the following criteria and indicate which, if any, might limit applicability

5. Dose and duration

Condition that might limit applicability are doses or treatment schedules not reflected in current practice.

Yes. If yes, please
explain

No

Unclear

6. Co-interventions

A condition that might limit applicability is the delivery of co-interventions that are likely to modify effectiveness of therapy.

Yes. If yes, please
explain:

No

Unclear

7. Level of care

A condition that might limit applicability is a level of care or visit frequency not used or likely to be feasible in typical practice.

Yes. If yes, please
explain:

No

Unclear

8. Training provided regarding pump administration

A condition that might limit applicability is the provision of intensive education that is not likely to be feasible in typical practice.

Yes. If yes, please
explain:

No

Unclear

COMPARISON

Please consider each of the following criteria and indicate which, if any, might limit applicability

9. Dose and schedule of comparator

A condition that is likely to limit applicability is an inadequate dose of comparison therapy

- Yes. If yes, please explain:
- No
- Unclear
- N/A - no comparison group (study of pump failure only) or comparison group received no treatment/placebo

10. Whether comparator is the best available alternative to terbutaline pump

A condition that might limit applicability is the use of a sub-standard alternative therapy

- Yes. If yes, please explain:
- No
- Unclear
- N/A - no comparison group (study of pump failure only) or comparison group received no treatment/placebo

OUTCOMES

Please consider each of the following criteria and indicate which, if any, might limit applicability

11. Clinical benefits on relative and absolute scale

Conditions that might limit applicability are the assessment of surrogate rather than clinical outcomes or failure to measure most important outcomes.

- Yes. If yes, please explain:
- No
- Unclear

12. Individual harms and how defined, on relative and absolute scale

A condition that might limit applicability is failure to distinguish minor from serious adverse effects.

- Yes. If yes, please explain:
- No
- Unclear

N/A - this is not a study of individual harms

TIMING OF OUTCOMES MEASUREMENT

Please consider each of the following criteria and indicate which, if any, might limit applicability

13. Timing of followup

A condition that might limit applicability is if followup is too short to detect important benefits or harms.

Yes. If yes, please explain:

No

Unclear

SETTING

Please consider each of the following criteria and indicate which, if any, might limit applicability

14. Geographic setting

A condition that might limit applicability is if within the study setting standards of care differ markedly from the setting of interest.

Yes. If yes, please explain:

No

Unclear

15. Clinical setting

A condition that might limit applicability is if the study setting serves a specialty population or level of care that differs importantly from that seen in standard tertiary care settings.

Yes. If yes, please explain:

No

Unclear

Appendix F. Evidence Tables

Table F1. Evidence Table: Detailed Study-Level Characteristics

Study Identification	Study Population	Definition of Preterm Labor	Comparison Group (N): mean daily dose ± SD (mg) Intervention Group (N): mean daily dose ± SD (mg)	Overall Risk of Bias with Explanation <i>(rating applies to all outcomes unless specified otherwise)</i>
<p>First Author (year): Guinn (1998)¹ Design: RCT Setting: Birmingham Hospital, Alabama (Nov 1994 – Apr 1997) Funding Source: MiniMed Technologies (supported in part)</p>	<p>n = 52 Mean Maternal Age ± SD (years): 21.6 ± 5.7 Mean Gestational Age ± SD (weeks)*: 30.6 ± 2.8 (T) Gestation: singletons Primary Tocolytic Treatment: Magnesium Sulphate (IV) (with or without indomethacin) Previous Maintenance Tocolytics[†]: NR Inclusion Criteria: singleton gestation; intact membranes; between 22 and 33^{6/7} weeks gestation; received parenteral magnesium sulfate therapy (with or without indomethacin); arrested preterm labor (<4 contractions/h for ≥ 24 hours) Exclusion Criteria: contraindication to tocolysis; persistent maternal tachycardia (>120 beats/min); history of cardiac arrhythmia; history of pulmonary edema; uncontrolled diabetes; suspected chorioamnionitis</p>	<p>Uterine contractions > 4 per hour and greater than or equal to one of the following: ≥ 1 cm cervical dilation, ≥ 80% cervical effacement, and documented cervical change.</p>	<p>C: Placebo (saline pump) (28): NA I: SQ terbutaline (24): NR</p>	<p>Medium The comparability of groups cannot be assessed for certain because information on all relevant factors has not been presented (e.g. prognostic factors, like cervical length and fetal fibronectin). Also, there is a potential for bias due to study funding. However, randomization was carried out properly and patients/health care providers were blinded to treatment allocation, which will limit selection and detection biases.</p>

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Received by entire study population, unless specified otherwise.

<p>First Author (year): Wenstrom (1997)² Design: RCT Setting: University of Iowa Hospital (Jan 1990 – Apr 1994) Funding Source: NR Companion Article: ³</p>	<p>n = 42 Mean Maternal Age ± SD (years): 26.2 ± 5.3 Mean Gestational Age ± SD (weeks): 30.4 ± 2.3 (T) Gestation: singletons or twins Primary Tocolytic Treatment: Magnesium Sulphate (IV) (if magnesium was insufficient, indomethacin (PO) was administered) Previous Maintenance Tocolytics: NR Inclusion Criteria: diagnosis of preterm labor Exclusion Criteria: contraindication to beta-mimetic therapy (i.e. heart disease, insulin-dependent diabetes mellitus, intolerance to terbutaline) or to continued tocolysis in general; cervical dilation > 4 cm</p>	<p>Regular, persistent uterine contractions that produce cervical change in gravidas ≥ 20 weeks and < 35 weeks.</p>	<p>C₁: Placebo (saline pump) (12): NA C₂: Oral Terbutaline (15): NR I: SQ terbutaline (15): NR</p>	<p>High (oral terbutaline arm) High (placebo arm) Placebo arm: The sample likely represents a very select group, since >90% of eligible subjects declined to participate. The study is likely to be underpowered. There is evidence that randomization was carried out properly, but blinding was not that effective. Missing information makes it difficult to judge comparability of groups in baseline characteristics and prognostic factors, primary tocolytic therapy, and level of care. Oral terbutaline arm: Same as above, except for complete absence of blinding.</p>
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<p>First Author (year): Lindenbaum (1992)^{4‡}</p> <p>Design: Nonrandomized Trial</p> <p>Setting: Hospital of the University of Pennsylvania (NR)</p> <p>Funding Source: NR</p>	<p>n = 91</p> <p>Mean Maternal Age ± SD (years): 32.4 ± 2.7</p> <p>Mean Gestational Age ± SD (weeks): 29.1 ± 1.7 (T)</p> <p>Gestation: singletons</p> <p>Primary Tocolytic Treatment: Magnesium Sulphate (IV) or Ritodrine (IV) (other agents may have been administered as well)</p> <p>Previous Maintenance Tocolytics: NR</p> <p>Inclusion Criteria: women between 26-36 weeks' gestation; diagnosis of preterm labor; admitted to labor floor of hospital; normal 1-hour oral glucose tolerance test between 24-28 weeks' gestation</p> <p>Exclusion Criteria: history of pre-gestational or gestational diabetes; macrosomia; current steroid therapy; multiple gestation</p>	<p>Documented cervical change or uterine contractions ≥ 6 per hour that was unresponsive to bed rest and intravenous hydration.</p>	<p>C: Oral Terbutaline (54): 30 ± NR</p> <p>I: SQ terbutaline (37): NR</p>	<p>High (birthweight and gestational age at delivery)</p> <p>Medium (maternal hyperglycemia)</p> <p>Primary flaw in this study is the difference in groups with respect to severity/prognosis (i.e. groups were divided based on length of primary tocolytic treatment). Also, comparability of groups cannot be assessed due to missing information.</p> <p>The potential difference in severity/prognosis among treatment and comparison groups should not impact the outcome of maternal hyperglycemia. However, issues pertaining to missing information still remain.</p>
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[‡] Data from a third treatment arm, which consisted of a control group without preterm labor, has not been presented.

<p>First Author (year): Morrison (2003)⁵ Design: Prospective Cohort Setting: NR (Jan 2001 – Dec 2001) Funding Source: NR</p>	<p>n = 60 Mean Maternal Age ± SD (years): 25.6 ± 5.2 Mean Gestational Age ± SD (weeks): 29.5 ± 2.3 (P) Gestation: singletons Primary Tocolytic Treatment: Magnesium Sulphate (IV) (If magnesium was insufficient, indomethacin (PR) or nifedipine (PO) was administered.) Previous Maintenance Tocolytics: NR Inclusion Criteria: two or more episodes of preterm labor; stabilized in hospital with IV tocolytics Exclusion Criteria: further continuation of pregnancy contraindicated (hypertension, fetal distress, intrauterine growth restriction, severe vaginal bleeding); insulin-dependent diabetes; preterm premature rupture of membranes; allergy to beta-sympathomimetic drugs; fetal anomalies; fetal death</p>	<p>Persistent uterine contractions (>12 per hour), cervical change in dilation, and effacement since first episode of PTL.</p>	<p>C: No Treatment (45): NA I: SQ terbutaline (15): NR</p>	<p>High Primary flaw with this study is that there is evidence that groups were not comparable (with respect to risk factors for preterm birth, primary tocolytic therapy, level of care).</p>
<p>First Author (year): Morrison (1992)⁶ Design: Prospective Cohort Setting: NR Funding Source: Vicksburg Hospital Medical Foundation (supported in part)</p>	<p>n = 69 Mean Maternal Age ± SD (years): 28.6 ± 4.7 Mean Gestational Age ± SD (weeks): NR Gestation: not specified (likely included a mixture of women with single and multiple gestation) Primary Tocolytic Treatment: NR Previous Maintenance Tocolytics: Oral tocolytics (NR) (only received by terbutaline pump group) Inclusion Criteria: treated with IV tocolysis for documented preterm labor; subcutaneous terbutaline group had failed maintenance oral tocolytic therapy (had RPTL) Exclusion Criteria: preterm rupture of membranes; agent discontinued due to failure of tocolysis or advanced cervical dilatation at < 37 weeks; scheduled cesarean deliveries; early delivery for obstetric/medical indications</p>	<p>Regular, persistent uterine contractions (usually > 12/hr) with associated cervical change from the previous exam or a change in cervical status with regular contractions, or contractions plus an initial cervical examination ≥ 2 cm</p>	<p>C: Oral Tocolytics - ritodrine or terbutaline (41): NR I: SQ terbutaline (28): NR</p>	<p>High Major flaw is that the subcutaneous pump group had RPTL and comparison group did not. Therefore, the intervention group may have had a more serious condition. Also, there is missing information, which makes it difficult to assess other potential limitations.</p>

