



# Legal, ethical and privacy issues with consumer-led atrial fibrillation screening

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## Background

- There has been a recent explosion in the availability of devices allowing consumers to screen themselves for atrial fibrillation (AF).
- These devices include wearables, smartphones, smartwatches which measure heart rhythm either using photoplethysmography (PPG) or single/six lead electrocardiogram (iECG).

## Aim

To document the range of important legal, ethical and privacy issues that arise with devices used for consumer-led screening for AF.

## Methods

A narrative review of key **legal and ethical** issues around the ownership and use of data, regulation of medical apps, issues for doctors treating patients with self-screening data, and issues for consumers using these devices.



*Regulatory frameworks need to cover and enforce privacy, safety/quality and consumer protection aspects of AF screening devices*

## Results

- Numerous regulatory gaps exist in relation to consumer AF screening devices
- Consumers have a legitimate expectation of the **privacy** of their health data.
- Often the **data** generated are not owned by consumers, who have little control or knowledge about how the information is used. Each app has its own privacy and data use policy, with huge variability in protection.
- Regulation of **software as a medical device** is developing. Existing consumer protection legislation requires device companies not to make representations that are misleading or deceptive, and to have a reasonable basis for claims of benefit.
- Consumers can benefit from empowerment of self-screening, which may allow better treatment.
- Doctors need more consensus guidance as to treatment thresholds for arrhythmias in low-risk age groups

## Conclusions

- There are some **important legal gaps** in relation to data and regulation of consumer screening apps and devices in many jurisdictions.
- Regulatory frameworks need to be updated to cover privacy, quality/safety and consumer-protection aspects of these devices.