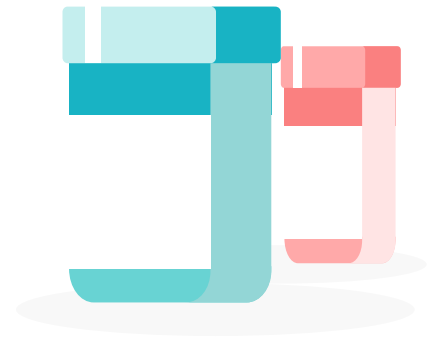




# AcetaSAFE

Developing a QR code on Acetaminophen  
OTC and prescription medications



# AcetaSAFE Team Members



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# Outline

FDA Safe Use Initiative

1



2



Issues to Address

3



AcetaSAFE Solution

4



Market Size & Impact

5



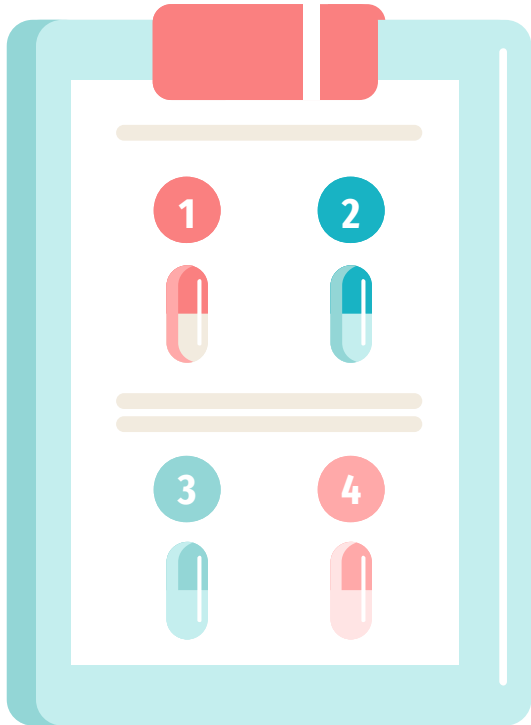
Comparison to other QR Codes

6



Future of AcetaSAFE

# FDA Safe Use Initiative



## Acetaminophen:

Improving prescription container labels for Acetaminophen-containing medicine

## Recommendations:

1. Identify when prescription pain relievers contain Acetaminophen
2. Compare the active ingredients in their prescription to over-the-counter labels
3. Take action to avoid taking two medications with Acetaminophen

# Acetaminophen: A Silent Killer

## Purpose:

To measure knowledge of Acetaminophen dosing

## Conclusion:

Patients have low levels of Acetaminophen knowledge which puts them at risk of an overdose

1

### Results:

80% were unable to determine that the following drugs contain Acetaminophen:

**Norco® (hydrocodone/ APAP)**  
**Vicodin®(hydrocodone/APAP)**  
**Percocet®(oxycodone/ APAP)**

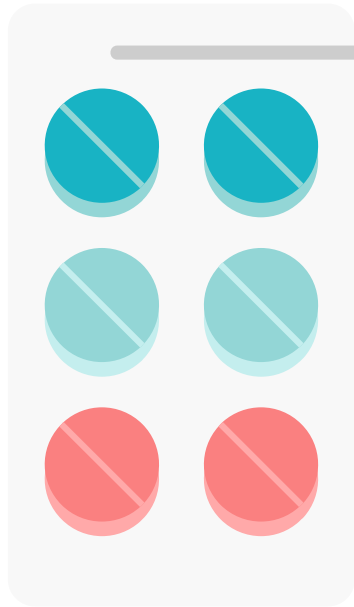
2

### Results:

Only 35% of the study's participants knew that Acetaminophen could cause liver damage