<p>First Author (year): Flick (2010)⁷ Design: Retrospective Cohort Setting: Throughout United States (Matria database) Funding Source: NR</p>	<p>n = 1366 Mean Maternal Age ± SD (years): 28.7 ± 6.1 Mean Gestational Age ± SD (weeks): 30.6 ± 2.9 (P) Gestation: singletons Primary Tocolytic Treatment: NR Previous Maintenance Tocolytics: Oral nifedipine mean daily dose ± SD (mg): 58.5 ± 26.5 Inclusion Criteria: singleton gestation; < than 35 weeks gestation; referred for hospitalization due to RPTL; prescribed oral nifedipine for maintenance tocolysis; hospitalized for a minimum of 24 hours; received preterm labor treatment; intact membranes; subsequently discharged to resume outpatient services with oral nifedipine or continuous subcutaneous terbutaline infusion Exclusion Criteria: delivered upon hospitalization; ruptured membranes; > 35 weeks gestation when hospitalized; did not resume outpatient services</p>	<p>NR</p>	<p>C: Oral Nifedipine (830): NR I: SQ terbutaline (536): NR</p>	<p>High Primary flaw is that groups were not similar in baseline characteristics and prognostic factors (i.e. differed in smoking status). Also, missing information makes it difficult to assess similarity of groups with respect to other factors.</p>
<p>First Author (year): de la Torre (2008)⁸ Design: Retrospective Cohort Setting: Throughout United States (Matria database) Funding Source: NR</p>	<p>n = 656 Mean Maternal Age ± SD (years): 30.3 ± 5.8 Mean Gestational Age ± SD (weeks): 30.1 ± 2.9 (P) Gestation: twins Primary Tocolytic Treatment: NR Previous Maintenance Tocolytics: Oral Nifedipine mean daily dose ± SD (mg): 62.3 ± 26.9 Inclusion Criteria: twin gestation; prescribed oral nifedipine as maintenance tocolysis after an initial episode of preterm labor; hospitalized at <35 weeks gestation for RPTL; at least a 24 hour hospital stay Exclusion Criteria: delivered within 48 hours of hospitalization; did not resume maintenance tocolysis; ruptured membranes; referred for hospital evaluation but not admitted</p>	<p>Uterine activity above 4-6 contractions per hour or maternal reports of persistent pelvic pressure, cramping, backache, or increased vaginal discharge.</p>	<p>C: Oral Nifedipine (418): 73.7 ± 23.4 I: SQ terbutaline (238): NR</p>	<p>Medium There is a lot of missing information, which makes it difficult to assess comparability of groups (in terms of baseline characteristics and prognostic factors, primary tocolytic therapy, and compliance). But difficult to say that there is any limitation that would invalidate the results for sure.</p>

<p>First Author (year): Fleming (2004)⁹ Design: Retrospective Cohort Setting: Throughout United States (Matria database) (Jun 1992 – Jun 2000) Funding Source: NR</p>	<p>n = 284 Mean Maternal Age ± SD (years): NR Mean Gestational Age ± SD (weeks): 30.4 ± 2.6 (P) Gestation: singletons Primary Tocolytic Treatment::: NR Previous Maintenance Tocolytics: Oral Nifedipine Inclusion Criteria: singleton gestation; prescribed nifedipine following an initial episode of preterm labor; subsequent hospitalization for RPTL at <34 weeks; stabilized by tocolysis per attending physician's plan of treatment; outpatient tocolysis resumed with nifedipine or continuous subcutaneous terbutaline Exclusion Criteria: subjects who could not be matched by gestational age</p>	<p>NR</p>	<p>C: Oral Nifedipine (142): 66.7 ± 37.1 I: SQ terbutaline (142): 3.2 ± 1.6</p>	<p>Medium There is considerable missing information, which makes it difficult to assess the comparability of groups. There is some indication that there are baseline differences (i.e. in age and marital status) and data on many other important factors have not been reported (e.g. cervical length, race, SES). However, there are no major flaws that can be singled out as invalidating the results.</p>
<p>First Author (year): Lam (2003)¹⁰ Design: Retrospective Cohort Setting: Throughout United States (Matria database) (Apr 1995 – Jan 1999) Funding Source: NR</p>	<p>n = 558 Mean Maternal Age ± SD (years): 27.4 ± 5.9 Mean Gestational Age ± SD (weeks): 31.6 ± 2.2 (P) Gestation: singletons Primary Tocolytic Treatment::: NR Previous Maintenance Tocolytics: NR Inclusion Criteria: singleton gestation; initial episode of preterm labor at > 20 weeks; subsequent hospitalization for RPTL < 35 weeks; stabilized and discharged home following RPTL Exclusion Criteria: not prescribed tocolytics; lost to followup; medically indicated delivery</p>	<p>NR</p>	<p>C: Oral Tocolytics (95.3% received oral terbutaline) (279): mean oral terbutaline dose 24.0 ± 9.3 I: SQ terbutaline (279): 3.5 ± 1.1</p>	<p>High Primary flaw is that groups were not similar at baseline (differed in smoking status and previous PTD). Also, missing data makes it difficult to assess several other potential limitations.</p>

<p>First Author (year): Lam (2001)¹¹ Design: Retrospective Cohort Setting: Throughout United States (Matria database) (Jan 1992 – Jul 1998) Funding Source: NR</p>	<p>n = 706 Mean Maternal Age ± SD (years): 28.8 ± 5.5 Mean Gestational Age ± SD (weeks): 31.3 ± 2.3 (P) Gestation: twins Primary Tocolytic Treatment: NR Previous Maintenance Tocolytics: NR Inclusion Criteria: twin gestation; initial episode of preterm labor which was treated with oral tocolysis; hospitalized for RPTL at < 35 weeks gestation; stabilized on an inpatient basis for RPTL and then discharged to outpatient services Exclusion Criteria: delivered after RPTL; remained hospitalized; discharged from outpatient services</p>	<p>NR</p>	<p>C: Oral Tocolytics (92.3% received oral terbutaline) (353): mean oral terbutaline dose 25.6 ± 10.4 I: SQ terbutaline (353): 3.9 ± 1.4</p>	<p>Medium There is a large amount of missing information, which makes it difficult to assess the comparability of groups and other potential limitations. But there are no major flaws that can be identified that would invalidate the results.</p>
<p>First Author (year): Allbert (1994)¹² Design: Retrospective Cohort Setting: NR Funding Source: Vicksburg Hospital Medical Foundation (supported in part) Companion Article:¹³</p>	<p>n = 64 Mean Maternal Age ± SD (years): 27.5 ± 4.3 Mean Gestational Age ± SD (weeks): 32.2 ± 2.7 (T) Gestation: not specified (likely included a mixture of women with single and multiple gestation) Primary Tocolytic Treatment: NR Previous Maintenance Tocolytics: NR Inclusion Criteria: documented RPTL; at 20-34 weeks' gestation; between the ages of 15 and 45 years Exclusion Criteria: continuation of pregnancy contraindicated (fetal distress, chorioamnionitis, intrauterine growth retardation, abruption, preeclampsia, etc.); insulin-dependent diabetes mellitus; allergy to beta-sympathomimetic drugs; premature rupture of membranes; cardiac arrhythmia; significant hemorrhage; fetal anomalies; fetal demise</p>	<p>Persistent uterine contractions and progressive cervical change.</p>	<p>C: Oral Terbutaline (32): NR I: SQ terbutaline (32): NR</p>	<p>Medium There is a lot of missing information, which makes it difficult to assess comparability among groups and whether groups were derived from the same population. There is a possibility that groups received a different level of care, since only the subcutaneous terbutaline group has been specified as receiving home nursing care. However, it is unclear if this factor alone would be sufficient to impact the results to a large extent.</p>

<p>First Author (year): Regenstein (1993)^{14§}</p> <p>Design: Retrospective Cohort</p> <p>Setting: NR (Dec 1986 – Jan 1992)</p> <p>Funding Source: National Institutes of Health Training</p>	<p>n = 69</p> <p>Mean Maternal Age ± SD (years): 31.4 ± 5.9</p> <p>Mean Gestational Age ± SD (weeks): NR</p> <p>Gestation: not specified (included a mixture of women with single and multiple gestation)</p> <p>Primary Tocolytic Treatment: NR</p> <p>Previous Maintenance Tocolytics: NR</p> <p>Inclusion Criteria: receiving home nursing care or care by perinatology service; gestational diabetes screening performed after initiation of chronic terbutaline tocolysis</p> <p>Exclusion Criteria: NR</p>	<p>NR</p>	<p>C: Oral Terbutaline (38): 25.9 ± 11.2</p> <p>I: SQ terbutaline (31): 2.5 ± 1.0</p>	<p>High</p> <p>Although the harm outcome of maternal hyperglycemia was defined and collected actively, the primary flaw with this study is that groups were not similar in baseline characteristics (i.e. in race and family history of gestational diabetes). Also, since no methods were used to control for confounders, there is a high likelihood that groups may differ in other baseline characteristics and prognostic factors, which have not been reported. There is also a lot of missing information which makes it difficult to assess the comparability of groups (e.g. primary tocolytic, loss to followup, differential level of care, compliance).</p>
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[§] Data from a third treatment arm, which consisted of a control group without preterm labor, has not been presented.

