Canada:
Regulation of Medical Devices with AI

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Unity Health Toronto - ChartWatch

Problem

Patient deterioration & unanticipated deaths/ICU admissions on internal medicine units

AI Solution

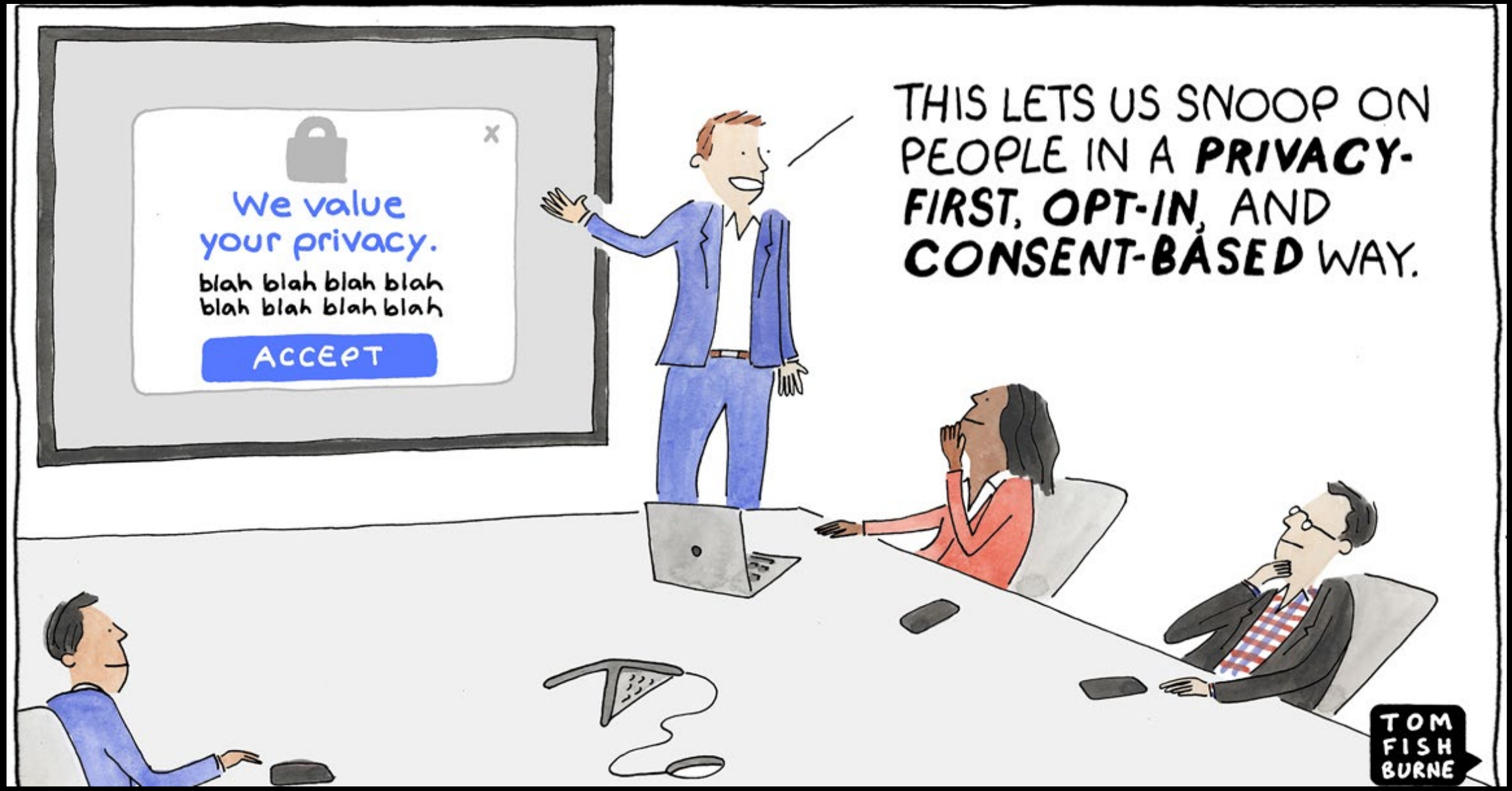
What does it do? Algorithm that recognizes patterns of deterioration based on 100+ data points, pages clinician/nurse when patient at high risk