# Issues to Address



1

## Patient Education

Viewed as a safe drug since it is also an OTC

2

## Toxicity

Detrimental long term effects to the liver

3

## Expenses

Costs the US Healthcare System billions of dollars annually



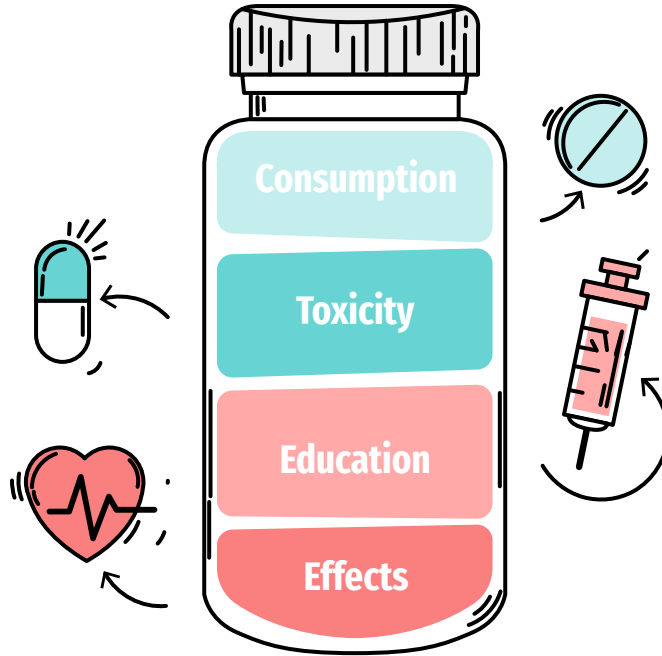
# Why Acetaminophen?

## Consumption

- Active ingredient in more than **600** drug products
- Over **60 million** use weekly
- **7 in 10** use OTCs to treat cold & flu symptoms a year, increase in use with COVID

## Toxicity

- **56,000** ED visits
- **10,000** hospitalizations
- **500** deaths a year



## Patient Education

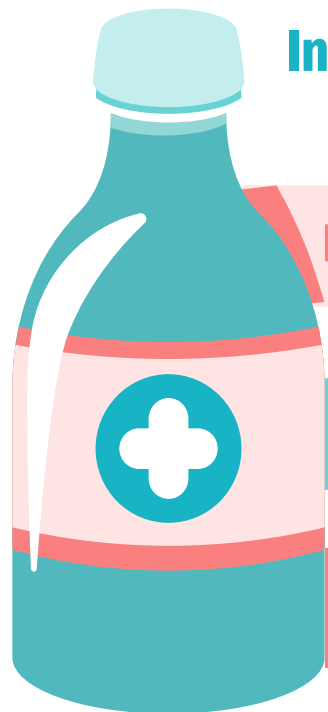
- **50%** of Emergency Department (ED) visits are unintentional overdosing
- **100,000** US Poison Control Center calls a year

## Long Term Effects

- Most common cause of liver transplantation in US
- **50%** of ED cases lead to Acute Liver Injury



# Solution: AcetaSAFE



**Initiate:** Usage of a QR code in order to safely use & learn about Acetaminophen

## Patient Education

Give patients an interactive platform to learn

## Toxicity

Awareness of liver damage and dosage

## Cost

Decrease the number of Acetaminophen induced hepatotoxicity hospitalizations



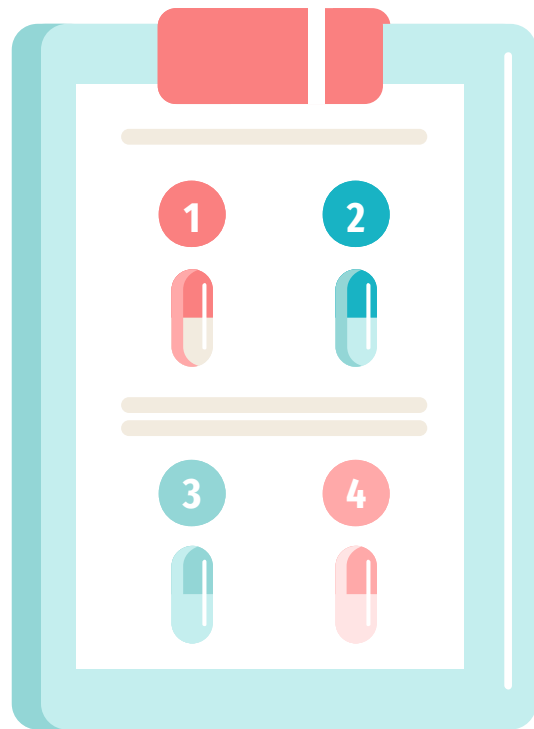


# AcetaSAFE's Objectives

**AcetaSAFE** fulfills the **FDA Safe Use Initiative** and provides more by:

1. Indication of Acetaminophen's use
2. Provision of Dosing Strategy
3. Precautions and Warnings
4. Side effects and Reporting

**AcetaSAFE** is associated with **ALL prescription** medications and **ALL OTC products** containing Acetaminophen



# International Serious Adverse Events Consortium (iSAEC)

## Integration

Aid from the consortium to adopt the QR Code on their bottle of Acetaminophen as well as maintain the information