<p>First Author (year): Adkins (1993)¹⁵</p> <p>Design: Case Series</p> <p>Setting: An urban obstetrics and gynecology group practice, Tennessee (Nov 1989 – Feb 1991)</p> <p>Funding Source: PharmaThera Inc.</p>	<p>n = 51</p> <p>Mean Maternal Age ± SD (years): 31.0 ± 4.0</p> <p>Mean Gestational Age ± SD (weeks): 29.1 ± 3.6 (T)</p> <p>Gestation: singletons or twins</p> <p>Primary Tocolytic Treatment: Magnesium Sulphate (IV) or Terbutaline (SC)</p> <p>Previous Maintenance Tocolytics: Oral Tocolytics (only received by some patients)</p> <p>Inclusion Criteria: 20 to 35 weeks gestation; established diagnosis of preterm labor; intact membranes; cervical dilation ≤ 4 cm</p> <p>Exclusion Criteria: contraindication to terbutaline therapy (abnormal fetal heart rate pattern, complete abruption placentae, chorioamnionitis, and progressive preeclampsia).</p>	<p>Uterine contractions > 4 per hour and progressive cervical change.</p>	<p>I: SQ terbutaline (51): NR</p>	<p>Medium</p> <p>There is missing information, which makes it difficult to assess some quality items. However, there was no high loss to followup and subjects were representative of source population. Adequacy of sample size is unclear (n=51), although it is larger than the previous case series of nine subjects.</p>
<p>First Author (year): Lam (1988)¹⁶</p> <p>Design: Case Series</p> <p>Setting: NR</p> <p>Funding Source: NR</p>	<p>n = 9</p> <p>Mean Maternal Age ± SD (years): NR</p> <p>Mean Gestational Age ± SD (weeks): 29.6 ± 3.7 (T)</p> <p>Gestation: not specified</p> <p>Primary Tocolytic Treatment: Magnesium Sulphate (IV)</p> <p>Previous Maintenance Tocolytics: Oral Terbutaline</p> <p>Inclusion Criteria: had RPTL during oral terbutaline treatment; intact membranes; cervical dilation < 4 cm; absence of fetal distress or anomalies; absence of maternal disease with which magnesium sulfate or beta-mimetic tocolysis might interfere</p> <p>Exclusion Criteria: NR</p>	<p>Regular uterine contractions > 4 per hour leading to progressive cervical change.</p>	<p>I: SQ terbutaline (9): NR</p>	<p>Medium</p> <p>There is a lot of missing information, which makes it difficult to assess potential for selection bias (e.g. were the nine subjects in the study the entire sample, or were these the number left over after losses to followup?). Also, harm outcomes have not been defined. However, the study does not have any obvious major flaws, which would invalidate the results.</p>
<p>SC: subcutaneous; IV: intravenous; NR: not reported; PTL: preterm labor; SD: standard deviation; RPTL: recurrent preterm labor; RCT: randomized controlled trial; SQ: subcutaneous</p>				

Table F2. Full-text question posed for criteria listed in risk of bias charts

RISK OF BIAS CHART	FULL QUESTION
Baseline characteristics/ prognostic factors	Are the treatment and comparison groups similar in terms of baseline characteristics and prognostic factors?
Primary tocolytic agent(s)	Did participants in the treatment and comparison groups receive the same (or a similar distribution of) primary tocolytic to control their acute episode of preterm labor?
Level of care	Was there a differential level of care (e.g. home uterine contraction monitoring, education, nurse visits, individualized dosing schedules, other co-interventions) between the treatment and comparison groups?
Population used to sample comparison and treatment groups	If this is an observational study or a nonrandomized trial, is the sample population from which the comparison group(s) was drawn the same as the sample population from which the treatment group was drawn?
Loss to followup	Was there either: (i) a differential loss to followup between the compared groups; or (ii) an overall high loss to followup?
Compliance with study protocol	Was compliance with the study protocol (i.e. treatment or comparator intervention) adequate in all study groups?
Methods to control for confounders	If this is an observational study or a nonrandomized trial, were appropriate methods undertaken to control for important confounders (e.g. matching)?
Representativeness of subjects to source	Were the subjects who were included in the study representative of the source population? For instance, subjects would be representative if the entire source population was recruited for the study, if a sample of consecutive patients was recruited, or if a random sample was obtained.
Blinding of patients to treatment allocation	If this is an experimental study, were patients blinded to treatment allocation?
Blinding of healthcare providers to treatment allocation	If this is an experimental study, were healthcare providers blinded to treatment allocation?
Blinding of outcome assessors to treatment allocation	If this is an experimental study, was the outcome assessor blinded to treatment allocation?
Blinding of healthcare providers to maternal contractions	If this is an experimental study, were healthcare providers blinded to the frequency and intensity of maternal contractions?
Generation of allocation sequence	If this is a randomized controlled trial, was the allocation sequence adequately generated?
Concealment of allocation sequence	If this is a randomized controlled trial, was the process of concealing the random allocation sequence adequate?
Prediction of future intervention assignments by study personnel	If this is a randomized controlled trial, at the time of study enrollment is there any indication that study personnel were able to predict future intervention assignments?
Intention-to-treat analysis	Was an intention-to-treat analysis conducted?
Sample size	Was the sample size adequate to determine a difference in outcomes between comparison groups or between pre and post intervention?
Selective outcome reporting	Is there any indication of selective outcome reporting?
Funding source	Are the study funders likely to have had any influence on study outcomes that might have biased the study results?
Reliability in outcome assessment (if multiple outcome assessors used)	If multiple outcome assessors were used, is it likely there was high reliability in outcome assessment between all assessors (e.g. inter-rater reliability testing was conducted and adequate)?
Consistency in outcome definition	If this is a retrospective study that used multiple data sources, is it likely there was consistency in outcome definition across those data sources?
Definition of primary outcome(s)	Were the primary outcomes in the study defined by either pre-specified or standardized clinical definitions?
Pre-specification of harm outcomes	For studies assessing maternal or neonatal harms: If the harm outcomes assessed in the study are not generally known to have standard definitions, then were these harms pre-defined using standardized or precise definitions?
Reporting of harm outcomes as active	If this is a study assessing maternal or neonatal harms, was the mode of harms collection specified as active (versus passive)?
Reporting of training/background of personnel collecting harms data	If this is a study assessing maternal or neonatal harms, did the report specify who collected harms data, including their training and background.

Table F3. Detailed risk of bias assessments for individual studies

Study design: Author (year)	Risk of bias criteria rated negatively	Risk of bias criteria rated positively	Risk of bias criteria rated as unclear	Final Rating by Outcome <i>(rating applies to all outcomes unless indicated otherwise)</i>
RCT: Guinn (1998) ¹	Potential bias due to study funding (supported in part by MiniMed Technologies).	<p>Groups similar in primary tocolytic therapy.</p> <p>Patients blinded to treatment allocation.</p> <p>Healthcare providers blinded to treatment allocation/Outcome assessor blinded to treatment allocation (assumed to be same as healthcare providers)</p> <p>Intention-to-treat analysis conducted.</p> <p>No differential or high loss to followup.</p> <p>Sample size adequate.</p> <p>No differential level of care among groups.</p> <p>No indication of selective outcome reporting.</p> <p>Allocation sequence was generated adequately.</p> <p>Allocation sequence concealed adequately.</p> <p>No indication that study personnel could predict future intervention assignments.</p> <p>Measured harms with standardized definition (maternal discontinuation of therapy).</p> <p>Mode of harms collection not explicitly specified as active. However, not relevant for harm of discontinuation of therapy.</p> <p>Report does not explicitly specify who collected harms data. However, not relevant for harm of discontinuation of therapy.</p> <p>Primary outcome (prolongation of pregnancy) has been defined.</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If healthcare providers were blinded to maternal contractions.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple outcome assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>Representativeness of subjects to source population.</p>	<p>Outcomes:</p> <p>(1) Maternal discontinuation of therapy.</p> <p>(2) NICU admission</p> <p>(3) Intraventricular hemorrhage</p> <p>(4) Prolongation of pregnancy</p> <p>(5) Gestational age at delivery</p> <p>(6) Birthweight</p> <p>MEDIUM: The comparability of groups cannot be assessed for certain because information on all relevant factors has not been presented (e.g. prognostic factors, like cervical length and fetal fibronectin). Also, there is a potential for bias due to study funding. However, randomization was carried out properly and patients/health care providers were blinded to treatment allocation, which will limit selection and detection biases.</p>

