



European
AIDS Treatment
Group

Risk communication, transparency

- What do patients say
- What do patients understand

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The slides reflect the speakers personal opinion

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Carcinogenicity of red & processed meat

WHO communicates per 50g daily intake of

- ✧ Red meat (mammalian muscle meat, including beef, veal, pork, lamb, mutton, horse, and goat)
 - ✧ Processed meat (hot dogs (frankfurters), ham, sausages, corned beef, and biltong or beef jerky)
- intestinal cancer risk will increase by 20%**

Most people and press understood that 20 people out of 100 fulfilling the criteria would develop intestinal cancer.

However

- ✧ 5% of people not eating sausage or meat will develop intestinal cancer, and
- ✧ 6% of people eating sausage or meat will do the same

Lesson learned

- ✧ 20% intestinal cancer increase by sausage sells better than 1%
- ✧ Public outcry in Switzerland: We want our sausage, our bacon, where's the fun without?
- ✧ WHO credibility questioned

Thromboembolic events & oral contraceptives

UK press reports 2011

- ✧ Use of 3rd generation oral contraceptives increases thromboembolic events by 100%
- ✧ Many women stop taking contraceptives, unknown number of unwanted pregnancies
- ✧ 14'000 abortions

However

- ✧ 1 out of 7 women using 2nd generation oral contraceptives will suffer from thromboembolic events, and
- ✧ 2 out of 7 women using 3rd generation oral contraceptives will do the same
- ✧ Older contraceptives have other unacceptable side effects

Thromboembolic events & oral contraceptives

Messy impact in Europe

- ✧ Very thorough communication by EMA on website
 - ✧ Missed opportunity for public hearing – legal basis?
 - ✧ Thorough risk minimisation measures recommended, not easy to understand
 - ✧ Danish NCA continues to recommend 2nd generation prescription over 3rd and 4th, and says many women preferring the newer – confusing message
 - ✧ Irish agency says overall side effects 3rd generation is marginally better than 2nd and cycle control is also better
- ✧ Swissmedic communication in line with EMA, very thorough information on website, includes detailed risk minimisation measures
 - ✧ Information not understandable for lay audience

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Background

- ✧ Communication on medicines have changed
- ✧ Open discussion between PCWP & HCPWP with communication experts to provide indicative lines of research supporting future advancements

Previous events

- ✧ EMA risk communication workshop 2014
ema.europa.eu/docs/en_GB/document_library/Report/2014/12/WC500178511.pdf
- ✧ Workshop on risk minimisation measures 2015
ema.europa.eu/docs/en_GB/document_library/Report/2015/12/WC500198810.pdf

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Surfacing issues

✧ ***Challenges for production***

- ✧ Need for rapid reactions
- ✧ Varying levels of literacy
- ✧ Different languages and cultural variations to be taken into account

✧ ***Opportunities and actions for production***

- ✧ Quality over quantity
- ✧ Transparency on source and unknowns
- ✧ Balanced, regularly updated summaries
- ✧ Appealing & individualised information
- ✧ Readability testing
- ✧ Culturally sensitive translations
- ✧ Changes to PL to increase use
- ✧ Side effects and how to manage them

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Surfacing issues

✧ *Challenges for dissemination*

- ✧ Fragmentation in access to information
- ✧ Maintenance of trust in regulators
- ✧ Lack of resources at key organisations

✧ *Opportunities and actions for dissemination*

- ✧ Structures strategy
- ✧ Dissemination is everyone's task
- ✧ A single portal
- ✧ Multiplatform use of EMA website
- ✧ EMA website optimisation
- ✧ Search engine and new media optimisation
- ✧ Alert system for new & important changes
- ✧ Clear differentiation of regulator information
- ✧ Links from stakeholder webpages
- ✧ Link to EMA on medicine box

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Using information – obstacles at point of care

✧ *Challenges for use*

- ✧ Preparing patients and HCP for share decision
- ✧ Information overload
- ✧ Time scarcity
- ✧ Health literacy

✧ *Opportunities and actions for use*

- ✧ Education on hot topics
- ✧ Explanation of regulators role
- ✧ Large role for organisations
- ✧ Use of patient networks and blogs
- ✧ Increased transparency of decisions

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Areas for improvement and further research

- ✧ Significant advances, creating greater transparency promoting shared, informed decision making
- ✧ Improving quality of information & providing summaries of key information still on agenda due to changing technologies & information overload – finding the right facts more difficult than ever
- ✧ Search engine optimisation to improve EMA visibility on Google – industry & Wikipedia results rank better
- ✧ Indicator to evaluate information impact and how it affects medicines use would be valuable
- ✧ Smartphone apps have potential to gather & disseminate information
- ✧ Initiatives such as the FDA users guide on R & B communication could be useful in Europe - *indeed*
- ✧ Improvements to the PL – graphics, effects table, QR codes, PL as educational tool
- ✧ **Communication advisory boards** – *Yes please, when?*

Personal thoughts

Recognising advances and improvements, the considerable effort & progress made in 20 years

- ✧ We spend too much time on trying to find the rational comprehensive magic bullet
- ✧ Be a little more "hands-on" and better use what is already here
- ✧ **Educate & teach risk literacy – sapere aude**
- ✧ Drug facts box by Schwartz & Woloshin – there is currently nothing better – published 2009 – what are we waiting for?
- ✧ In Switzerland, a private health insurance company starts using the tool & publishing good clips (PSA screening, mammography, colonoscopy)
 - ✧ Suboptimal, perceived as economically interested party trying to limit access to approved interventions
 - ✧ Authorities & payers should collaborate and use the tool
- ✧ Puzzled by national competent authorities not saying the same online after having contributed to the same decision making process at EMA
- ✧ Reaching out to WHO much needed, they seem far behind
- ✧ Need to move on with PL – most important & most visible

Thanks

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