

Experience IN BENEFIT RISK REFERRAL PROCEDURE – combined Hormonal contraceptives

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CHCs – involvement in benefit/risk referral

- On request of French Agency due to concerns about VTE risk with certain CHCs
- Invited to Ad hoc expert group meeting
- Contributed to Written Consultation on the best way to present risk

Opportunity to contribute Women's Health perspective

- Women who take CHCs are healthy not patients
- They need to be better informed about their risk of VTE and ATE when they receive CHCs prescription
- These women may not interact regularly with health professionals, unlike chronic disease patients
- Women have to understand their risk better
- The regulatory information has to clearly communicate the benefit/risk balance to be better understood by lay person.
- Checklist for doctors to be balanced with a checklist for women
- Women themselves to be involved in drawing up check list

Women not fully aware of their risk factors

- Smoking, age, hypertension, diabetes, obesity, family history are main risk factors
- Risk needs to be explained using understandable language
- Put into context: compare with smoking

Consultation - how to represent risk

- Graphical presentation of VTE risk
 - Text, table, bar chart, piling plate
- Bar chart was preferred for SmPC
- Simple table with incidence rates of ATE in PL
- Health professional found pregnancy as comparator helpful, women found this confusing
- Women preferred comparison with smoking