<p>RCT: Wenstrom (1997)² <i>Saline pump arm</i></p>	<p>Patients were not adequately blinded (the intention was to blind, but 60% in terbutaline pump group and 67% in saline pump group had to be unblinded).</p> <p>Healthcare providers were not adequately blinded (the intention was to blind, but 60% in terbutaline pump group and 67% in saline pump group had to be unblinded)/Same consideration applies to outcome assessors, since they are assumed to be the same as healthcare providers.</p> <p>Sample size too small.</p> <p>Harms outcomes do not have standard clinical definitions and were not predefined (local skin irritation, local pain, neonatal hypoglycemia).</p> <p>Mode of harms collection not specified as active.</p> <p>Report does not specify who collected harms, including training and background.</p> <p>Subjects were not representative of source population because >90% of eligible subjects declined to participate.</p>	<p>Intention-to-treat analysis conducted.</p> <p>No differential or high loss to followup.</p> <p>Allocation sequence generated adequately.</p> <p>Allocation sequence concealed adequately.</p> <p>No indication that study personnel could predict future intervention assignments.</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If groups were similar in primary tocolytic therapy.</p> <p>If healthcare providers were blinded to maternal contractions.</p> <p>If there was differential level of care among groups.</p> <p>If there was bias due to study funding.</p> <p>If there was selective outcome reporting.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <ol style="list-style-type: none"> (1) Gestational age at delivery (2) Birthweight (3) Prolongation of pregnancy (4) Local skin irritation (5) Local pain (6) Neonatal hypoglycemia (7) Sepsis (8) Retinopathy of prematurity (9) NICU (10) Perinatal deaths <p>HIGH: The sample likely represents a very select group, since >90% of eligible subjects declined to participate. The study is likely to be underpowered. There is evidence that randomization was carried out properly, but blinding was not that effective. Missing information makes it difficult to judge comparability of groups in baseline characteristics and prognostic factors, primary tocolytic therapy, and level of care.</p>
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<p>RCT: Wenstrom (1997)²</p> <p><i>Oral terbutaline arm</i></p>	<p>Patients were not blinded to treatment allocation.</p> <p>Healthcare providers were not blinded to treatment allocation/Same applies to outcome assessors since they are assumed to be the same as healthcare providers.</p> <p>Sample size too small.</p> <p>Harm outcomes do not have standard clinical definitions and were not predefined (local skin irritation, local pain, neonatal hypoglycemia).</p> <p>Mode of harms collection not specified as active.</p> <p>Report does not specify who collected harms, including training and background.</p> <p>Subjects were not representative of source population because >90% of eligible subjects declined to participate.</p>	<p>Intention-to-treat analysis conducted.</p> <p>No differential or high loss to followup.</p> <p>Allocation sequence generated adequately.</p> <p>Allocation sequence concealed adequately.</p> <p>No indication that study personnel could predict future intervention assignments.</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If groups were similar in primary tocolytic therapy.</p> <p>If healthcare providers were blinded to maternal contractions.</p> <p>If there was differential level of care among groups.</p> <p>If there was bias due to study funding.</p> <p>If there was selective outcome reporting.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <ol style="list-style-type: none"> (1) Gestational age at delivery (2) Birthweight (3) Prolongation of pregnancy (4) Local skin irritation (5) Local pain (6) Neonatal hypoglycemia (7) Sepsis (8) Retinopathy of prematurity (9) NICU (10) Perinatal deaths <p>HIGH: The sample likely represents a very select group, since >90% of eligible subjects declined to participate. The study is likely to be underpowered. There is evidence that randomization was carried out properly, but patient and healthcare providers were not blinded to treatment allocation. Missing information makes it difficult to judge comparability of groups in baseline characteristics and prognostic factors, primary tocolytic therapy, and level of care.</p>
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<p>Nonrandomized Trial: Lindenbaum (1992)⁴</p>	<p>Patients were not blinded to treatment allocation.</p> <p>Healthcare providers not blinded to treatment allocation/Same applies to outcome assessors, since they are assumed to be the same as healthcare providers.</p> <p>Healthcare providers not blinded to maternal contractions.</p> <p>Comparison group not drawn from same population as treatment group.</p> <p>Appropriate methods not taken to control for confounders.</p>	<p>No differential or high loss to followup.</p> <p>No indication of selective outcome reporting.</p> <p>Harm outcome (maternal hyperglycemia) was pre-defined.</p> <p>Mode of harms collection was specified as active.</p> <p>Report does not explicitly specify who collected harms data. However, GTT results will likely be obtained by trained laboratory personnel and interpreted by qualified healthcare professionals.</p> <p>Subjects were representative of source population.</p> <p>Primary outcome (maternal hyperglycemia) has been defined.</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If groups were similar in primary tocolytic treatment.</p> <p>If an intention-to-treat analysis was conducted.</p> <p>If sample size was adequate.</p> <p>If there was differential level of care among groups.</p> <p>If there was bias due to funding.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <p>(1) Gestational age at delivery</p> <p>(2) Birthweight</p> <p>(3) Maternal hyperglycemia</p> <p>HIGH (birthweight and gestational age at delivery): Primary flaw in this study is the difference in groups with respect to severity/prognosis (i.e. groups were divided based on length of primary tocolytic treatment). Also, comparability of groups cannot be assessed due to missing information.</p> <p>MEDIUM (maternal hyperglycemia): The potential difference in severity/prognosis among treatment and comparison groups should not impact the outcome of maternal hyperglycemia. However, issues pertaining to missing information still remain.</p>
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<p>Prospective Cohort: Morrison (2003)⁵</p>	<p>Groups differ in baseline characteristics and prognostic factors (in particular, differ in risk factors for preterm birth).</p> <p>Groups differ in primary tocolytic.</p> <p>Differential level of care received by groups (only terbutaline group received home uterine contraction monitoring).</p> <p>Indication of selective outcome reporting (amount terbutaline infused and neonatal morbidity not reported).</p> <p>Methods to control for confounders insufficient (matched for several factors, but there are still differences in the risk factors for preterm birth).</p> <p>Mode of harms collection not specified as active.</p>	<p>No differential or high loss to followup.</p> <p>Measured harms with standard definitions (maternal arrhythmia and maternal discontinuation of therapy).</p> <p>Report does not explicitly specify who collected harms data. However, it can be assumed that arrhythmia would be detected by qualified healthcare professionals.</p> <p>Subjects were representative of source population.</p>	<p>If an intention-to-treat analysis was conducted.</p> <p>If sample size adequate.</p> <p>If there was bias due to funding.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple outcome assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>If comparison group was drawn from same population as treatment group.</p>	<p>Outcomes:</p> <p>(1) Maternal arrhythmia</p> <p>(2) Maternal discontinuation of therapy.</p> <p>(3) Gestational age at delivery.</p> <p>(4) Prolongation of pregnancy.</p> <p>(5) PPI</p> <p>(6) Birthweight</p> <p>(7) Intraventricular hemorrhage</p> <p>(8) Necrotizing enterocolitis</p> <p>(9) NICU admission</p> <p>HIGH: Primary flaw with this study is that there is evidence that groups were not comparable (with respect to risk factors for preterm birth, primary tocolytic therapy, level of care).</p>
<p>Prospective Cohort: Morrison (1992)⁶</p>	<p>Groups were not similar in baseline characteristics and prognostic factors (subcutaneous terbutaline group had RPTL but other group did not).</p> <p>Comparison group not drawn from the same population as treatment group.</p> <p>Appropriate methods not taken to control for confounders.</p>	<p>No indication of selective outcome reporting.</p> <p>Primary outcome has been defined (interval from discontinuance of tocolytic to spontaneous labor).</p>	<p>If groups were similar in primary tocolytic treatment.</p> <p>If an intention-to-treat analysis was conducted.</p> <p>If there was differential or high loss to followup.</p> <p>If sample size was adequate.</p> <p>If there was differential level of care among groups.</p> <p>If there was bias due to study funding.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>If subjects were representative of source population.</p>	<p>Outcomes:</p> <p>(1) Gestational age at delivery</p> <p>HIGH: Major flaw is that the subcutaneous pump group had RPTL and comparison group did not. Therefore, the intervention group may have had a more serious condition. Also, there is missing information, which makes it difficult to assess other potential limitations.</p>

<p>Retrospective Cohort: Flick (2010)⁷</p>	<p>Groups were not similar in baseline characteristics and prognostic factors (in particular, differed in smoking status).</p> <p>Appropriate methods not undertaken to control for confounders.</p>	<p>No differential or high loss to followup. No differential level of care. No indication of selective outcome reporting.</p> <p>Comparison group drawn from the same population as treatment group.</p> <p>Subjects were representative of source population.</p> <p>Primary outcome (prolongation of pregnancy) has been defined.</p>	<p>If groups were similar in primary tocolytic therapy.</p> <p>If an intention-to-treat analysis was conducted.</p> <p>If sample size was adequate.</p> <p>If there was bias due to study funding.</p> <p>If there was reliability among multiple outcome assessors (data from Matria database, so likely there were multiple outcome assessors, but cannot determine reliability among them).</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <p>(1) Prolongation of pregnancy (2) Gestational age at delivery (3) Birthweight (4) NICU admission</p> <p>HIGH: Primary flaw is that groups were not similar in baseline characteristics and prognostic factors (i.e. differed in smoking status). Also, missing information makes it difficult to assess similarity of groups with respect to other factors.</p>
<p>Retrospective Cohort: de la Torre (2008)⁸</p>	<p>No methods to control for confounders</p>	<p>No differential or high loss to followup. No differential level of care between groups. No indication of selective outcome reporting.</p> <p>Comparison and treatment groups drawn from same sample population.</p> <p>Subjects were representative of source population.</p> <p>Primary outcome (prolongation of pregnancy) was defined.</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If groups were similar in primary tocolytic therapy.</p> <p>If intention-to-treat analysis conducted.</p> <p>If sample size adequate.</p> <p>If there was bias due to funding source.</p> <p>If there was reliability among multiple outcome assessors (likely that there were multiple outcome assessors, since women were from the Matria database. But reliability among assessors cannot be assessed.)</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <p>(1) Prolongation of Pregnancy (2) Gestational Age at Delivery (3) Birthweight (4) NICU Admission</p> <p>MEDIUM: There is a lot of missing information, which makes it difficult to assess comparability of groups (in terms of baseline characteristics and prognostic factors, primary tocolytic therapy, and compliance). But difficult to say that there is any limitation that would invalidate the results for sure.</p>