## Incentive

To reduce acetaminophen related adverse event and decrease healthcare burden seen with overdoses

## Objective

Analysis of genetic variation with risk of drug-induced serious adverse events



## Support

Abbott, GlaxoSmithKline, Johnson & Johnson, Pfizer, Roche, Sanofi-Aventis, Novartis, Takeda, and Daiichi Sankyo

## Outcome

Improving product development & decision making to prevent specific serious adverse events



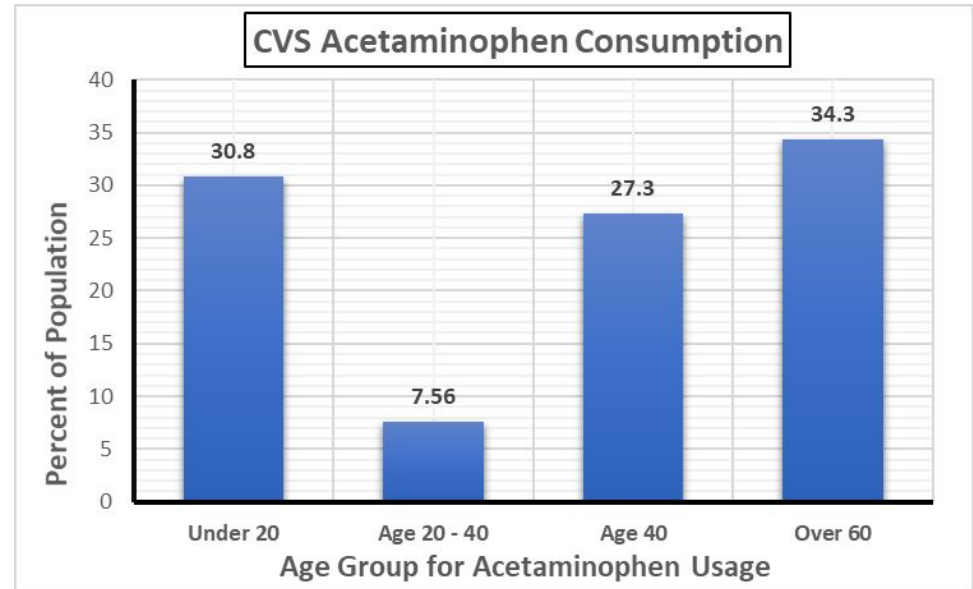
# US Population Market Size



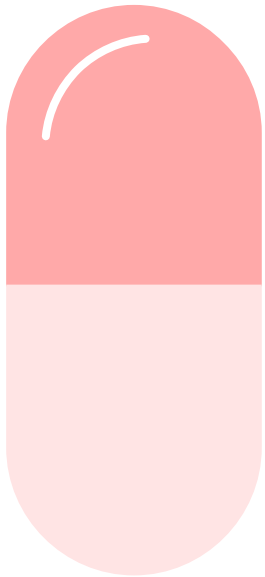
**85%** of Adult Americans own a Smartphone, thus have QR Code accessibility



**23%** of U.S adults use an Acetaminophen containing medicine each week



# US Economic Market Impact



Acetaminophen overdose costs the US healthcare system \$1.06 billion annually

Acetaminophen overdose accounts for 20% of liver transplants, & the US avg cost for liver transplantation is \$163,438

Avg cost for N-acetylcysteine IV administration is \$7607.82 per patient



# Advantages of QR Codes



## Accessibility & Aesthetics

- ✗ Bulky packages
- ✗ Long paper inserts with small font
- ✓ QR Codes are 2D

## Multimedia Content

- ✗ Complicated medical text
- ✓ Layman's terms
- ✓ Tailored learning with various formats

## Informational Updates

- ✗ Remove & reprint outdated media info
- ✓ Instant Dynamic updates
- ✓ Sustainable

