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**Document: THE OPIOID DEPENDENCE EPIDEMIC: EDUCATIONAL AND PACKAGING DEFICIENCIES – WITH AN ANALYSIS AROUND CHILD RESISTANT PACKAGING**

To attempt to write regarding opioid substitution issues raises difficult and potentially controversial thoughts and the subject requires a review of statistics that many of us would rather avoid. As responsible for influencing the design of pharmaceutical packaging for child resistance, however one feels obligated to conduct this overview without commercial bias and taking into consideration current opioid packaging.

Opioid dependence is increasing both in the UK, Europe and globally on a scale that some regard as epidemic [1]. It is clearly apparent from data that the current crisis hasn't developed overnight and with respect, an attempt has been made to raise awareness of the looming crisis. There are guidelines issued by many national and regional bodies as to how opioids should be prescribed, dispensed and administered and particular structure has long since been considered essential to support effective weaning treatments. Whilst the available information is extensive the issue continues to grow and we note two particular areas of concern; gaps in the education needed to raise awareness at all levels of the dangers of opioids in the home, and secondly; a review of the **pharmaceutical closures** and packaging used for dispensing and storing these drugs.

Methadone is amongst the opiate products prescribed to effectively relieve suffering and pain during serious illness or disease, it is also used commonly to provide the foundation for dependency-weaning programs for those who have become dependent on opioids. Evidence proves that it is in these situations where the greatest danger lies of accidental child ingestion (medicine poisoning) [2].

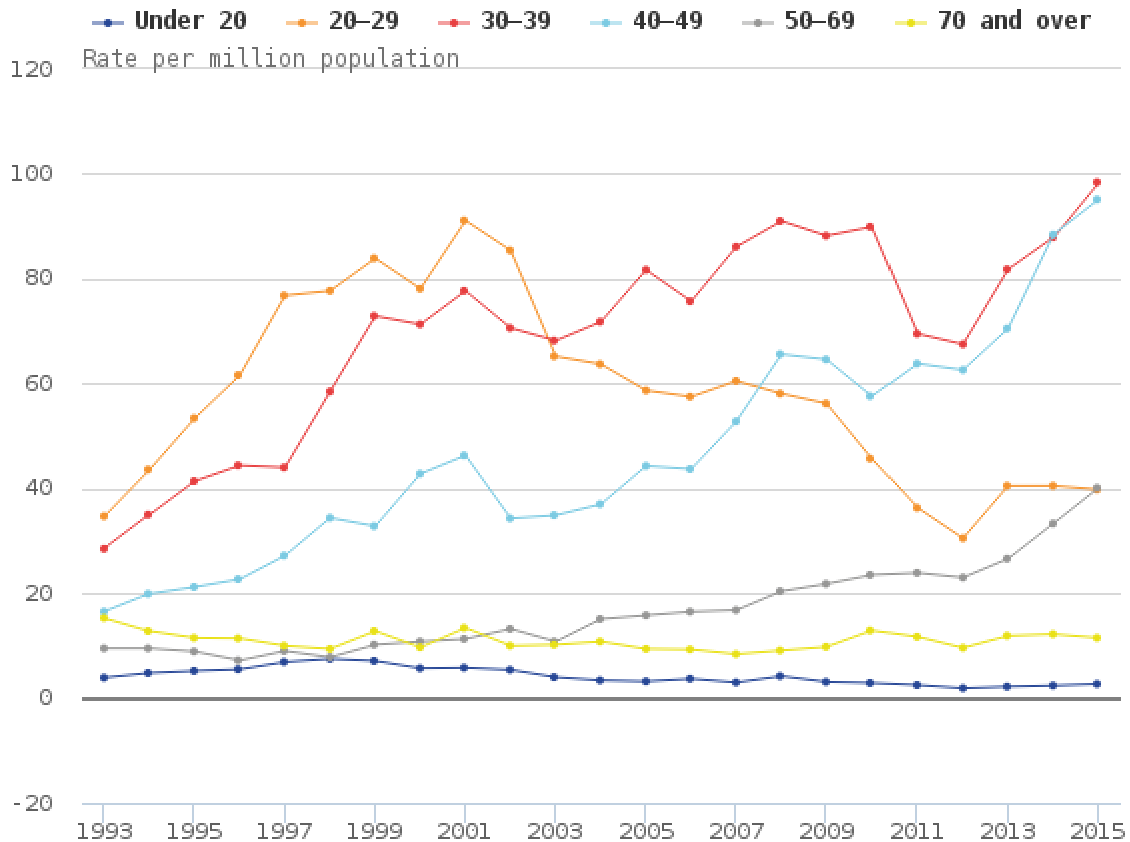
No one would underestimate the value of substitutes such as methadone and buprenorphine, they are essential elements in the treatment of opioid dependent patients and there are many testimonies to their efficacy when managed and controlled. The most touching accounts give insight into complete recovery from seemingly irrecoverable situations, to stable relationships and happy family life. Such revelations are rays of light in what is becoming an increasingly dark picture in other spheres.

