EVIDENCE-BASED PRACTICE SUMMARY FORM
Date: September 23, 2011
Reviewer: Brandon D Rachal
Clinical Question: *In children with persistent asthma (P) what is the effect of a combination inhaled long acting beta agonist and inhaled corticosteroid (I) in comparison to inhaled corticosteroids alone (c) on asthma control measured by morning peak expiratory flow [PEF] volumes (O) over a 12 week period (T)?*

CITATION	POPULATION	STUDY DESIGN	RESULTS	VALIDITY THREATS	IMPLICATIONS	QOE
Tal, et al., 2002	**286 Total** children with asthma, minimum 6 months **Exp: 148** Boys: 90 Girls: 58 **Control: 138** Boys: 87 Girls: 51 Age Range: 4-17 Mean Age: 11 years *On inhaled corticosteroids (ICS) at constant dose for at least 6 weeks prior to study* *FEV_1 40-90% of predicted value* *Ability to demonstrate correct use of inhaler* Exclusions: Known hypersensitivity to study medication	12 week (longitudinal), prospective, double blind, double dummy randomized, parallel-group study IV: **inhaled combination budesonide/formoterol** *Level 1*: inhaled combination budesonide/formoterol *Level 2:* inhaled budesonide DV: morning PEF **Methods:** Patients were randomized 1:1 to receive 12 weeks inhaled treatment with either budesonide/ formoterol two inhalations twice daily or an equivalent dose of budesonide, two inhalations twice daily **Measurements:** PEF in L/min using a Mini-Wright peak flow meter recorded by patients via diary cards **Statistical Analysis:** ITT ANOVA	<table><tr><th></th><th>AX</th><th>PX</th><th>Mean Difference</th></tr><tr><td>Exp</td><td>257</td><td>280</td><td>23.1</td></tr><tr><td>Control</td><td>274</td><td>285</td><td>11.1</td></tr></table> *p=<0.001* ***Difference between two groups 12 L/min***	Does not specify a value for asthma symptom score as an inclusion criterion Patients with very low or zero asthma symptom score were eligible; mean baseline asthma symptom score was 0.58 (0-4.8) in control group and 0.67 (0-5.8) in experimental group indicating study population had low to mild asthma Small number of patients in the age range 4-8 Overall adherence to treatment good; does not represent general asthma population	Statistically significant: **Y** Direction of findings: **Expected** Magnitude of difference: **Medium** *Based on this 1 study I **recommend** the inhaled combination beta agonist and corticosteroids (I) over inhaled corticosteroids alone (C).*	High

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CITATION	POPULATION	STUDY DESIGN	RESULTS	VALIDITY THREATS	IMPLICATIONS	QOE
Pohunek, Kuna, & Boeck, 2006	**630 Total** children with asthma **Exp_1: 216** Males: 140 Females: 76 **Control: 213** Males: 147 Females: 66 Age Range: 4-11 Mean Age: 8 years *On ICS at constant dose for at least 3 months prior to study* *PEF ≥50% predicted value* *Ability to demonstrate correct use of inhaler and peak flow meter* *Total asthma symptom score of at least 1 (0-6) on a minimum of 4 of 7 days prior to study* Exclusions: Known hypersensitivity to study medication	12 week (longitudinal), prospective, double blind, double dummy, randomized parallel-group, active-controlled study IV: **inhaled combination budesonide/formoterol** *Level 1*: inhaled budesonide/formoterol *Level 2:* inhaled budesonide DV: morning PEF **Methods:** Patients were randomized to one of three treatment groups. Combination budesonide/ formoterol, budesonide and formoterol separately, budesonide alone **Measurements:** PEF in L/min using a Mini-Wright peak flow meter recorded by patients or family via diary cards **Statistical Analysis:** ITT ANOVA	<table><tr><th></th><th>AX</th><th>PX</th><th>Mean Difference</th></tr><tr><td>Exp_1</td><td>212</td><td>241</td><td>**30**</td></tr><tr><td>Control</td><td>216</td><td>235</td><td>**19**</td></tr></table> *p=<0.001* ***Difference between two groups 10.9 L/min***	Significant proportion of the population (12%) were aged 4-5 Although symptomatic asthma symptom score required for inclusion, mean baseline was only 0.63 (0-6) indicating low to mild asthma	Statistically significant: **Y** Direction of findings: **Expected** Magnitude of difference: **Medium** *Based on this 1 study I **recommend** the inhaled combination beta agonist and corticosteroids (I) over inhaled corticosteroids alone (C).*	High

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CITATION	POPULATION	STUDY DESIGN	RESULTS	VALIDITY THREATS	IMPLICATIONS	QOE
Morice, Peterson, Beckman, & Zuzana, 2008	**622 Total** children with asthma at least 6 months **Exp_1: 212** Males: 141 Females: 71 **Control: 207** Males: 137 Females: 70 Age Range: 6-11 Mean Age: 9 years *On ICS at constant dose for at least 30days prior to study* *PEF ≥50% predicted value* *Ability to demonstrate correct use of inhaler and peak flow meter* *Total asthma symptom score of at least 1 (0-6) on a minimum of 4 of 7 days prior to study* Exclusions: Known hypersensitivity to study medication	12 week (longitudinal), prospective, phase III, double blind, double dummy, randomized parallel-group study IV: **inhaled combination budesonide/formoterol** *Level 1*: inhaled budesonide/formoterol *Level 2:* inhaled budesonide DV: morning PEF **Methods:** Patients were randomized to one of three treatment groups. Combination budesonide/ formoterol (DPI), combination budesonide/ formoterol (pMDI), budesonide alone **Measurements:** PEF in L/min using a Mini-Wright peak flow meter **Statistical Analysis:** ITT ANOVA	<table><tr><th></th><th>AX</th><th>PX</th><th>Mean Difference</th></tr><tr><td>Exp_1</td><td>221</td><td>251</td><td>**30.2**</td></tr><tr><td>Control</td><td>224</td><td>244</td><td>**19.9**</td></tr></table> *p=<0.001* ***Difference between two groups 10.3***	Significant proportion of the population (12%) were aged 4-5 Although symptomatic asthma symptom score required for inclusion, mean baseline was only 1.6 indicating to mild to moderate asthma	Statistically significant: **Y** Direction of findings: **Expected** Magnitude of difference: **Medium** *Based on this 1 study I **recommend** the inhaled combination beta agonist and corticosteroids (I) over inhaled corticosteroids alone (C).*	High