<p>Retrospective Cohort: Fleming (2004)⁹</p>	<p>Primary outcome of gestational age < 35 weeks has not been adequately specified (i.e. method for determining gestational age not described)</p>	<p>No differential level of care. No indication of selective outcome reporting. Comparison group drawn from same population as treatment group.</p>	<p>If groups were similar in baseline characteristics and prognostic factors. If groups were similar in primary tocolytic therapy. If intention-to-treat analysis conducted. If there was differential or high loss to followup. If sample size was adequate. If there was bias due to study funding. If there was reliability in outcome assessors (likely that there were multiple outcome assessors, since the Matria database was used. But reliability among assessors cannot be determined). If compliance with study protocol was adequate. If appropriate methods were used to control for important confounders. If subjects were representative of source population.</p>	<p>Outcomes:</p> <ol style="list-style-type: none"> (1) Pregnancy Prolongation (2) Gestational age at delivery (3) Stillbirths/Neonatal deaths (4) NICU admission (5) Birthweight <p>MEDIUM: There is considerable missing information, which makes it difficult to assess the comparability of groups. There is some indication that there are baseline differences (i.e. in age and marital status) and data on many other important factors have not been reported (e.g. cervical length, race, SES). However, there are no major flaws that can be singled out as invalidating the results.</p>
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<p>Retrospective Cohort: Lam (2003)¹⁰</p>	<p>Groups differ in baseline characteristics and prognostic factors (in particular: smoking status and previous preterm delivery).</p> <p>Intention-to-treat analysis not done (losses to followup excluded)</p> <p>Methods were not sufficient to control for confounders (only matched by gestational age at delivery).</p>	<p>No differential level of care between groups.</p> <p>Comparison group drawn from the same sample population as treatment group.</p> <p>Measured harms with standardized definitions (maternal pulmonary edema and maternal death).</p> <p>Mode of harms collection not explicitly specified as active. However, this is not very relevant for outcomes of pulmonary edema and maternal death.</p> <p>Report does not explicitly specify who collected harms data. However, it is reasonable to assume that pulmonary edema would be assessed by qualified healthcare professionals.</p>	<p>If groups were similar in primary tocolytic therapy.</p> <p>If there was differential or high loss to followup (losses to followup were excluded).</p> <p>If sample size was adequate.</p> <p>If there was bias due to funding source.</p> <p>If there was selective outcome reporting.</p> <p>If there was reliability in outcome assessors (data was from Matria database, so likely that there were multiple outcome assessors. But reliability among assessors cannot be determined).</p> <p>If compliance with study protocol was adequate.</p> <p>If subjects were representative of source population.</p>	<p>Outcomes:</p> <ol style="list-style-type: none"> (1) Pregnancy Prolongation (2) Gestational age at delivery (3) Birthweight (4) NICU admission (5) Stillbirth (6) Ventilator required (7) Maternal pulmonary edema (8) Maternal deaths <p>HIGH: Primary flaw is that groups were not similar at baseline (differed in smoking status and previous PTD). Also, missing data makes it difficult to assess several other potential limitations.</p>
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<p>Retrospective Cohort: Lam (2001)¹¹</p>		<p>No high or differential loss to followup. No differential level of care among groups. Comparison group drawn from same population as treatment group. Measured harms with standard definitions (maternal pulmonary edema and maternal deaths). Mode of harms collection not explicitly specified as active. However, this is not very relevant for harms of maternal pulmonary edema and maternal death. Report does not explicitly specify who collected harms data. However, it can be assumed that pulmonary edema and death would be assessed by qualified personnel. Subjects were representative of source population.</p>	<p>If groups were similar in baseline characteristics and prognostic factors. If groups were similar in primary tocolytic therapy. If an intention-to-treat analysis was conducted. If sample size was adequate. If there was bias due to study funding. If there was selective outcome reporting. If there was reliability among multiple outcome assessors (data from Matria database, so likely there were multiple outcome assessors, but reliability among assessors cannot be determined). If compliance with study protocol was adequate. If appropriate methods used to control for confounders (matched by gestational age at hospitalization for recurrent preterm labor).</p>	<p>Outcomes:</p> <ul style="list-style-type: none"> (1) Prolongation of pregnancy (2) Gestational age at delivery (3) Birthweight (4) NICU admission (5) Stillbirth/Neonatal deaths (6) Maternal pulmonary edema (7) Maternal deaths <p>MEDIUM: There is a large amount of missing information, which makes it difficult to assess the comparability of groups and other potential limitations. But there are no major flaws that can be identified that would invalidate the results.</p>
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<p>Retrospective Cohort: Allbert (1994)¹²</p>	<p>Differential level of care among groups (it appears that only the subcutaneous terbutaline group received home nursing care).</p>	<p>No indication of selective outcome reporting.</p> <p>Consistency in outcome definition among multiple data sources (Not clear if multiple data sources were used. However, use of multiple data sources should not make much of a difference because all outcomes have been defined or are self-explanatory).</p> <p>Primary outcome defined (gestational age \geq 37 weeks and method for determining gestational age specified).</p>	<p>If groups were similar in baseline characteristics and prognostic factors.</p> <p>If groups were similar in primary tocolytic therapy.</p> <p>If an intention-to-treat analysis was conducted.</p> <p>If there was high or differential loss to followup.</p> <p>If sample size was adequate.</p> <p>If there was bias due to study funding.</p> <p>Reliability among multiple outcome assessors (unclear of there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>If comparison group came from same sample population as treatment group.</p> <p>If appropriate methods were undertaken to control for confounders (matched for age, race, parity, gestational age and cervical dilation at the diagnosis of recurrent labor).</p> <p>If subjects were representative of source population.</p>	<p>Outcomes:</p> <p>(1) Gestational age at delivery</p> <p>(2) PPI</p> <p>(3) Birthweight</p> <p>MEDIUM: There is a lot of missing information, which makes it difficult to assess comparability among groups and whether groups were derived from the same population. There is a possibility that groups received a different level of care, since only the subcutaneous terbutaline group has been specified as receiving home nursing care. However, it is unclear if this factor alone would be sufficient to impact the results to a large extent.</p>
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<p>Retrospective Cohort: Regenstein (1993)¹⁴</p>	<p>Groups are not similar in baseline characteristics and prognostic factors.</p> <p>No methods to control for confounders.</p>	<p>No bias due to study funding.</p> <p>No indication of selective outcome reporting.</p> <p>Harm outcome (maternal hyperglycemia) was predefined using precise definition based on 3-hour GTT.</p> <p>Harms data collection was specified as active versus passive.</p> <p>Report does not explicitly specify who collected harms data, including their training and background. However, GTT results will likely be obtained by trained laboratory personnel and interpreted by qualified healthcare professionals.</p> <p>Primary outcome (glucose intolerance i.e. maternal hyperglycemia) is defined based on 1-hour and 3-hour GTT.</p>	<p>If groups were similar in primary tocolytic therapy.</p> <p>If intention-to-treat analysis conducted.</p> <p>If there was differential or high loss to followup.</p> <p>If sample size adequate.</p> <p>If there was differential level of care between groups.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple outcome assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>If comparison group was drawn from the same population as treatment group.</p> <p>If subjects were representative of source population.</p>	<p>Outcomes:</p> <p>(1) Maternal hyperglycemia (gestational diabetes)</p> <p>(2) Gestational age at delivery</p> <p>(3) Birthweight</p> <p>HIGH (Maternal Hyperglycemia - Harm outcome): Although this harm outcome was defined and collected actively, the primary flaw with this study is that groups were not similar in baseline characteristics (i.e. in race and family history of gestational diabetes). Also, since no methods were used to control for confounders, there is a high likelihood that groups may differ in other baseline characteristics and prognostic factors, which have not been reported. There is also a lot of missing information which makes it difficult to assess the comparability of groups (e.g. primary tocolytic, loss to followup, differential level of care, compliance).</p> <p>HIGH (all other outcomes): same reasons as above.</p>
<p>Case series: Adkins (1993)¹⁵</p>	<p>Bias due to study funding (From PharmaThera Inc).</p> <p>Harms were not predefined (pump malfunction and dislodgment).</p> <p>Mode of harms collection not specified as active.</p> <p>Report does not specify who collected harms data, including background and training.</p>	<p>No high loss to followup.</p> <p>Subjects were representative of source population.</p>	<p>If sample size was adequate.</p> <p>If there was selective outcome reporting.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p>	<p>Outcomes:</p> <p>(1) Pump malfunction</p> <p>(2) Dislodgment</p> <p>MEDIUM: There is missing information, which makes it difficult to assess some quality items. However, there was no high loss to followup and subjects were representative of source population. Adequacy of sample size is unclear (n=51), although it is larger than the previous case series of nine subjects.</p>

<p>Case series: Lam (1988) 16</p>	<p>Harm outcomes of mechanical failures/complications and infusion site infections have not been defined.</p> <p>Harms data collection not specified as active.</p> <p>Report does not specify who collected harms data, including their training and background.</p>		<p>If there was high loss to followup.</p> <p>If sample size was adequate.</p> <p>If there was bias due to study funding.</p> <p>If there was selective outcome reporting.</p> <p>If there was reliability among multiple outcome assessors (unclear if there were multiple assessors).</p> <p>If compliance with study protocol was adequate.</p> <p>If subjects were representative of source population.</p>	<p>Outcomes:</p> <p>(1) Mechanical failures and complications</p> <p>(2) Infusion site infection</p> <p>MEDIUM: There is a lot of missing information, which makes it difficult to assess potential for selection bias (e.g. were the nine subjects in the study the entire sample, or were these the number left over after losses to followup?). Also, harm outcomes have not been defined. However, the study does not have any obvious major flaws, which would invalidate the results.</p>
<p>GTT: glucose tolerance test; NICU: neonatal intensive care unit; PPI: pregnancy prolongation index; PTD: preterm delivery; RCT: randomized controlled trial; SES: socioeconomic status</p>				

Table F4. Studies that reported neonatal health outcomes (Key Question 1)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks)*	Comparator(s)	Results		
						SQ terbutaline pump: % (n/N)	Comparison: % (n/N)	OR (95% CI)
BPD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Death, neonatal	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	0% (0/142)	0% (0/142)	1.00 (0.02, 50.75)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	0.1% (1/706)	1.6% (11/706)	0.09 (0.01, 0.70)
	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	0% (0/19)	C ₁ : 0% (0/15) C ₂ : 0% (0/16)	0.79 (0.01, 42.38) 0.85 (0.02, 45.00)
Death within initial hospitalization	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IVH (Grade III/IV)	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	0% (0/15)	8.9% (4/45)	0.30 (0.02, 5.85)
	Guinn (1998) ¹	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	0% (0/23) [*]	0% (0/28)	1.21 (0.02, 63.48)
NEC	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	0% (0/15)	2.2% (1/45)	0.96 (0.04, 24.74)
PVL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Retinopathy of prematurity	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	5.3% (1/19)	C ₁ : 0% (0/15) C ₂ : 0% (0/16)	2.51 (0.10, 66.20) 2.68 (0.10, 70.31)
Seizures	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Sepsis	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	0% (0/19)	C ₁ : 0% (0/15) C ₂ : 6.2% (1/16)	0.79 (0.01, 42.38) 0.26 (0.01, 6.97)
Stillbirth	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	1.4% (2/142)	0.7% (1/142)	2.01 (0.18, 22.47)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	0.4% (1/279)	0% (0/279)	3.01 (0.12, 74.23)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	0.4% (3/706)	0.6% (4/706)	0.75 (0.17, 3.36)

BPD: bronchopulmonary dysplasia; CI: confidence interval; GA: gestational age; IVH: intraventricular hemorrhage; N/A: not applicable; NEC: necrotizing enterocolitis; NR: not reported; OR: odds ratio; PVL: periventricular leukomalacia; RCT: randomized controlled trial; SQ: subcutaneous

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

† Study population consisted exclusively of women with RPTL.

‡ Study population consisted exclusively of women with twin gestation. Denominator is number of infants.

