

David Thorne

25th October 2022 CORESTA ST48



Study Context





Public Health England:

Our new review enforces the finding that vaping is a fraction of the risk of smoking,

at least 95% less harmful

and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know...



E-cigarette context



e-cigarette testing is essential but avoiding data misinterpretation is fundamental



Mechanistic Approaches |

In vitro mechanistic studies are easy to conduct with few quidelines or standards leaving read across between studies almost impossible



Cigarette Context

Many studies lack the required cigarette smoke data to contextualise ecigarette responses



Human Context

E-liquid studies lack relevance and don't account for artefactual and physiological changes as a result of exposure



Device Detail

Information on device detail and flavour inclusions are often limited. When elevated concentrations of ingredients are used, they are not contextualised against commercial formulations



Dose Monitoring

Lack of dose measures restrict data extrapolation and human context



Duty of Care

Recognised duty of care approaches. when designing studies are not widely considered when detailing adverse outcomes







Weight of evidence regarding ecigarette reduced risk potential

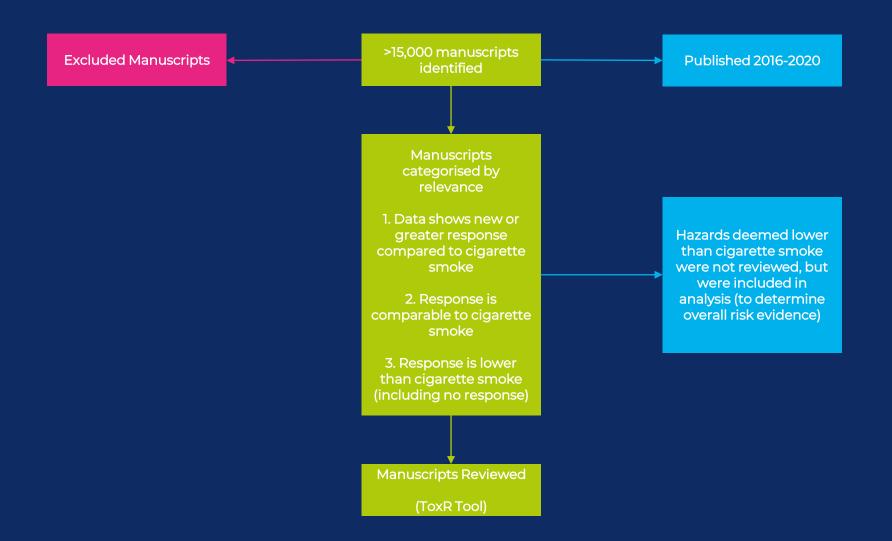


Correlate outcomes from in vitro to in vivo*

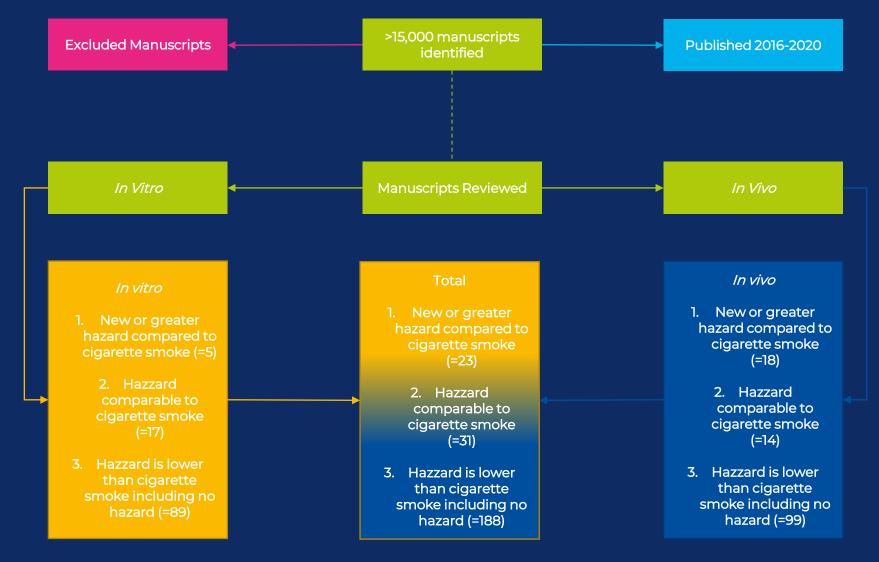
studies

Approach



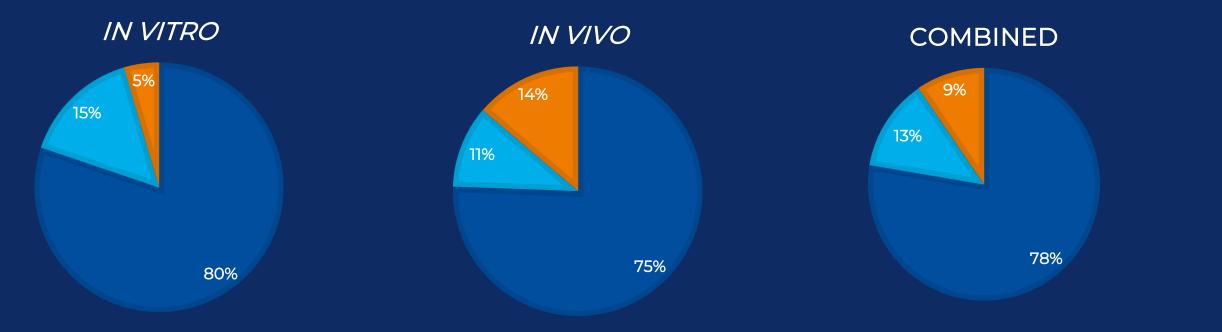






Results





Response lower than cig* Response comp to cig Response worse than cig

"These products may contain nicotine, an addictive substance and are not risk free"

^{* =} data inclusive of response both lower than cig and no observed response

Future Considerations



Of the papers reviewed, many studies (both *in vitro* and *in vivo*) were hampered by incomplete or inadequate reporting of key experimental parameters...

- The inclusion of cigarette smoke (reference cigarettes) and appropriate controls will give valuable context and information on discriminating power, thus clarifying the scale of risk
- The development of a reference range of ECs would allow standardisation. The application of standardised puffing parameters (many studies used bespoke regimens and human puffing behaviours) would strengthen data and *in vitro* to *in vivo* read across
- 3 "Dry-wicking" and other unintended laboratory missuses were often not documented. Vaping angle, number of puffs per cartomiser and battery duration were generally not discussed
- 4 Often, significant biological outcomes (*in vitro*) were detailed on e-liquid exposures only, without appropriate caveats on dose and limitations of such approaches
- All ECs were treated equal. Very few studies if any detailed within category comparisons

Conclusions



"These products contain nicotine, an addictive substance and are not risk free"

- Of more than 15,000 studies initially identified, only a small percentage showed adverse responses to EC aerosol that were comparable, greater than cigarette smoke or revealed new potential hazards
- This review has demonstrated that the wider literature substantiates the reduced risk potential of EC use (*in vitro + in vivo*)
- Reasuringly consistent observations were made between *in vitro* and *in vivo*datasets in terms of numbers of studies substantiating the reduced risk potential of

 EC use ToxR provided a powerful tool to assess reliability of studies for risk

 asssessment purposes
- Overall, we found that the *in vitro* effects of increased harm with ECs either did not translate into similar *in vivo* responses or had not been assessed in a consistent manner to allow comparisons
- Clearer reporting on device specifics, formulations, settings and the use of standardised approaches where possible will strengthen future data



Thank You & Questions?

david_thorne@bat.com