What is the outcome? Reduction in unanticipated deaths & ICU admissions by >20%

Garbage *in* Garbage **OUT**

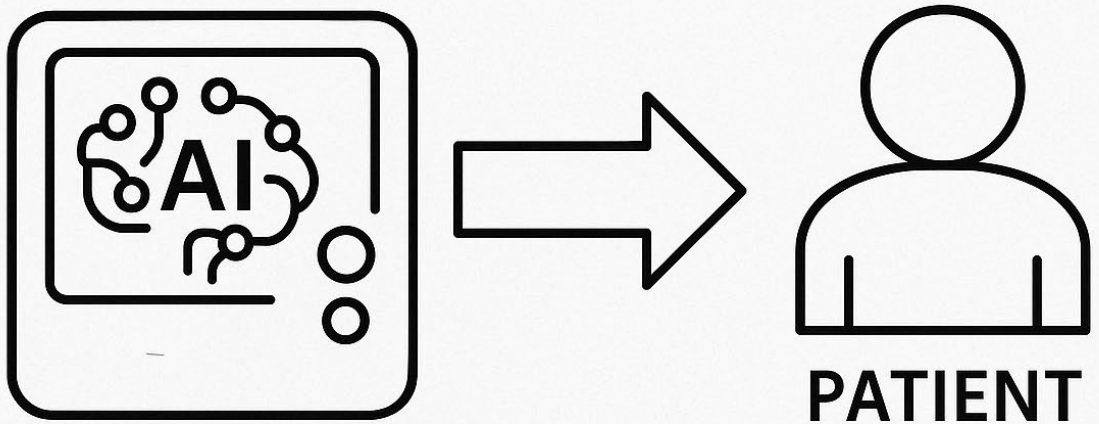
Algorthmic Bias

The key is that AI tools must be trained on data reflecting the populations they are designed to serve. For instance, if an AI tool is for elderly, immunocompromised women, they must be well-represented in the training data. Pursuing "perfect" data is a folly; what matters is relevance.


We value your privacy.
blah blah blah blah blah blah blah blah
ACCEPT
THIS LETS US SNOOP ON PEOPLE IN A PRIVACY-FIRST, OPT-IN, AND CONSENT-BASED WAY.
TOM FISH BURNE

Reliance on Private Law to Ensure Quality/Safety?

Regulating AI in Medical Devices



AI evolves over time, posing challenges for regulation throughout the life cycle of medical devices


MIND THE GAP
REGULATORS' FOCUS ON PRE-MARKET APPROVAL
NEED FOR POST-MARKET SURVEILLANCE
SAFETY / EFFECTIVENESS OF AI FOR HEALTH CARE