An opioid dependence can start imperceivably, indeed it is not conceivable that anyone would set out to become dependent on narcotics. Whilst cases of deliberate abuse exist it is important to understand that many of today's increasing number of dependents are facing the trauma of the condition, and no doubt a degree of stigmatism attached, are suffering through no fault of their own. One of the saddest aspects to this situation are the innocent new born babes entering the world with an inherited dependence. Opioid abuse is a blight affecting humanity, abuse in the adult population can have an adverse effect on children in several ways;

- Evidence supports that uncontrolled use of opioid medicines leads to reduced awareness, commonly referred to in the case of accidental ingestion as diminished responsibility
- The presence of opioids in the home increases the risk for accidental paediatric poisoning. Children aged 5 years and younger are the most at risk with effects of breathing difficulties, coma, and mortality.
- Neonatal abstinence syndrome (a result of opioid withdrawal) endangers newborn babes with numerous medical complications, including seizures.

Accidental medicine ingestions are traumatic and change lives of all involved. The risk taken in using non-compliant bottles is significant and standards have been created with a view to protecting the profession as well as the consumer and insistence on approved packaging is crucial to the protection of young life.

**Age-specific mortality rates for deaths related to drug misuse, deaths registered in 1993 to 2015 in England and Wales** (source: ONS)




Effective opioid dependency programs enable patients to achieve stability, they reduce drug use, crime, and improves health. However regular review is essential to ensure the patient continues to derive benefit. Prescribers and pharmacists receive little training on substance use disorders [5]. With improved understanding they may be better able to prevent, recognise and care for patients suffering from this condition. Training could include both information as well as direct skill development in assessment and treatment of opioid addiction.

Such knowledge could then be shared and emphasised to sufferers during the treatment programs and information generally disseminated about the care of these drugs, how they are stored, as well as the obvious warnings of continued misuse and opioid addiction or substance abuse. Until a more united approach to education is adopted it is unlikely that the statistics are going to improve, and our ethical and moral responsibility, especially in paediatric terms, will remain inadequate.

Dispensing opioid substitutes such as methadone presents a daily challenge and recognition is due to the dispensing profession who administrate this significant responsibility with such care and consideration. One has observed the procedure of dispensing methadone many times and can witness to the often unpleasant situations pharmacists encounter in their course of duty. There are some effective 'shared care' schemes operating in the UK[3] which support the pharmacist, promoting a coordinated approach between GP's, pharmacists, social services and specialist support groups and clinics.

However effective the support structure for these opioid dependency programs may be, the final stage of the process is the physical dispensing and dosage of the drug and this will take place in one

of two forms; supervised or unsupervised. GP's are empowered to dictate which method should be adopted although it is not legally binding on the dispenser to follow this instruction. In supervised cases the dose is taken within the pharmacy or clinic under supervision and the patients record is duly updated after each dose. Unsupervised dosing is also permitted where necessary and this allows the patient to take the product away from the protection of the dispensary into their own, uncontrolled environment.

The container used for this activity is *critically important*. Whilst our packaging meets the UK (MHRA requirements for Europe) and the US andd is compliant with both the ISO or US Standard for medicine **containers and closures in pharmaceuticals** (EN ISO8317 for the UK and 16CFR1700.20 for the U.S.), there is virtually no effort made to enforce these standards on a day-to-day basis. In the absence of such enforcement an array of plastic and glass bottles are being used, some are good and some are not good. Whilst non-compliant packaging may have crept in unobserved, so also has the risk of serious repercussion if these products give place to an accidental ingestion. We do not suggest that poor packaging is accountable for these tragic deaths, we do suggest most strongly however that the increasing volume of opioids in circulation present a major risk to children who find themselves in proximity to the danger. Therefore the packaging used and the education provided are critical to child safety.

To a casual observer and to the profession it is impossible to identify if a bottle and cap are approved to the current Standard. The assumption that if a child resistant cap 'clicks' then it is child safe is misguided, screw cap packaging is torque dependent and for a package to be truly compliant, the bottle and the cap must be tested *together* under specific conditions and to a fixed protocol. Successful packs that emerge are certified child resistant but never child *safe* – an important difference! The danger of making assumptions regarding what is safe in terms of packaging is that should an accidental ingestion or poisoning occur, then the container and cap become one of the key focal points that the authorities will investigate.

There are products in existence that have been specifically tested for opioid substitute methadone, Unopac [4] for example, a packaging brand found widely throughout the UK has been developed to deliver ultimate compliance. These products have been tested beyond the mandatory child safe testing protocol to embrace also stability testing, to ensure methadone is contained safely. The manufacturing process and the materials used for containing any medicine products are both very important factors in ensuring against leakage and the cap should be designed specifically to fit the bottle neck.

**Conclusion**

It is totally unrealistic to expect pharmacists and dispensary technicians to have an in-depth knowledge of the bottles and child resistant caps used for dispensing liquid and solid dose medicines. Nevertheless, they are responsible to use approved packaging and it is completely within their rights to ask for supporting evidence as they see fit, indeed it is good practice to do so. If an ingestion occurs the container and cap will be scrutinised, as will the processes of dispensing and any storage of dispensed medicine. Having a copy of the certification for your child resistant packaging is not a legal requirement but it costs nothing to obtain. If you are involved in dispensing methadone it is also wise to obtain a declaration of conformance for stability.

[1] asam.org

[2] poison.org

[3] awp.nhs.uk

[4] originltd.com

[5] jhsph.edu