## Promote Education

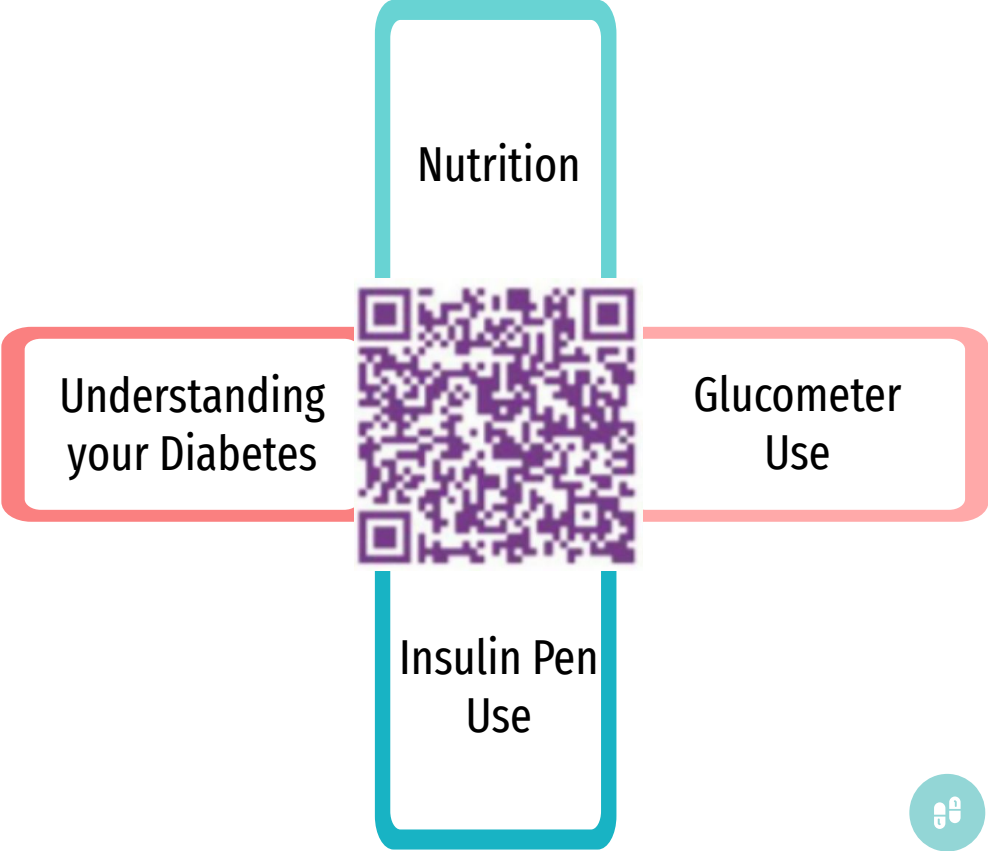
- ✗ Professional exclusive knowledge
- ✓ Influence communication
- ✓ Increase patient awareness



# Diabetes Patient Education

During the COVID-19 pandemic, Saint Francis Hospital in New England implemented QR codes to provide “hands free” patient education on diabetes.

<p><b>Inpatient Glycemic Initiative Diabetes Education</b></p> <p>Created by: Diabetes &amp; Endocrinology Center</p> <p>The videos included in these guides are meant to give you a comprehensive education on diabetes self-management*. Scan the below QR codes with your smartphone in order to view the videos.</p> <p><b>English Version</b></p> 	<p><b>Iniciativa glucémica de educación sobre la diabetes para el paciente internado</b></p> <p>Creado por: Centro de Diabetes y Endocrinología</p> <p>Los videos incluidos en estas guías tienen por objeto brindarle una educación integral sobre el autocontrol de la diabetes*. Escanee los siguientes códigos QR con su teléfono inteligente para ver los videos.</p> <p><b>Versión en español</b></p> 
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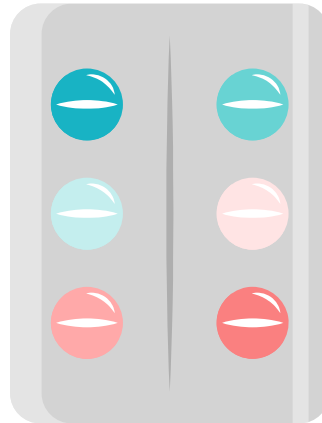
# Track and Trace

Allows for tracking of a drug, medical device or vaccine from the time it leaves the warehouse to the its final destination like a drugstore or pharmacy. This system is adopted internationally and is used in almost every market in the world.

Gives drugs, medical devices, and vaccines a unique identify allowing it to be tracked 24/7

Unique code allows for:

- Fast recall management
- Brand protection
- Quick & efficient product returns



# European Medical Agency (EMA)

The European Medical Agency (EMA) indicated the importance of a centralized procedure to use mobile scanning & quick response (QR) as a way to provide information to patients & healthcare professionals.

Implementation of QR to allow for identification of medical products and verification of their authenticity

Pharmaceutical Company provisions:

- Drug manufacturing information
- Optional additional instructions regarding drug administration



# Acetaminophen Safety



What can I  
use this  
for?

