

IVRS/IWRS and the patient and HCP

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16th June 2011

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Agenda

- What is IVRS/IWRS
- Experience and Expectations
- Current issues
- Next Steps

IVRS/IWRS what can they do?

How does this affect the patient?
How does this affect the healthcare provider?

History

- Interactive Voice Response System (IVRS)
- Interactive Web Response System (IWRS)
- In existence 15 or more years
- Increasingly more complex
- Use to control Expiry Dates
- Medication Pooling

Solutions – just one of the many for industry



- Types of things they can do
 - Patient enrolment, screening, randomisation
 - Titration
 - Expiry updates
 - Blind breaking
 - Drug tracking
 - Recall

Solutions – could be solution for others

- Un-blinding
 - Envelopes not sent
 - Envelopes not readily available
 - May affect treatment

- Expiry date handling
 - Update label application
 - Poor procedure
 - Lack of documentation
 - Packs not clear after re-labelling.

Potential Issues



Issues

Expiry Date removal:

- What information is given to the patient?
 - Document with Expiry date?
 - Label on the medication?
 - Nothing?
 - Overall Statement?
- Staff at the site:
 - Documentation with the expiry on?
 - Expiry on the medication packs?

Use of the system to control Expiry – Rationale considered by inspectors currently

- Phase I setting
- Where patient is an in-patient
- When a pharmacist includes a label on the packaging with the Expiry date.

Issues (2)

Medication Pooling

- Same medication across protocols
- Regulator would expect that it is clear on the pack which protocol this was to be used in.

Issues for site:

- Confusion between protocols
- Confusion in drug accountability

Current status

Expiry Date

- Reflection paper will be released to facilitate comments from all sectors
- Discussion with Industry in September
- Continued discussion with PCWP and HCP colleagues
- Final paper on expectations of the regulator on IVRS/IWRS

Any Questions? Time for discussion.



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