§ Study population consisted of women with single and twin gestation. Denominator is number of infants

** One infant born at 33 weeks gestation was unavailable for followup.

Table F5. Studies that reported mean gestational age at delivery (Key Question 2)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks)	Comparator(s)	Results		
						SQ terbutaline pump: Mean ± SD	Comparison: Mean ± SD	Difference in Means (95% CI)
Mean GA at delivery <i>Results are reported as mean GA at delivery in weeks</i>	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	36.7 ± 1.9	36.0 ± 2.9	0.70 (0.42, 0.98)
	de la Torre ^{†, **} (2008) ⁸	Retrospective Cohort (n=656)	30.3 ± 5.8	30.1 ± 2.9 (P)	Oral nifedipine	34.8 ± 2.2	34.1 ± 2.5	0.70 (0.43, 0.97)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	36.6 ± 2.1	35.7 ± 3.1	0.90 (0.28, 1.52)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	36.5 ± 2.1	35.7 ± 2.8	0.80 (0.39, 1.21)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	36.7 ± 1.7	33.3 ± 3.0	3.40 (1.80, 5.00)
	Lam ^{†, **} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	35.2 ± 2.0	34.5 ± 2.3	0.70 (0.48, 0.92)
	Guinn (1998) ¹	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	34.4 ± 3.4	34.9 ± 4.1	-0.50 (-2.57, 1.57)
	Wenstrom ^{††} (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	35.7 ± 3.0	C ₁ : 35.4 ± 3.0 C ₂ : 34.3 ± 4.0	0.30 (-1.73, 2.33) 1.40 (-0.92, 3.72)
	Regenstein ^{††} (1993) ¹⁴	Retrospective Cohort (n=69)	31.4 ± 5.9	NR	Oral terbutaline [§]	35.2 ± 3.3	36.6 ± 2.7	-1.40 (-2.82, 0.02)
	Lindenbaum (1992) ⁴	Nonrandomized comparative trial (n=91)	32.4 ± 2.7	29.1 ± 1.7 (T)	Oral terbutaline [§]	36.6 ± 1.2	37.9 ± 1.3	-1.30 (-1.83, -0.77) ^{***}
Morrison ^{***, †††} (1992) ⁶	Prospective Cohort (n=69)	28.6 ± 4.7	NR	Oral tocolytics	37.5 ± 1.2	37.1 ± 0.96	0.40 (-0.11, 0.91)	

CI: confidence interval; GA: gestational age; NR: not reported; RCT: randomized controlled trial; SD: standard deviation; SQ: subcutaneous

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted exclusively of women with RPTL.

[§] A third comparison arm (control group) was not extracted because this group did not have preterm labor.

^{**} Study population consisted exclusively of women with twin gestation.

^{††} Study population consisted of women with single and twin gestation.

^{†††} Gestation not specified, although study population likely consisted of women with single and multiple gestation.

^{***} Gestational age at delivery was calculated by adding the variables gestational age at tocolytic cessation and interval to delivery. The associated standard deviations were calculated based on the reported standard deviations for interval to delivery (standard deviation of gestational age at tocolytic cessation was assumed to be 0 for both groups).

^{††††} Gestation not specified, although study population likely included a mixture of women with single and multiple gestation.

*** There were discrepancies in the information presented in the text and table of this paper. Mean gestational age at delivery for SQ terbutaline pump was reported as 36.6 weeks in table (as reported above) and 37.2 weeks in text.

Table F6. Studies that reported incidence of delivery at various gestational ages (Key Question 2)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks) [*]	Comparator(s)	Results		
						SQ terbutaline pump: % (n/N)	Comparison: % (n/N)	OR (95% CI)
Incidence of delivery < 28 weeks	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Incidence of delivery < 32 weeks	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	2.6% (14/536)	8.4% (70/830)	0.29 (0.16, 0.52)
	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 ± 5.8	30.1 ± 2.9 (P)	Oral nifedipine	9.2% (44/476)	17.7% (148/836)	0.47 (0.33, 0.68)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	2.8% (4/142)	12.7% (18/142)	0.20 (0.07, 0.61)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	2.5% (7/279)	10.8%(30/279)	0.21 (0.09, 0.50)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	0% (0/15)	46.7% (21/45)	0.04 (0.00, 0.65)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	6.2% (44/706)	11.3% (80/706)	0.52 (0.35, 0.76)
Incidence of delivery < 34 weeks	Guinn (1998) [†]	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	41.7% (10/24)	42.8% (12/28)	0.95 (0.32, 2.87)
Incidence of delivery < 37 weeks	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	51.3% (275/536)	59.3% (492/830)	0.72 (0.58, 0.90)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	52.1% (74/142)	59.2% (84/142)	0.75 (0.47, 1.20)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	52.7% (147/279)	61.3% (171/279)	0.70 (0.50, 0.98)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	46.7% (7/15)	95.6% (43/45)	0.04 (0.01, 0.23)
	Guinn (1998) [†]	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	70.8% (17/24)	60.7% (17/28)	1.57 (0.49, 5.02)
	Allbert ^{†,§} (1994) ¹²	Retrospective Cohort (n=64)	27.5 ± 4.3	32.2 ± 2.7 (T)	Oral terbutaline	34.4% (11/32)	84.4% (27/32)	0.10 (0.03, 0.32)

CI: confidence interval; GA: gestational age; N/A: not applicable; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SQ: subcutaneous

^{*} Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted exclusively of women with RPTL.

[‡] Study population consisted exclusively of women with twin gestation. Denominator is number of infants.

§ Gestation not specified, although population most likely included women with single and multiple gestation. Denominator is number of women.

Table F7. Studies that reported prolongation of pregnancy (Key Question 2)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks) [†]	Comparator(s)	Results		
						SQ terbutaline pump: Mean ± SD or % (n/N)	Comparison: Mean ± SD or % (n/N)	Either Difference in Means (95% CI) or OR (95% CI)
Mean Prolongation of Pregnancy <i>Results are reported as mean prolongation in days</i>	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	44.0 ± 23.0 <i>Measured from hospital admission for RPTL</i>	36.5 ± 24.0	7.50 (4.94, 10.06)
	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 ± 5.8	30.1 ± 2.9 (P)	Oral nifedipine	34.7 ± 18.8 <i>Measured from episode of RPTL</i>	27.5 ± 19.9	7.20 (4.10, 10.30)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	43.3 ± 21.6 <i>Measured from episode of RPTL</i>	37.1 ± 24.8	6.20 (0.79, 11.61)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	33.9 ± 19.0 <i>Measurement interval not specified</i>	28.4 ± 19.8	5.50 (2.28, 8.72)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	49.8 ± 19.2 <i>Measured from episode of RPTL</i>	24.5 ± 12.8	25.30 (16.77, 33.83)
	Guinn (1998) [†]	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	28.8 ± 22.0 <i>Measured from random assignment</i>	27.9 ± 22.9	0.90 (-11.36, 13.16)
	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	35.0 ± 28.7 <i>Measurement interval not specified</i>	C ₁ : 35.0 ± 17.5 C ₂ : 29.4 ± 27.3	0.00 (-18.53, 18.53) 5.60 (-14.45, 25.65)
Pregnancy prolongation > 7 days	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	98.7% (529/536) <i>Measured from hospital admission for RPTL</i>	90.6% (752/830)	7.84 (3.59, 17.12)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	96.5% (137/142) <i>Measured from episode of RPTL</i>	91.5% (130/142)	2.53 (0.87, 7.38)
Pregnancy prolongation > 14 days	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	93.8% (503/536) <i>Measured from hospital admission for RPTL</i>	81.4% (676/830)	3.47 (2.34, 5.15)
	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 ± 5.8	30.1 ± 2.9 (P)	Oral nifedipine	84.4% (201/238) <i>Measured from episode of RPTL</i>	68.7% (287/418)	2.48 (1.65, 3.73)
	Fleming [†] (2004) ⁹	Retrospective Cohort (284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	93.0% (132/142) <i>Measured from episode of RPTL</i>	82.4% (117/142)	2.82 (1.30, 6.12)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	85.7% (239/279) <i>Measurement interval not specified</i>	71.3% (199/279)	2.40 (1.57, 3.67)
	Lam ^{†,‡}	Retrospective	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3%)	73.6% (260/353)	59.2%	1.93 (1.40, 2.65)

	(2001) ^{††}	Cohort (n=706)			received oral terbutaline)		(209/353) ^{**}	
						<i>Measured from episode of RPTL</i>		
CI: confidence interval; GA: gestational age; N/A: not applicable; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; RPTL: recurrent preterm labor; SD: standard deviation; SQ: subcutaneous								

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

† Study population consisted exclusively of women with RPTL.

* Study population consisted exclusively of women with twin gestation. Denominator is number of infants.

§ Study population consisted of women with single and twin gestation.

** Additional reported data: SQ terbutaline pump group gained an average of 4.5 gestational days (95% CI: 2.3-6.8) compared with oral tocolytic group.¹¹

Table F8. Studies that reported birthweight (Key Question 2)

Please note Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks) [*]	Comparator(s)	Results		
						SQ terbutaline pump: Mean \pm SD or % (n/N)	Comparison: Mean \pm SD or % (n/N)	Either Difference in Means (95% CI) or OR (95% CI)
Mean Birthweight <i>Results are reported as mean birthweight in grams</i>	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 \pm 5.8	30.1 \pm 2.9 (P)	Oral nifedipine	2252 \pm 501	2089 \pm 564	163 (102, 224)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 \pm 2.6 (P)	Oral nifedipine	2900 \pm 568	2638 \pm 784	262 (103, 421)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 \pm 5.9	31.6 \pm 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	2941 \pm 556	2676 \pm 667	265 (163, 367)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 \pm 5.2	29.5 \pm 2.3 (P)	No treatment	2700 \pm 464	1979 \pm 670	721 (355, 1087)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 \pm 5.5	31.3 \pm 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	2343 \pm 493	2207 \pm 523	136 (83, 189)
	Guinn (1998) ¹	RCT (n=52)	21.6 \pm 5.7	30.6 \pm 2.8 (T)	Placebo	2349 \pm 770	2324 \pm 768	25 (-394, 444)
	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 \pm 5.3	30.4 \pm 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	2688 \pm 599	C ₁ : 2457 \pm 727 C ₂ : 2204 \pm 808	231 (-214, 676) 484 (17, 951)
	Allbert ^{†,***} (1994) ¹²	Retrospective Cohort (n=64)	27.5 \pm 4.3	32.2 \pm 2.7 (T)	Oral terbutaline	2853 \pm 702	2682 \pm 528	171 (-133, 475)
	Regenstein ^{††} (1993) ¹⁴	Retrospective Cohort (n=69)	31.4 \pm 5.9	NR	Oral terbutaline ^{††}	2558 \pm 838	3262 \pm 567	-704 (-1037, -371)
	Lindenbaum (1992) ⁴	Nonrandomized comparative trial (n=91)	32.4 \pm 2.7	29.1 \pm 1.7 (T)	Oral terbutaline ^{††}	3017 \pm 303	3229 \pm 584	-212 (-417, -7) ^{§§}
Incidence of low birthweight (< 2500 g)	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 \pm 6.1	30.6 \pm 2.9 (P)	Oral nifedipine	20.3% (109/536)	32.9% (273/830)	0.52 (0.40, 0.67)
	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 \pm 5.8	30.1 \pm 2.9 (P)	Oral nifedipine	67.2% (320/476)	78.3% (655/836)	0.57 (0.44, 0.73)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 \pm 2.6 (P)	Oral nifedipine	23.2% (33/142)	43.0% (61/142)	0.40 (0.24, 0.67)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 \pm 5.9	31.6 \pm 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	20.8% (58/279)	38.0% (106/279)	0.43 (0.29, 0.62)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 \pm 5.2	29.5 \pm 2.3 (P)	No treatment	20.0% (3/15)	51.1% (23/45)	0.24 (0.06, 0.96)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 \pm 5.5	31.3 \pm 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	61.5% (432/702)	71.5% (494/691)	0.64 (0.51, 0.80)
Incidence of very low	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 \pm 5.8	30.1 \pm 2.9 (P) F-31	Oral nifedipine	6.5% (31/476)	15.0% (125/836)	0.40 (0.26, 0.60)

birthweight (< 1500 g)	Fleming [†] (2004) [§]	Retrospective Cohort (n=284)	NR	30.4 \pm 2.6 (P)	Oral nifedipine	2.1% (3/142)	7.0% (10/142)	0.28 (0.08, 1.06)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 \pm 5.9	31.6 \pm 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	1.4% (4/279)	6.1% (17/279)	0.22 (0.07, 0.67)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (706)	28.8 \pm 5.5	31.3 \pm 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	4.1% (29/702)	8.5% (59/691)	0.46 (0.29, 0.73)

CI: confidence interval; GA: gestational age; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SD: standard deviation; SQ: subcutaneous

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted exclusively of women with RPTL.