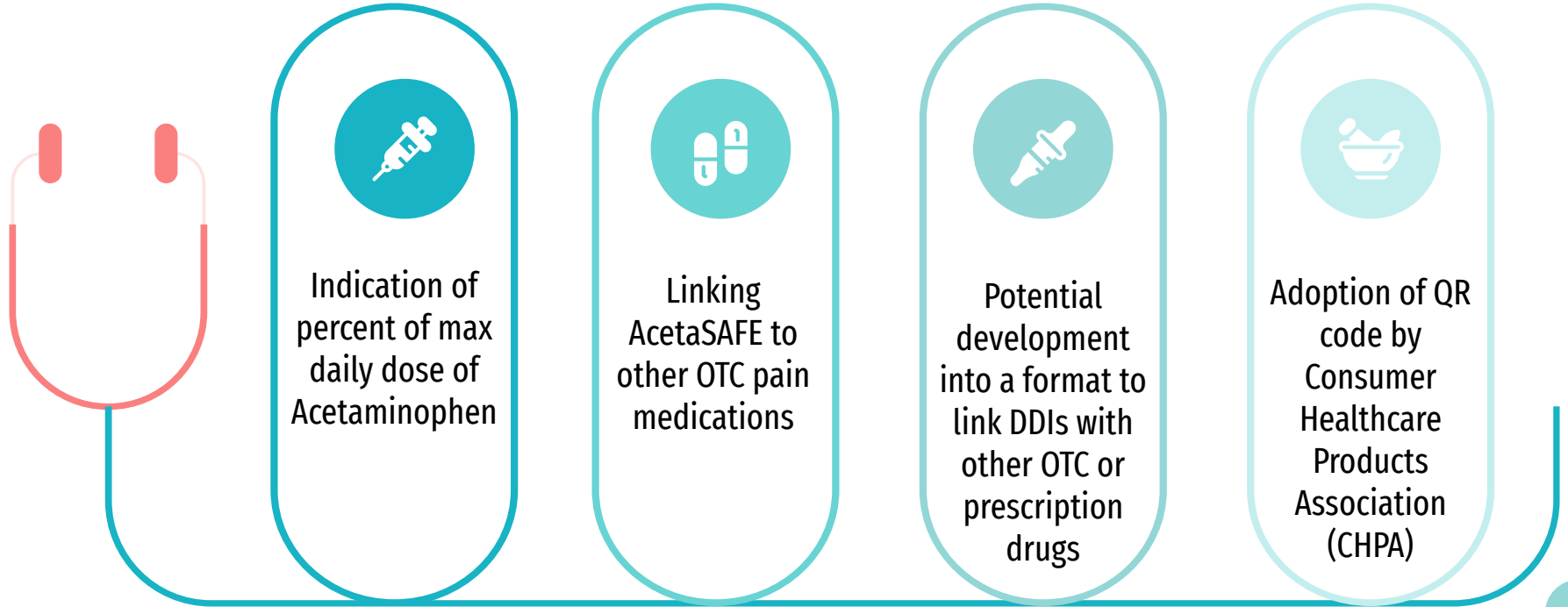
How and  
how much  
can I take?

How can I be  
cautious  
taking it?

Side  
Effects and  
Reporting



# Future Integration of AcetaSAFE



Indication of percent of max daily dose of Acetaminophen



Linking AcetaSAFE to other OTC pain medications



Potential development into a format to link DDIs with other OTC or prescription drugs



Adoption of QR code by Consumer Healthcare Products Association (CHPA)

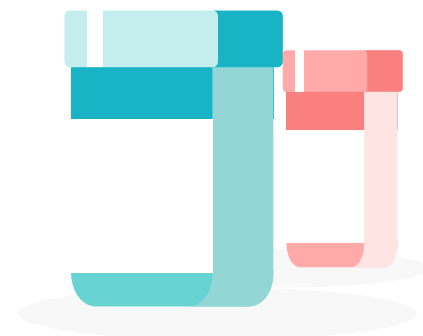




# Feel Safe with AcetaSAFE



## Acknowledgements to our wonderful mentors:

- **James Polli, PhD M-CERSI**
  - **Erin Wood, PhD CDER/OPQ**
  - **Michael Folkendt, CDER/OPQ/OPRO**
  - **Omnia A. Ismaiel, PhD DARS/OCP/OTS/CDER**
- 

# References:

## FDA Safe Use Initiative:

- <https://www.fda.gov/drugs/safe-use-initiative/safe-use-initiative-current-projects#acetaminophen>
- <https://www.fda.gov/drugs/drug-safety-and-availability/safe-use-initiative>