Health Canada's Authority under Food & Drugs Act

- ***"device*** means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

- **(a)** diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals…

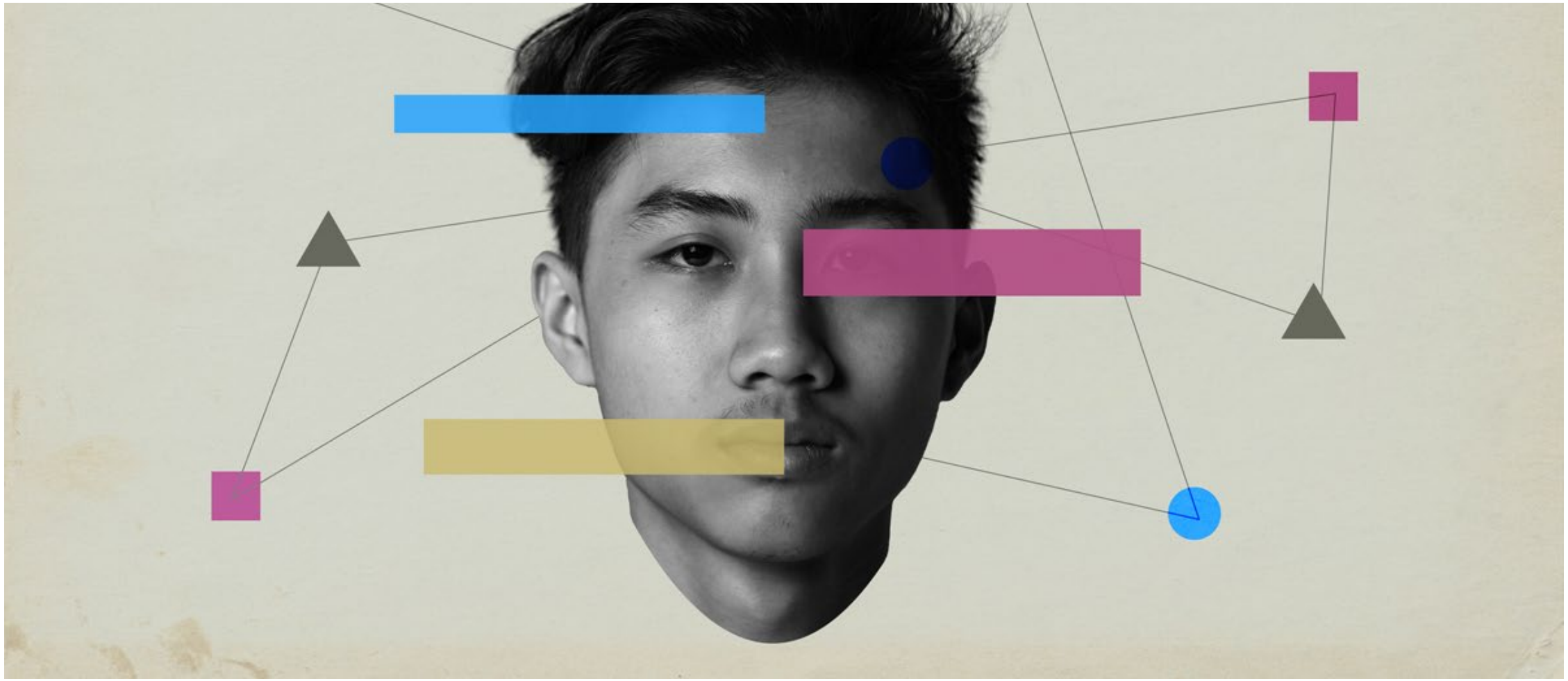
Gaps in Regulation

- Relies heavily on risk assessment by vendors
- Gaps in regulation (e.g. within hospitals)
- Insufficient attention to algorithmic bias
- Over-reliance on a ‘human-in-the-loop’
- Post-market surveillance is critical but structures rely on self-reporting

Pre-market guidance for machine learning-enabled medical devices

Canada

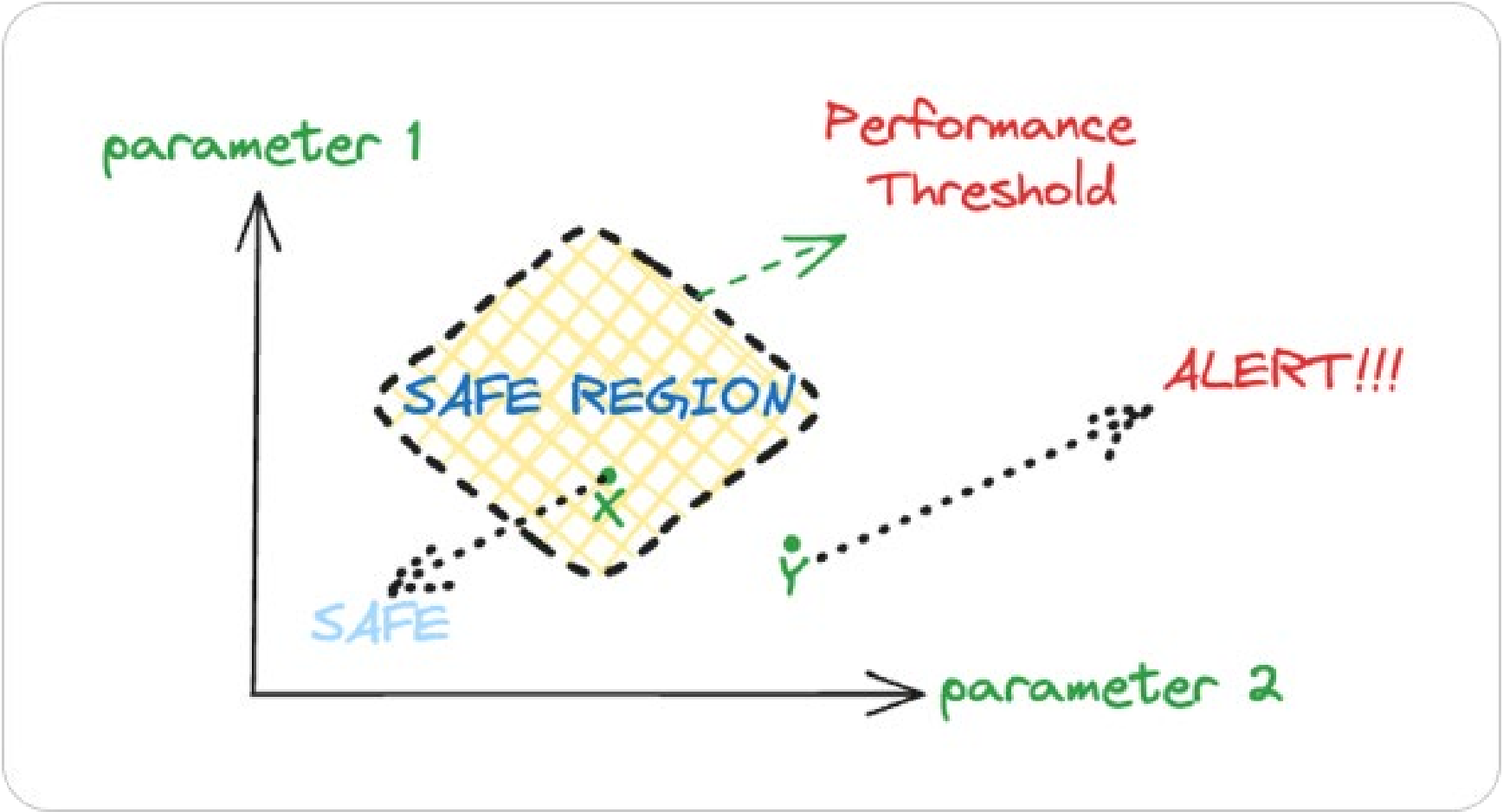
Flexible vs. Permissive



Algorithmic Bias

Transparency on Regulatory Standards

Mechanisms for Safety Monitoring



Thank you!

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