[‡] Study population consisted exclusively of women with twin gestation. Denominator is number of infants.

[§] Study population consisted of women with single and twin gestation.

** Gestation not specified, although population most likely included women with single and multiple gestation.

^{††} Gestation not specified, although study population likely consisted of women with single and multiple gestation. Reported mean birthweight is for singletons only.

^{‡‡} A second comparison group, consisting of women without preterm labor, was not extracted.

^{§§} There were discrepancies in the information presented in the text and table of this paper. The table reported the numbers as indicated above.

However, the text reported groups with the reverse numbers (i.e. SQ terbutaline pump: 3229 \pm 584 and oral terbutaline: 3017 \pm 303).

Table F9. Studies that reported other outcomes (Key Question 2)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks)	Comparator(s)	Results		
						SQ terbutaline pump: Mean ± SD or % (n/N)	Comparison: Mean ± SD or % (n/N)	Either Difference in Means (95% CI) or OR (95% CI)
Need for assisted ventilation	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	24.4% (68/279)	26.2% (73/279)	0.91 (0.62, 1.33)
						<i>Only assessed for those with NICU admission</i>		
Need for oxygen per nasal cannula	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NICU admission incidence	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	23.1% (124/536)	34.0% (282/830)	0.58 (0.46, 0.75)
	de la Torre ^{†,‡} (2008) ⁸	Retrospective Cohort (n=656)	30.3 ± 5.8	30.1 ± 2.9 (P)	Oral nifedipine	44.7% (213/476)	52.9% (442/836)	0.72 (0.58, 0.91)
	Fleming [†] (2004) ⁹	Retrospective Cohort (n=284)	NR	30.4 ± 2.6 (P)	Oral nifedipine	23.2% (33/142)	43.7% (62/142)	0.39 (0.23, 0.65)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	18.6% (52/279)	26.2% (73/279)	0.65 (0.43, 0.97)
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	33.3% (5/15)	64.4% (29/45)	0.28 (0.08, 0.95)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	38.5% (270/702)	55.0% (380/691)	0.51 (0.41, 0.63)
	Guinn (1998) ¹	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	43.5% (10/23)	46.4% (13/28)	0.89 (0.29, 2.69)
					<i>Neonates remaining in NICU > 24 hours</i>			
NICU mean length of stay	Flick [†] (2010) ⁷	Retrospective Cohort (n=1366)	28.7 ± 6.1	30.6 ± 2.9 (P)	Oral nifedipine	2.8 ± 9.2	6.5 ± 17.2	-3.70 (-5.29, -2.11)
	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics(95.3% received oral terbutaline)	14.1 ± 17.7	21.0 ± 22.5	-6.90 (-10.26, -3.54)
						<i>NICU (Level III) admission</i>		
	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	1.9 ± 4.9	19.8 ± 29.3	-17.90 (-32.88, -2.92)
	Lam ^{†,‡} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	17.3 ± 16.1	20.8 ± 17.4	-3.50 (-5.26, -1.74)
	Wenstrom [§] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	10.9 ± 19.4	C ₁ : 15.0 ± 18.8 C ₂ : 15.4 ± 17.0	-4.10 (-17.06, 8.86) -4.50 (-16.70, 7.70)

Mean PPI	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	0.92 ± 0.19	0.51 ± 0.28	0.41 (0.26, 0.56)
	Allbert ^{†,‡} (1994) ¹²	Retrospective Cohort (64)	27.5 ± 4.3	32.2 ± 2.7 (T)	Oral terbutaline	0.86 ± 0.25	0.72 ± 0.25	0.14 (0.02, 0.26)
Ratio of birthweight/GA at delivery	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CI: confidence interval; GA: gestational age; N/A: not applicable; NICU: neonatal intensive care unit; NR: not reported; OR: odds ratio; PPI: pregnancy prolongation index; RCT: randomized controlled trial; SD: standard deviation; SQ: subcutaneous								

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted exclusively of women with RPTL.

[‡] Study population consisted exclusively of women with twin gestation. Denominator is number of infants.

[§] Study population consisted of women with single and twin gestation.

** Gestation not specified, although population most likely included women with single and multiple gestation.

Table F10. Studies that reported maternal harms (Key Question 3)

Please note: Subjects were women with singleton gestation only, unless indicated otherwise.

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks)	Comparator(s)	Results		
						SQ terbutaline pump: % (n/N)	Comparison: % (n/N)	OR (95% CI)
Arrhythmia	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	20.0% (3/15)	0% (0/45)	25.48 (1.23, 526.64)
						<i>Defined as tachycardia, nervousness</i>		
Heart Failure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Hyperglycemia	Regenstein [‡] (1993) ¹⁴	Retrospective Cohort (n=69)	31.4 ± 5.9	NR	Oral terbutaline [§]	20.0% (6/30)	11.4% (4/35)	1.94 (0.49, 7.65)
<i>Reported results indicate women with gestational diabetes, based on 3-hour GTT.</i>	Lindenbaum (1992) ⁴	Nonrandomized comparative trial (n=91)	32.4 ± 2.7	29.1 ± 1.7 (T)	Oral terbutaline [§]	5.4% (2/37)	11.1% (6/54)	0.46 (0.09, 2.40)
Hypokalemia	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mortality	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	0% (0/279)	0% (0/279)	1 (0.02, 50.58)
	Lam ^{†,**} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	0% (0/353)	0% (0/353)	1 (0.02, 50.54)
Myocardial Infarction	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pulmonary Edema	Lam [†] (2003) ¹⁰	Retrospective Cohort (n=558)	27.4 ± 5.9	31.6 ± 2.2 (P)	Oral tocolytics (95.3% received oral terbutaline)	0% (0/279)	0.4% (1/279)	0.33 (0.01, 8.19)
	Lam ^{†,**} (2001) ¹¹	Retrospective Cohort (n=706)	28.8 ± 5.5	31.3 ± 2.3 (P)	Oral tocolytics (92.3% received oral terbutaline)	0.3% (1/353)	0% (0/353)	3.01 (0.12, 74.11)
Refractory Hypotension	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Therapy Discontinuation	Morrison [†] (2003) ⁵	Prospective Cohort (n=60)	25.6 ± 5.2	29.5 ± 2.3 (P)	No treatment	0% (0/15)	N/A	N/A
	Guinn (1998) [†]	RCT (n=52)	21.6 ± 5.7	30.6 ± 2.8 (T)	Placebo	45.8% (11/24)	32.1% (9/28)	1.79 (0.58, 5.52)
WDAE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

CI: confidence interval; GA: gestational age; GTT: glucose tolerance test; N/A: not applicable; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SQ: subcutaneous; WDAE: withdrawal due to adverse effects

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted exclusively of women with RPTL.

[‡] Gestation not specified, although study population likely consisted of women with single and multiple gestation.

[§] Data for a second comparison group, which consisted of women without preterm labor, was not extracted.

** Study population consisted exclusively of women with twin gestation.

Table F11. Studies that reported neonatal harms (Key Question 4)

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks) [*]	Comparator(s)	Results		
						SQ terbutaline pump: % (n/N)	Comparison: % (n/N)	OR (95% CI)
Hypoglycemia	Wenstrom [†] (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	0% (0/19)	C ₁ : 6.7% (1/15) C ₂ : 0% (0/16)	0.25 (0.01, 6.53) 0.85 (0.02, 45.03)
Hypocalcemia	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ileus	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

CI: confidence interval; GA: gestational age; N/A: not applicable; OR: odds ratio; RCT: randomized controlled trial; SQ: subcutaneous

^{*} Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

[†] Study population consisted of women with single and twin gestation. Denominator is number of infants.