## Silent Killer:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5225146/pdf/JCTH-4-281.pdf>
- [https://www.sciencedirect.com/science/article/pii/S1544319115301321?casa\\_token=xZNLGFsrmjoAAAAA:McZK3M3VOHUEeBYDtexi6K14Nht5JJtMvcXjp1MqvxlZSDaK-bMpf-1AzfWRhnN5-D1aP2xiQY0](https://www.sciencedirect.com/science/article/pii/S1544319115301321?casa_token=xZNLGFsrmjoAAAAA:McZK3M3VOHUEeBYDtexi6K14Nht5JJtMvcXjp1MqvxlZSDaK-bMpf-1AzfWRhnN5-D1aP2xiQY0)

## AcetaSAFE's Objectives:

- <https://www.fda.gov/drugs/safe-use-initiative/safe-use-initiative-current-projects>
- <https://link.springer.com/content/pdf/10.1007/s11606-012-2096-3.pdf>

## Advantages of QR Codes:

- <https://journals.sagepub.com/doi/full/10.1177/1847979018812323>
- <https://scanova.io/blog/qr-codes-in-pharmaceutical-industry/>
- <https://content.iospress.com/articles/technology-and-health-care/thc00778>
- [https://journals.sagepub.com/doi/10.1177/0897190019885245?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%20%20pubmed](https://journals.sagepub.com/doi/10.1177/0897190019885245?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed)

## iSAEC:

- <https://www.nature.com/articles/nrd4441.pdf>

## Why Acetaminophen:

- <https://oce-ovid-com.proxy-hs.researchport.umd.edu/article/00006205-201911000-00010/PDF>
- <https://www.ncbi.nlm.nih.gov/books/NBK441917/>
- <https://pubmed-ncbi-nlm-nih-gov.proxy-hs.researchport.umd.edu/29605069/>
- <https://www1.racgp.org.au/ajgp/2019/april/paracetamol-allergy-in-clinical-practice>
- [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7649790/#:~:text=Acetaminophen%20induced%20hepatotoxicity%20is%20one,annually%20\(1%E2%80%9333\).](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7649790/#:~:text=Acetaminophen%20induced%20hepatotoxicity%20is%20one,annually%20(1%E2%80%9333).)
- [https://www.sciencedirect.com/science/article/pii/S0749379711001826?casa\\_token=-yeKqhMO9OMAAAAA:FqG5\\_XhWuYu2Xa\\_HZPeXn2-UkSmq\\_Y14S-m2ZlKdsINSLDxrh0ph\\_b8MemxnYhsGKjrfdp4yXLLY](https://www.sciencedirect.com/science/article/pii/S0749379711001826?casa_token=-yeKqhMO9OMAAAAA:FqG5_XhWuYu2Xa_HZPeXn2-UkSmq_Y14S-m2ZlKdsINSLDxrh0ph_b8MemxnYhsGKjrfdp4yXLLY)

# References Continued:

## Market Size:

- <https://www.chpa.org/our-issues/otc-medicines/acetaminophen>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6475729/pdf/BCP-85-1028.pdf>
- <https://www.cvs.com/drug/acetaminophen/patient-statistics>
- <https://www.pewresearch.org/internet/fact-sheet/mobile/>

## Market Impact:

- <https://pubmed.ncbi.nlm.nih.gov/18981263/#:~:text=Meta%2Danalysis%20was%20used%20to,121%2C582>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7649790/>
- <https://www.tandfonline.com/doi/pdf/10.3109/15563650903409799?needAccess=true>

## Diabetes Education:

- [https://journals-sagepub-com.proxy-hs.researchport.umd.edu/doi/10.1177/19322968211030572?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%20%20pubmed](https://journals-sagepub-com.proxy-hs.researchport.umd.edu/doi/10.1177/19322968211030572?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed)

## Track and Trace:

- <https://rfxcel.com/what-is-track-and-trace-for-pharmaceuticals/#:~:text=When%20designed%20and%20implemented%20correctly,in%20the%20supply%20chain%2C%20all>

## EMA:

- [https://ec.europa.eu/health/sites/default/files/files/falsified\\_medicines/qa\\_safetyfeature\\_en.pdf](https://ec.europa.eu/health/sites/default/files/files/falsified_medicines/qa_safetyfeature_en.pdf)
- [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorized-medicinal-products\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorized-medicinal-products_en.pdf)