Table F12. Risk of bias ratings for level of maternal activity

First Author (year)	Marital Status	Working Status	Caring for other Children	Social Support	Bed Rest	Restriction of Maternal Activities	Overall Rating
RCTs							
Guinn (1998) ¹	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Multiparity: 57% of placebo group and 63% of terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
Wenstrom (1997) ²	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Median parity provided for all groups INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Patients were instructed to remain at bed rest LOW	Not reported INSUFFICIENT DATA TO MAKE RATING	LOW <i>Based on bed rest</i>
NONRANDOMIZED TRIALS							
Lindenbaum (1992) ⁴	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
PROSPECTIVE COHORTS							
Morrison (2003) ⁵	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Bed rest advised LOW	Interdiction of intercourse advised LOW	LOW
Morrison (1992) ⁶	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Parity reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
RETROSPECTIVE COHORTS							
Flick (2010) ⁷	Married: 71.8% in nifedipine group and 85.3% in terbutaline group	Not reported	Not reported	Not reported	Not reported	Not reported	UNCLEAR

	INSUFFICIENT DATA TO MAKE RATING	INSUFFICIENT DATA TO MAKE RATING	INSUFFICIENT DATA TO MAKE RATING	INSUFFICIENT DATA TO MAKE RATING	INSUFFICIENT DATA TO MAKE RATING	INSUFFICIENT DATA TO MAKE RATING	
de la Torre (2008) ⁸	Married: 80.9% in nifedipine group and 87.8% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Nulliparous: 56% in nifedipine group and 58.8% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
Fleming (2004) ⁹	Married: 71.8% in nifedipine group and 85.2% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Nulliparous: 43% in nifedipine group and 40.8% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
Lam (2003) ¹⁰	Married: 69.2% in oral tocolytic group and 84.2% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
Lam (2001) ¹¹	Married: 77.3% in oral tocolytic group and 87.8% in SQ terbutaline group INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
Allbert (1994) ¹²	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Parity provided for oral terbutaline and SQ terbutaline groups INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Bed rest advised LOW	Prohibition of intercourse advised LOW	LOW

Regenstein (1993) ¹⁴	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Parity reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
CASE SERIES							
Adkins (1993) ¹⁵	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	If contractions were detected, patients were instructed to void, hydrate, remain at bed rest. LOW	Not reported INSUFFICIENT DATA TO MAKE RATING	LOW <i>Based on bed rest</i>
Lam (1988) ¹⁶	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Patients were instructed to remain in bed, but were permitted bathroom privileges LOW	Not reported INSUFFICIENT DATA TO MAKE RATING	LOW <i>Based on bed rest</i>
RCT: randomized controlled trial; SQ: subcutaneous							

Table F13. Ratings for level of maternal care

First Author (year)	Nursing Assessments	Home Uterine Activity Monitoring	Home Visits	Education about Preterm Labor	Telephone Support	Restriction of Maternal Activities	Other Cointerventions	Overall Rating
RCTs								
Guinn (1998) ¹	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Educated about signs and symptoms of preterm labor "The women were also educated about early signs and symptoms of preterm labor" LOW	Nursing support available 24 hours/day to answer questions and monitor therapy. HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Outpatients were followed up on a weekly basis until 36 weeks gestation. MODERATE	MODERATE
Wenstrom (1997) ²	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Patients were instructed to remain at bed rest MODERATE	Patients seen in outpatient clinic weekly or biweekly MODERATE	UNCLEAR
NONRANDOMIZED TRIALS								
Lindenbaum(1992) ⁴	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
PROSPECTIVE COHORTS								
Morrison (2003) ⁵	Not reported	Patients in terbutaline group received a uterine contraction monitor and were instructed to monitor twice daily. A daily telephone call by a perinatal nurse was done to gather this information.	Not reported	Educated about the signs and symptoms of preterm labor "Women in the study and control groups were taught the signs and symptoms associated with preterm labor"	Patients were given a 24 hour hotline number to call if they had any questions.	Bed rest and interdiction of intercourse advised.	Patients were followed up in a preterm birth prevention clinic.	PUMP GROUP: HIGH CONTROL: MODERATE

	INSUFFICIENT DATA TO MAKE RATING	RATING CANNOT BE MADE DUE TO CONFOUNDING	INSUFFICIENT DATA TO MAKE RATING	LOW	HIGH	MODERATE	MODERATE	
Morrison (1992) ⁶	Intensive perinatal nurse assessments were available INSUFFICIENT DATA TO MAKE RATING	Monitored uterine activity twice a day MODERATE	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
RETROSPECTIVE COHORTS								
Flick (2010) ⁷	To identify barriers to care or issues that may make it difficult for the patients to comply with plan of care. MODERATE	An electronic device used to monitor minimum of twice per day and as needed for PTL symptoms. Data transmitted by telephone to a care center and interpreted by perinatal nurses. HIGH	Initial home visit by an experienced perinatal nurse to provide written and verbal education about condition MODERATE	Initial home visit by an experienced perinatal nurse to provide written and verbal education about condition HIGH	Available 24 hours a day, 7 days a week, by perinatal nurses and pharmacists. HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	HIGH
de la Torre (2008) ⁸	Nursing assessment to identify barriers to care HIGH	Patients monitored uterine contractions minimum of twice/day and as needed for PTL symptoms. This data was transmitted by telephone to a care center and interpreted by a perinatal nurse. HIGH	A perinatal nurse conducted an initial visit to each patient's home MODERATE	A perinatal nurse conducted an initial visit to each patient's home to provide written and verbal education about her condition (review of signs and symptoms of preterm labor, medication compliance, adverse effects, electronic uterine contraction monitor, clinical protocols) HIGH	Telephone support by nurses and pharmacists available 24 hours/day 7 days/week HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	HIGH

Fleming (2004) ⁹	Adherence to the prescribed regimen was encouraged, assessed, and documented daily. MODERATE	Uterine contraction data collected at least twice daily and were transmitted to a perinatal center staffed with nurses who evaluated the data and completed a telephone assessment of signs and symptoms. HIGH	Initial home visit and followup visits conducted as needed. MODERATE	Individual patient teaching sessions with a nurse about the signs and symptoms of preterm labor HIGH	Perinatal nurses were available 24 hours/day for 7 days/week for data evaluation, patient calls, and nursing support. HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	HIGH
Lam (2003) ¹⁰	Daily nursing assessments of electronically transmitted uterine activity data and assessment of patients' clinical condition. The extent of adherence to the prescribed regimen was also assessed and adherence encouraged during each nurse-patient contact. MODERATE	Use of a monitoring device for uterine contractions and data electronically transmitted HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Individual patient teaching sessions with a nurse about the signs and symptoms of preterm labor HIGH	Nursing staff available at all times for patient phone calls. HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	HIGH
Lam (2001) ¹¹	Daily telephone nursing assessment of objective patient data and subjective symptoms. MODERATE	Home uterine activity monitoring (no further details provided) MODERATE	Not reported INSUFFICIENT DATA TO MAKE RATING	Educated about the signs and symptoms of preterm labor "This program included patient education regarding the signs and symptoms of preterm labor" LOW	Daily telephone nursing assessment MODERATE	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	MODERATE

Allbert (1994) ¹²	Not reported INSUFFICIENT DATA TO MAKE RATING	Patients conducted home uterine contraction monitoring twice daily. MODERATE	Home nursing care received by SQ terbutaline group, appears only in this group. RATING CANNOT BE MADE DUE TO POTENTIAL CONFOUNDING	Not reported INSUFFICIENT DATA TO MAKE RATING	Daily phone contact by a perinatal nurse MODERATE	Bed rest and prohibition of intercourse advised MODERATE	Not reported INSUFFICIENT DATA TO MAKE RATING	PUMP GROUP: HIGH CONTROL: MODERATE
Regenstein (1993) ¹⁴	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Study included women receiving home nursing care or care by perinatology service, so cannot be sure whether equal number of patients in oral and SQ terbutaline groups received home care. RATING CANNOT BE MADE DUE TO POTENTIAL CONFOUNDING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	UNCLEAR
CASE SERIES								
Adkins (1993) ¹⁵	Not reported INSUFFICIENT DATA TO MAKE RATING	Uterine self-palpitation was taught as a method for detecting contractions twice daily. MODERATE	Home infusion therapy nurse-clinician made an initial home visit. F/U care included: weekly appointments with physicians, frequent telephone calls from home infusion therapy nurse-clinician and physician's offices, and home visits as needed. MODERATE	Patients educated about the signs and symptoms of preterm labor. "Patients received individual instruction from both physicians and nurses regarding the signs and symptoms of preterm labor" HIGH	F/U care included: weekly appointments with physicians, frequent telephone calls from home infusion therapy nurse-clinician and physician's offices. MODERATE	Bed rest recommended when there was an increase in uterine contractions. MODERATE	Standard nonpharmacologic interventions, such as bed rest and oral hydration, were a part of the therapeutic regimen. MODERATE	MODERATE

Lam (1988) ¹⁶	Not reported INSUFFICIENT DATA TO MAKE RATING	Uterine activity was monitored at least twice daily and data was transmitted to study center. HIGH	Weekly followup home visits were carried out by perinatal nurses. HIGH	Not reported INSUFFICIENT DATA TO MAKE RATING	Not reported INSUFFICIENT DATA TO MAKE RATING	Patients were instructed to remain in bed, but were permitted bathroom privileges. MODERATE	Patients noted their perceived uterine activity on daily preterm labor logs HIGH	HIGH
RCT: randomized controlled trial; SQ: subcutaneous								

Table F14. Studies that reported pump-related outcomes (Key Question 6)

Outcome	First Author (year)	Study Design (n=sample size)	Mean Maternal Age (years)	Mean GA (weeks)*	Comparator(s)	Results		
						SQ terbutaline pump: % (n/N)	Comparison: % (n/N)	OR (95% CI)
Dislodgment	Adkins (1993) ¹⁵	Case Series (n=51)	31.0 ± 4.0	29.1 ± 3.6 (T)	No comparator	2.0% (1/51)	N/A	(exact central CI, 0.5%, 10%)
Missed Doses	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Overdose	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Other:								
• Infusion site infection	Lam (1988) ¹⁶	Case Series (n=9)	NR	29.6 ± 3.7 (T)	No comparator	0% (0/9)	N/A	N/A
• Local pain	Wenstrom (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	13.3% (2/15)	C ₁ :17% (2/12) C ₂ : 0% (0/15)	0.77 (0.09, 6.45) 5.74 (0.25, 130.38)
• Local skin irritation	Wenstrom (1997) ²	RCT (n=42)	26.2 ± 5.3	30.4 ± 2.3 (T)	Placebo (C ₁) Oral terbutaline (C ₂)	6.7% (1/15)	C ₁ : 0% (0/12) C ₂ : 0% (0/15)	2.59 (0.10, 69.34) 3.21 (0.12, 85.21)
• Pump malfunction/ Mechanical failures and complications	Lam (1988) ¹⁶ Adkins (1993) ¹⁵	Case Series (n=9) Case Series (n=51)	NR 31.0 ± 4.0	29.6 ± 3.7 (T) 29.1 ± 3.6 (T)	No comparator No comparator	0% (0/9) 2.0% (1/51)	N/A N/A	N/A (exact central CI, 0.5%, 10%)

CI: confidence interval; GA: gestational age; N/A: not applicable; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; SQ: subcutaneous

* Either at preterm labor (indicated by P) or at start of subcutaneous terbutaline therapy (indicated by T). If study population stated RPTL as an inclusion criterion, then this is the gestational age at the episode of RPTL.

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